FAACT
Food Allergy & Anaphylaxis Connection Team
AWARENESS • ADVOCACY • EDUCATION

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To Whom It May Concern:

FAACT's mission is to educate, advocate and raise awareness for all individuals and families affected by food allergies and life-threatening anaphylaxis through outreach, education, advocacy and research. We are writing to share that proposed HB 101 will negatively impact a patient's ability to choose the best treatment for themselves or a loved one.

We are asking the committee to reject HB 101 and to ensure all FDA-approved epinephrine auto-injectors are available to prevent barriers to access in a life-threatening circumstance.

KnowTheFAACTs:

- There are 15 million Americans are at risk for anaphylaxis, a severe life-threatening allergic reaction.
- The prevalence of food allergies appears to be increasing among children under the age of 18, that is 2 students in every classroom.
- Anaphylaxis is a serious allergic reaction that comes on quickly and has the potential to become life-threatening. Symptoms can develop within minutes of exposure to an allergen, and prompt administration of epinephrine is crucial to surviving.
- Every day in the United States, 1-2 individuals die from anaphylaxis. The most common reason is due to delay in administration of epinephrine.
- Each epinephrine auto-injector possesses unique attributes – for example, 3 second vs. 10 second hold; 1 cap vs. 2 caps to remove; audible instructions, etc.
- Unfamiliarity with a device could cost a family precious moments when responding to a life-threatening reaction.
- Patients at risk for anaphylaxis may choose to self-carry the epinephrine auto-injector that they are more familiar with and are prepared to use when the need arises.

It is important to require pharmacists to dispense the prescriptions as written. We believe all patients should have equal access to all FDA-approved epinephrine auto-injectors so they may decide with their doctor which is the best option given their unique circumstances. We understand patient and physician choice of treatment is a challenge that often includes complex considerations, such as accurate medical diagnosis, access to care, education level, ability to self-administer or self-advocate, cost, coverage, and potential side effects. By allowing pharmacists to substitute, many patients could be forced to seek unscheduled office visits, physician callbacks, ER visits, and hospitalizations due to the lack of familiarity and understanding of the alternate device. It also overrides the role of the physician. There are 3 distinctly different epinephrine auto-injectors on the market. Two of these have generic versions that work identically to the brand version. The brands are not approved as substitutable by FDA to each other and each generic is only approved as substitutable to one brand each because they work differently. This legislation, while well intentioned, could be dangerous.

Further, by requiring a physician to specify 'Dispense as Written' on a prescription in order to prevent substitution of the prescribed epinephrine auto-injector with one that operates differently, this legislation would also result in pharmacists being unable to dispense a lower cost generic for the prescribed auto-injector. There are currently FDA-approved substitutable generics to both Adrenaclick and EpiPen on the market but these would not be substitutable for the brand if a physician writes DAW in order to block a substitution between 2 brand auto-injectors. These unintended consequences must be fully considered.

Thank you in advance for hearing our concerns on behalf of the thousands of families living in Ohio who are at risk for anaphylaxis.

All my best,

Eleanor Jarrow

President & CEO