Chairman Huffman, Vice Chair Johnson, Ranking Member Antonio, and members of the Senate Health Committee, I am writing to you today to provide my personal opposition testimony against House Bill 73. My name is Brandon Spears, and I have been a practicing clinical pharmacist in Ohio since 2019. As a clinical pharmacist, it is my responsibility to safeguard my patients against the improper use of prescription medications through the process of drug utilization review; which, I am legally obligated to perform according to OAC Rule 4729:5-5-08. Beyond my legal obligation, I am morally obliged by God and ethically obliged by the Hippocratic oath, which I have professed, to protect the health and well-being of my fellow man or, at the very least, to do them no harm. There are times during the practice of my profession that a patient's life may literally hang upon the proficiency with which I do my job. With one swift stroke this bill, if enacted, would render the seven years I spent studying for my doctorate, the almost five years' experience I have as a practicing pharmacist, and the countless hours of self-study I have put myself through completely meaningless as with the simple phrase "off-label use" all clinical objections I could raise against the use of a drug would be impotent leaving my patient at the mercy of a physician with delusions of grandeur who would be able to use them as a lab rat while enjoying the legal protections of said bill. My goal in writing this testimony is to illustrate the potential dangers this bill exposes Ohioans to while offering no benefits to counterbalance its risks given that medications already can be, and very commonly are, used for off-label indications.

First and foremost, my greatest concern with this bill comes from the phrase, "A pharmacist ***SHALL*** dispense," (emphasis mine) written in line 92. This verbiage coerces the pharmacist to dispense a medication if the physician says it is being used off-label as long as the pharmacist cannot cite religious/ethical objections to dispensing it and the patient does not have a documented allergy to it. Appropriate use, clinical data, medication safety, dosing guidelines, drug interactions, pharmacokinetics/dynamics, nor clinical judgment can be cited to raise objection to the use of said medication because this bill offers the pharmacist no legal alternative to simply dispensing the drug, completely contrary to the edicts of OAC Rule 4729:5-5-08 and; thus, places the pharmacist in a legal quagmire being legally obligated to adhere to two laws that are irreconcilable with one another. The patient finds himself in an even worse predicament, because he no longer enjoys the protection a pharmacist's knowledge normally provides. Informed consent does very little to protect a patient who has zero training in understanding the intricacies of medicine much like a sign reading "Warning: Sharks in the Water" doesn't protect a fish because a fish cannot read. When the informant themself is misinformed or misunderstands then what is the patient to do? Even worse, what if the physician is in error but is adamant they perfectly understand and are correct in what they are prescribing?

I have had numerous confrontations with various physicians throughout my time in pharmacy. As an intern at a Kroger pharmacy, I had physicians constantly not just overdosing but double dosing children on Augmentin for ear infections. I have had a physician order pentobarbital thinking he was ordering pentamidine. The latter is an antifungal while the former is the primary drug used for lethal injection. I have had a physician try to order 135 mg of methadone on a patient who hadn't received an opioid for more than a month or which stood a very good chance of killing them. These are all just a handful of examples, and in every single situation I was able to prevent harm to the patient because I was legally empowered to refuse to

dispense the medication, even in the cases where the physicians fought tooth and nail that they were correct and berated me in an attempt to force me to dispense. If this bill were to pass the physician would simply have to claim they were using the drug for an off-label indication and my hands are tied. Worst of all, the bill does not even require the physician to provide any evidence upon which he claims a drug can be used for said off-label indication. Any dose of any drug via any route of administration can be prescribed for any indication and the pharmacist would be legally obligated to dispense the drug, no matter how egregious the order. Those who think I am exaggerating the risks of legally allowing physicians free reign in prescribing or that I believe physicians are intentionally trying to harm patients are wrong on both counts. I simply come with first hand knowledge of how often drugs are dangerously and erroneously prescribed completely unintentionally by physicians who in turn often fight with the pharmacist, either through wounded pride or honest misunderstanding, when the latter points out the error in the prescription. Prescription medications are restricted as they are for a reason, they can be highly dangerous, even lethal, with only minor errors.

