

Epinephrine Access Legislative Initiative

The issue: Anaphylaxis is a growing health concern in the U.S. and public access to epinephrine, the first-line treatment for anaphylaxis, is critical.

In recent years, there has been an increase in life-threatening (severe) allergic reactions, also known as anaphylaxis. Anaphylaxis can be triggered by certain foods, insect stings, medications, latex or other allergens. **It causes approximately 1,500 deaths in the U.S. annually**, and children and adolescents are among those most at risk.^{1,2} **An estimated 1 in 13 children in the U.S. has a food allergy** — a common cause of anaphylaxis — and studies have shown that as many as **1 in 20 adults are at risk for anaphylaxis**.^{3,4} Life-threatening allergic reactions can occur quickly and without warning.⁵ **Anaphylaxis to food allergies alone results in approximately 90,000 emergency department visits each year in the U.S.**⁶



Access Can Make a Difference

Andrue didn't know he had a life-threatening food allergy until he ate raspberries and soy nuts for the first time in a home economics class. Within minutes, his throat tightened, he developed a rash and his eyesight got blurry. A law enacted in 2013 in Nevada, where Andrue lived, requires all public schools to stock epinephrine auto-injectors; school personnel administered a stock epinephrine auto-injector to Andrue. **According to his physicians, had it not been for the access to an epinephrine auto-injector, Andrue might have died.**

A Reaction Can Happen Anywhere, At Any Time

Fifteen-year-old Diallo died after having an allergic reaction to a white chocolate and macadamia nut cookie he ate at a national chain restaurant, where he had been dining with his soccer teammates. **Diallo had never before had a reaction to a macadamia nut, but within minutes of consuming the cookie, he was lying unconscious on the floor.** Paramedics arrived and took him to a local hospital, but he never regained consciousness and died less than two days later.

Access to Epinephrine Auto-Injectors in Public Entities

Access in Schools



A number of studies in public schools have found that **between 20 and 55 percent of anaphylactic events occurred in the absence of an established or known allergic trigger**.⁷

On Nov. 13, 2013, the federal School Access to Emergency Epinephrine Act (U.S. H.R. 2094) was signed into law, encouraging states to adopt laws requiring schools to supply stock epinephrine auto-injectors. **Since 2010, the number of states that allow or require schools to stock and administer undesignated epinephrine auto-injectors has grown from eight to 47.**

Did You Know? Through its school access program, **Mylan provides free epinephrine auto-injectors** to qualifying schools in the U.S.

Access Beyond Schools

Other environments where someone may come into contact with his or her allergens and experience anaphylaxis for the first time — such as colleges and universities, child care facilities, summer camps, recreational facilities and restaurants — should be permitted to stock undesignated epinephrine auto-injectors that can be used by trained individuals to respond in the event such an emergency occurs.

A number of states have taken action to address the need for such access:

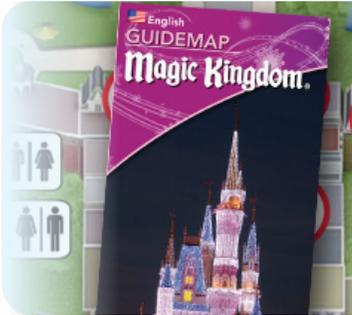
- 19 states have passed broad legislation for access to stock epinephrine auto-injectors in public entities.
- New Jersey, Indiana and New Hampshire allow stock epinephrine auto-injectors in colleges and universities.
- Ohio, New York and Maryland allow stock epinephrine auto-injectors in summer camps.



A study revealed that 82 percent of fatal anaphylactic reactions to insect venom occurred in people who had never before experienced a severe reaction.⁸

Walt Disney Parks and Resorts

Mylan has collaborated with Walt Disney Parks and Resorts to help enhance access to epinephrine auto-injectors and increase anaphylaxis awareness.



The alliance focuses on:

Providing updated maps and signage in Disney's domestic theme parks and cruise ships highlighting locations of epinephrine auto-injectors.

Over time, introducing educational resources designed to increase awareness of and preparedness for severe allergic reactions.



Legislative Aims

- Allowing trained individuals to administer epinephrine auto-injectors in an emergency situation.
- Allowing health care professionals to prescribe epinephrine auto-injectors to an authorized public place, similar to what has been legislated for schools.
- Tracking epinephrine auto-injector administration in authorized public entities.
- Allowing for undesignated epinephrine auto-injectors at authorized public entities such as:



Colleges and universities



Child care facilities



Recreational facilities



Shopping malls



Restaurants



Amusement parks

Providing liability protection to:

- Authorized public entities that stock epinephrine auto-injectors for use in emergency situations.
- Personnel who administer an epinephrine auto-injector in an emergency situation.
- Healthcare providers who prescribe to public entities.

References: 1. Neugut AI, Ghatak AT, Miller RL. Anaphylaxis in the United States. *Arch Intern Med.* 2001;161(1):15-21. 2. Simons FER. Anaphylaxis. *J Allergy Clin Immunol.* 2010;125(suppl2):S161-S181. 3. Gupta RS, Springston EE, Warriar MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics.* 2011;128(1):e9-e17. 4. Wood RA, Camargo, Jr., CA, Lieberman, P, et al. Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States. *J Allergy Clin Immunol.* 2014;133(2): 461-467. 5. Sampson HA, Muñoz-Furlong A, Campbell RL, et al. Second symposium on the definition and management of anaphylaxis: summary report—Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network symposium. *J Allergy Clin Immunol.* 2006;117(2):391-397. 6. Clark S, Espinola J, et al. Frequency of U.S. emergency department visits for food-related acute allergic reactions. *J Allergy Clin Immunol.* 2011; 127(3): 682-683. 7. Data on file and Lilliana DeSantiago-Cardenas, L, Rivkina, V, Whyte, S, et. al. Emergency Epinephrine Use for Food Allergy Reactions in Chicago Public Schools. *Am J Prev Med.* 2015;48(2): 170-173. 8. Pumphrey RSH. Lessons for management of anaphylaxis from a study of fatal reactions. *Clin Exp Allergy.* 2000;30(8):1144-1150.

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