Chairman Huffman, Vice Chair Johnson, Ranking Member Antonio, and members of the Senate Health Committee, thank you for the opportunity to provide my personal opponent testimony on House Bill 73.

My name is Diana Gabelman, and I have been a pharmacist for 14 years, working in retail and specialty pharmacy. I have cared for countless patients during my career and hope to continue caring for Ohioans in a safe manner. I am writing to express my concern that House Bill 73 will harm the Ohio patients whom I care for.

First and foremost, I want to acknowledge the genuine intentions behind this bill. Improving access and empowering patients should always be a goal in healthcare. However, I must respectfully disagree with the approach taken by HB 73 due to serious concerns about protecting patient safety and maintaining prudent checks and balances in our healthcare system.

Off-label use is when a medication is prescribed for an indication or in a manner outside of FDA-approved labeling. Medications are approved only after going through controlled trials in which specified patient populations are studied. Manufacturers cannot claim a medication will work in an unstudied population, nor can manufacturers claim a medication works on an indication that was not part of study endpoints. Studies for manufacturers are time consuming and expensive, which explains why there are not unlimited labeled indications.

Allowing providers to prescribe off-label allows treatment for unmet medical needs, improves medication access to special populations (e.g. pediatrics) and giving options for patients with limited or no therapeutic alternatives (e.g. rare diseases, terminal diseases). **Providers are legally able to prescribe a medication to treat a condition for which the FDA has not approved. Pharmacists dispense off-label medications every day.** Up to 21% of U.S. outpatient prescribing, 23% of inpatient prescribing in adults, and 60% of prescribing in pediatric patients are for off label use. This demonstrates that pharmacists filling off-label orders is not the issue. The issue is when a medication is prescribed in an unsubstantiated manner that lacks **unbiased and balanced** evaluation of the available safety and efficacy evidence. Emotionally charged anecdotes must never override the results of large, well-designed clinical trials.

Much of the proponent testimony highlights a desire for access to treatments that deviated from the hospital treatment protocols, like ivermectin, while patients were hospitalized with COVID-19. Amid swiftly evolving circumstances, healthcare providers, hospital systems and government agencies worked diligently to develop treatment protocols based on the best available clinical evidence and expertise. After reviewing proponent testimony and attending the IP meeting on 2/28/2024, I believe the perceived obstacle the bill is trying to resolve is the ability to deviate from treatment protocols when there is a provider or patient request to do so; again, the obstacle is not pharmacists refusing to dispense off label orders.

Policies and procedures must be in place to support the appropriate use of off-label drugs, including a defined method for providers and/or patients to be able to request changes from treatment protocols. Responsibility should be shared between providers, pharmacists, and patients, with the support of the health system's leadership and pharmacy and therapeutics (P&T) committee. P&T committees are comprised of physicians, pharmacists and nurses; the chairperson at the system I work for is a physician. The role of the P&T committee in off-label medications includes developing criteria for use, relying on scientific evidence to guide decisions, as well as establishing a process for monitoring ongoing use. Collecting efficacy and adverse events

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data should be shared and published, as off-label practice may be a starting point for future research and direction for new indications and unmet clinical needs.

The proposed solution of mandating that pharmacists dispense any off-label prescription without discretion sacrifices crucial safeguards. It enables diversion and overprescribing (exacerbating drug shortages) while undermining the very principles of evidence-based medicine that protect us all. In addition, requiring pharmacists to dispense certain medications without checking for essential labs will increase risk of patient harm. We need interdisciplinary collaboration, including patients, to ensure that off-label prescriptions are based on the best available evidence and are in the patient's best interest.

Thank you for the opportunity to provide this written testimony in opposition to House Bill 73 and for your time considering the threat that it poses to Ohio patients.

Sincerely,
Diana Gabelman, PharmD, CSP