Another grievance I would like to raise against this bill is that, by its nature, it claims that pharmacists are more or less a flaw in the healthcare system or are guilty of some evil this body of government is seeking to redress. Medications can already be used for off-label indications (the fact that this bill refers to “off-label drugs” as if this were a real term supports my fear that the legislators who drafted this bill do not have sufficient understanding of the medical field to be legislating it). Physicians are already able to write prescriptions wherein a drug will be used for aforementioned off-label indication. The only party this bill affects is the pharmacist who is hamstrung by it. Therefore the only logical conclusion that can be derived from the intended effects of this legislation is that Ohio legislators have determined that pharmacists are the enemy of their patients and are routinely denying patients essential medications without just cause. Is the belief then that pharmacists refuse to dispense medications out of spite? Do we hate our patients and wish them harm and; therefore, deny them a drug we secretly know will cure them? Perhaps most importantly, is there any evidence suggesting that pharmacists are regularly refusing to dispense medications simply because they are being used off-label without the pharmacist having a legitimate clinical rationale for not doing so and that this has lead to patient harm directly attributable to the patient not receiving said medication and this is a widespread and frequent enough occurrence to warrant legislation? If even one of these three criteria are not met then this legislation invalidates one of the most effective safety measures put in place to protect Ohio’s patients without any benefit to be had, because the problem, believed to be redressed through this legislation, does not exist.

While stripping the pharmacist of his autonomy as a healthcare professional, House Bill 73 also crushes him, and the pharmacy generally, with excessive documentation and logistical burdens. For starters, the paragraph containing lines 105 through 119 states that after my hands have been bound and I have been forced against my will and medical judgment to dispense a medication to a patient to be used off label, when harm befalls the patient I am protected from civil and administrative retaliation ***IF*** I, “document in the patient’s medical record the objective, good faith, and scientific objection, by stating with particularity the basis of that objection, which must be based on an individualized assessment of the patient and the off-label drug.” So not only am I prevented, by law, from refusing to dispense said drug, but I am also liable for any harm that comes to the patient unless I satisfactorily document my objections. I am looking

forward to the next piece of legislation wherein you make me liable for the bodily harm someone causes themselves by driving a car off a cliff, of their own free will, while I have been tied to a tree and forced to watch, because I didn't write them a dissertation explaining how Newton's Law of Universal Gravitation suggests that driving a car off a cliff is, in fact, a bad idea. Beyond this absurdity, House Bill 73 also requires inpatient pharmacies to go to ridiculous lengths to acquire the medication to be used off-label if it is not in stock or on formulary. The bill goes so far as to say that if the pharmacy in question does not have the medication and cannot order it, then they must reach out to other hospitals, inpatient facilities, and drug distributors in an effort to obtain this drug and document along the way the efforts made to obtain said drug. This stretches already thin workforces to breaking point and takes away from pharmacists ability to perform their clinical responsibilities which increases the likelihood of medication errors and patient harm. If all these efforts fail and the patient somehow has means of obtaining it themselves, then the hospital ***MUST*** allow the patient to have the drug brought in to be "identified" so the patient can use it. Problematically, there are no minimum requirements categorizing what is meant by identifying the drug in question. The current verbiage seems to imply that as long as the drug brought in looks like the expected drug then the hospital is obligated to allow the patient to take it even though most hospitals' policies require, at a minimum, that in order to use a patient's own medication it must be confirmed that the drug was prescribed to the patient and comes in proper packaging with a pharmacy label bearing the patient's name and proper instructions, is not expired, has been stored properly, and has not been tampered with or adulterated. Fentanyl powder can be pressed into any shape one could desire, and many patients in Ohio have been sent to the hospital or perished after consuming fentanyl, unknowingly, because it was disguised as something else or used to adulterate other drugs. This legislation merely eliminates established safety precautions and replaces them with new avenues through which harm can come to our patients.

Furthermore, this bill poses a significant problem to the ability of hospitals to maintain a proper formulary along with appropriate restrictions. Beyond the logistical burden placed on pharmacies to obtain whatever drug is desired, which I mentioned earlier, pharmacies would no longer be able to effectively manage drug shortages, which are alarmingly frequent and greatly impact patient care. To illustrate this point take the recent intravenous Ativan shortages for example. Ativan is a drug of vital importance in patients with seizures and who are undergoing alcohol withdrawal. During the recent shortages, most facilities put in place restrictions limiting the use of IV Ativan to only these indications in order to preserve the extremely limited supplies. This bill does not allow for a restriction of this kind if a physician wishes to use IV Ativan for an off-label indication. What happens when a patient presents to the ER seizing and there is no IV Ativan available because the supply had been squandered by an ENT physician using it off-label for nasal polyps because of one article he read published in China in 1980 that vaguely claimed IV Ativan could potentially shrink nasal polyps? HB 73 leaves no legal option for the pharmacist, the pharmacy, or the hospital to deny the dispensing of IV Ativan in this situation. Formulary restrictions are in place to protect patients and to prevent the use of certain drugs by healthcare providers who do not have the adequate training to use them properly. Nitroprusside sodium, for example, is an intravenous medication used for acute hypertension and/or acute decompensated heart failure. As recommended by the drug's monograph, this drug is restricted such that it can not be run any faster than 10 mcg/kg/min and can only be run at this rate for no

