Ohio House Bill 101 Proponent Testimony

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Chairman Burke, Vice Chair Beagle, Ranking Member Tavares, and members of the Ohio Senate Health, Human Services and Medicaid, thank you for the opportunity to provide testimony in support of House Bill 101, the "Epinephrine Accessibility Act". This bill improves access to the life-saving medication ephinephrine through epinephrine autoinjector substitution and the dispensing of epinephrine autoinjectors without a prescription under a physician-established protocol.

My name is Kelli Barnes, and I am a faculty member at The Ohio State University College of Pharmacy. In addition to teaching at the college, I am a practicing pharmacist at The Ohio State University General Internal Medicine clinics. In these clinics, I work with physicians, nurses, medical assistants, social workers, and other team members to provide chronic disease state management, comprehensive medication reviews, and important education to patients and other providers. In my practice, I encounter patients on a daily basis that cannot afford their medications. Patients commonly tell me they are going without medications or taking less than the prescribed amount of medication to try to make their medications last longer. These same patients are very worried about the impact that their inability to afford medications may have on their health. I have also worked with patients over the phone to manage chronic disease states in collaboration with my partnering physicians because these patients can't afford the cost of coming in to see their physicians in the office. In the case of patients with severe allergies, the inability to afford their ephinephrine autoinjector or to see their physician for a new prescription can be life-threatening.

As a student, approximately 10 years ago, I was working in a traditional community pharmacy late on a Sunday evening when a man and woman rushed up to the pharmacy. The man insisted that we give the woman with him an Epi-Pen®. He reported that she had accidentally eaten a desert with a peanut in it and her throat was starting to swell shut. The pharmacist I worked with instinctively ran to the shelf, grabbed an ephinephrine autoinjector and gave it to the man to administer to the woman. I remember standing there as a student thinking to myself, "are we allowed to give a patient an Epi-Pen® without a prescription?" and "I don't know if this is allowed, but she's going to die if we don't." The pharmacist I was working with was instinctive, experienced and intelligent. She knew that she was acting in the best interest of the patient and that we would worry about procedure after we called 911 and the patient was receiving appropriate medical attention.

Unfortunately, I'm familiar with similar situations that have not gone as well. Dillon Mueller, an 18 year old from Wisconsin, recently died after he was stung by a bee. Dillon suffered anaphylactic shock and was unconscious within 10 minutes, which is commonly the case in these terrible situations. It is likely that Dillon would be alive today if an epinephrine autoinjector was

available. It is because of cases like this, that legislation aimed at increasing access to epinephrine autoinjectors has been introduced in many states throughout the country.

Allergic reactions can be caused by many different types of exposure: food, medications, insect stings, latex products, and more. Every 3 minutes in America, a food allergy reaction sends someone to the emergency department – that is more than 200,000 emergency department visits per year. The Food Allergy and Anaphylaxis Network (FAAN) estimates that 150 to 200 Americans die each year as a result.

Today, with my patients who have difficulty affording their medications and office visits and Dillon Mueller's anaphylactic situation in mind, I want to talk with you about why it's incredibly important that we increase access to epinephrine autoinjectors. Severe allergic reactions from insect stings, food allergies, or other circumstances are unpredictable. Use of epinephrine autoinjectors for these severe reactions are effective, have few adverse effects, and have no contraindications. Specifically, epinephrine is most effective when used within the first few minutes after exposure to the allergen. Adverse effects are minor and include dizziness, restlessness and headache. Myocardial ischemia (decreased oxygen to the heart) is a more serious adverse effect, but it is quite rare with the low, measured doses delivered by the autoinjector. Additionally, untreated anaphylaxis is associated with myocardial ischemia and changes in heart rhythm as well. Additionally, well known practice guidelines from medical allergy associations indicate that there are no contraindications to epinephrine administration for anaphylaxis.[1]

In 2016, legislation allowing restaurants, swimming pools, colleges, and other public places to stock non-patient specific epinephrine to use in the event of an allergic reaction took effect in Ohio. This was an important step to increasing accessibility to epinephrine, however it is still cumbersome for these entities to obtain a prescription from a physician before securing the medication to use in an emergency. HB 101 will ease this unnecessary step, increasing access to a lifesaving medication with no contraindications – all of which is done under the direction of a protocol developed by a physician. Additionally, this bill will allow pharmacists to dispense epinephrine to patients who are unable to see their physician to get a prescription, whether it be due to cost (like some of my patients), transportation, long wait times, or other barriers.

The other portion of HB 101 allows pharmacists to substitute pharmaceutically equivalent epinephrine autoinjectors for one another. This will allow pharmacists to substitute less expensive autoinjectors for more expensive brand-name epinephrine autoinjectors with the patient's consent. Currently, this is not permissible under existing generic drug laws, because these laws indicate that drugs cannot be approved as generic equivalents if a patient has to be re-educated on a new way to administer the medication. There are slight differences in the administration techniques with different epinephrine autoinjectors, and thus generic substitution under existing law is not allowed. With this being said, pharmacists are highly trained to provide patients with medication device education. The pharmacist who is dispensing the epinephrine autoinjector will know which device the patient is receiving and will be able to provide the most appropriate education on that device. HB 101 will allow for the switching of pharmaceutically equivalent epinephrine autoinjectors to decrease cost without diminishing the safe and effective use of this

medication. By enhancing options at the pharmacy counter, the patient now has the ability to work with the pharmacist to select the autoinjector that best meets their needs; whether it's based upon financial accessibility, health plan coverage, or ease of use.

HB 101 is excellent legislation. It decreases cost for patients and the healthcare system, and it increases access to life-saving medication. My patients will benefit from this legislation, both by saving hundreds of dollars per year and from the ease of mind knowing there are fewer barriers to an important treatment modality for a life-threating situation. Thank you for your time. I would be happy to answer any questions you may have. If you would like to reach me after this hearing, please see my contact information below.

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Reference: (1) Lieberman P, Nicklas RA, Oppenheimer J, et al. The diagnosis and management of anaphylaxis practice parameter. 2010 Update. J Allergy Clin Immunol. 2010; 126(3). 477.