OHIO PHARMACISTS ASSOCIATION
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Chairman Huffman, Vice Chairman Johnson, Ranking Member Antonio and members of the Senate Health Committee: my name is David Burke, and I am a pharmacist and the Executive Director of the Ohio Pharmacists Association. I represent thousands of pharmacists across the state of Ohio as well as the practice of pharmacy in our state.

Today, the process of prescribing and dispensing medications for indicated use or off-label use is straight forward and unencumbered. Off-label use of drugs is common, constituting up to one-third of all prescriptions for common drugs in the United States overall, and up to 97% of drug use in some patient populations[i]. In 2019 and according to IQVIA, 159,915,863 prescriptions were filled at the retail level in Ohio (IQVIA, 2020). Because most prescriptions do not contain a diagnosis, a pharmacist must use inference to decern the condition being treated. The primary role of a pharmacist is not making a diagnosis but in protecting the patient from harm and improving the desired outcome through use of the medication. Among other things, professional judgement and training are used to avoid drug/drug interactions, drug/condition interactions, contraindications with nonprescriptive items such as alcohol, certain foods or actives that may cause patient harm. All this occurs today whether the prescription contains a diagnosis or not.

Should House Bill 73 become law, this process would change. A pharmacist will first have to determine if a prescription falls within House Bill 73. To do this, a diagnosis would be required, specific to each medication. Off-label use of a medication is for a purpose, dose or route for which the drug is not indicated. To determine this when filling a prescription, a pharmacist would need a diagnosis to ascertain approved use or off-label use. Amending the bill to require prescribers to include a diagnosis code for each medication prescribed would seem the only way to make the bill functional, all other issues aside. Without this, a pharmacy or pharmacists would directly expose themselves to liability without knowing whether a state law applied to the function to which they were about to perform. A couple of real-world examples follow:

A child with an ear infection presents to the pharmacy with an eye drop prescription for an antibiotic/steroid combination to be used in the ear. As prescribers and pharmacists know, eye drops are sterile and can generally be used in the ear. The inverse is not true. That said, using an eye drop in the ear is not an indicated use and therefore off-label. Without a diagnosis for use on the prescription, the pharmacists can only infer and not confirm the diagnosis of the patient and if House Bill 73 applies. The pharmacist must then stop their work and contact to the prescriber to obtain a diagnosis. The mother and child must delay their treatment due to House Bill 73.

Further common examples would include when a drug is used for a disease or medical condition that it is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers, say at James Cancer Center, use it to treat a different type of

cancer. Other examples include when a drug is given by different route or form, such as when a drug is approved as a capsule, but it is given instead in an oral solution or given in a different dose, such as when a drug is approved at a dose of one tablet every day, but a patient is told by their healthcare provider to take two tablets every day. At the pharmacy this would translate into examples such as Clomid being used for male infertility, gabapentin used to treat diabetic neuropathy, amitriptyline for fibromyalgia, escitalopram for bipolar disorder and I could go on. Under House Bill 73 this practice halts, and the patient is left waiting until the pharmacist can determine if the prescription falls inside or outside of House Bill 73 at the time of dispensing.

The above examples are further clouded by House Bill 73 as the prescriber does not have to provide the pharmacist with a diagnosis, lab result or indication. Still, the law mandates a pharmacist shall dispense the medication. Without a diagnosis, it is unclear how a pharmacist would determine if House Bill 73 applies to any prescription being filled. This question is key to House Bill 73 as for the law to apply, the pharmacist must know if the prescription is being used off-label or not.

As you can imagine, attorneys would quickly capture this information in a court case. The protections House Bill 73 attempts to afford only apply if the pharmacist knows the prescription is being used for off-label purposes. Only a diagnosis for which the prescription is being written can confirm this and the pharmacist can then bifurcate their process to either accommodate or disregard House Bill 73 for each prescription. As I mentioned before, this process will consume prescriber time, pharmacist time and worse, delay patient care for the treatment they are rightfully entitled to receive and ironically, are receiving today without such delay. Mind you, the patient does not need to be a knowledgeable or even willful participant of the law for it to apply to them.

Mr. Chairman and members of the committee, my testimony has only focused only on one thing related to House Bill 73: the need for a diagnosis to which the prescriber is not obligated to provide the pharmacist. The outcome is simple, retail pharmacies will grind to a halt with each new prescription that does not contain a diagnosis specific to that medication. I will leave you with the notion of non-maleficence that embodies this legislation and the medical ethics principle that is "to refrain from doing any harm first, before doing any good".

Thank you, Mr. Chairman and members of the committee. I would be happy to answer any questions you may have at this time.

Respectfully,

David E. Burke, RPh, MBA
Executive Director
Ohio Pharmacists Association

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[i] Off-Label Use vs Off-Label Marketing of Drugs
Part 1: Off-Label Use—Patient Harms and Prescriber Responsibilities
Gail A. Van Norman, MD*