more than 10 minutes. Nitroprusside has a few off-label indications that it is already used for, including blood pressure management in acute ischemic stroke. What if a physician has a 90 kg patient with acute ischemic stroke and the physician starts running nitroprusside at 10 mcg/kg/min and the patient improves but is still just outside the BP goal the physician has in mind. So, after two minutes, the physician reasons that he can try to run it at 15 mcg/kg/min since he is using it off label and the hospital nor the pharmacist can prevent this due to HB 73. This does the trick so well that after ten minutes the physician orders for the nitroprusside to be continued indefinitely at 15 mcg/kg/min as long as the patient's BP remains at goal. The physician does not have much experience using nitroprusside first hand, but reasons that as long as the patient remains stable maybe they simply tolerate it better than average and the restriction shouldn't apply to this patient. Two hours pass by and suddenly the patient starts to destabilize, their oxygen levels drop, and they become dangerously acidotic. The physician orders that the normal treatment protocols be followed but, regardless, the patient dies. Unbeknownst to the physician, he has given his patient a lethal dose of cyanide. He was unaware that nitroprusside, once in the body, results in the production of cyanmethemoglobin and cyanide. Under this bill, as it is currently worded and structured, there would be no legal means for the pharmacist or the hospital to prevent this scenario playing out if the physician were to ignore hospital policy and/or warnings from the pharmacist about the risk.

My final complaint regards lines 245 through 254 wherein healthcare facilities are prohibited from denying a patient, "sufficient means of fluids or nutrition," except in cases where it is the patient's wish or is required for a procedure. To begin with, "sufficient" as determined by whom? And what are the provided fluids and nutrition to be sufficient for? To simply sustain life? To maintain weight? To gain weight? The bill is irresponsibly ambiguous and doesn't provide exceptions for other instances where fluid and/or nutrition restrictions are necessary. Take heart failure, for example, where fluid and sodium restrictions play a significant role in therapy. Also, patients with hyponatremia are best managed through fluid restriction. It is ridiculous for this legislative body to take it upon themselves to interfere with how we manage our patients as if we don't already have the best interests of the patient in mind or as if you somehow understand how to care for these patients better than those of us who have studied our various areas of expertise for decades. Researchers have dedicated their lives testing and analyzing various disease states and their treatment and have published libraries worth of papers describing their work. We have decades upon decades of peer-reviewed research on which we base our decisions when treating our patients. House Bill 73 is making all of this for not with a few vague lines of legislation.

In conclusion, naming this bill a "Patient and Health Provider Protection Act," is satire belonging more in an episode of *Family Guy* than our state legislature. House Bill 73 removes safeguards which have been erected to guard patients against the misuse of dangerous drugs. Billions of dollars worth of research, decades of rigorous testing, a plethora of post-market data will all be made meaningless if this poorly thought out piece of legislation were to become law. Pharmacists will be robbed of their autonomy as healthcare professionals. Worse than this, they will be forced to play an active part in treatments that will inevitably harm or kill patients and will then be at risk of being held liable if they don't satisfactorily document how they wanted to prevent the treatment in the first place. Hospitals will be prevented from enforcing formulary restrictions which are essential during drug shortages and prevent dangerous drugs from being

used by those who don't understand them well enough or in places without the equipment or personnel required to ensure patient safety. Patients will be exposed to harm from medical malpractice and be left with no means of seeking redress, because this bill also prevents the proper authorities from revoking the license of, or disciplining in any way, any practitioner inappropriately prescribing medications. With there being no requirement to provide even a shred of evidence supporting using a drug off-label, how can anything be considered reckless or grossly negligent? Given the rampant medical malpractice that will be enabled through this inconceivably dim-witted piece of legislation, I feel a more appropriate name should be applied, "Make Snake Oil Great Again."

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