

# People with Life-Threatening Allergies Need to be Better Protected

## The Issue

Food allergies, which can sometimes lead to a life-threatening allergic reaction, or anaphylaxis, are a large and growing public health problem.<sup>1,3</sup> Today, one out of 13 children in the U.S. has a food allergy, a considerably higher number than previously known.<sup>2</sup>

Potentially life-threatening allergic reactions to food have occurred across the U.S. due to a lack of awareness, an absence of protocols for preventing and dealing with severe food allergies, and because people, including school-aged children, are not carrying epinephrine auto-injectors that have been prescribed for them.<sup>3,4</sup>

This situation needs to change. More Americans need to

- be **AWARE** of the risk of anaphylaxis,
- understand the signs and symptoms of anaphylaxis,
- be **PREPARED** to respond when anaphylaxis occurs and
- have immediate **ACCESS** to epinephrine auto-injectors.

## Epinephrine is the First-line Treatment for Anaphylaxis<sup>5</sup>

In December 2010, the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first-line treatment for anaphylaxis.<sup>5</sup>

Epinephrine works to relieve the life-threatening symptoms of anaphylaxis, giving affected individuals more time to seek additional emergency medical treatment.<sup>6</sup> Common side effects of epinephrine may include upset stomach, vomiting, sweating, dizziness, nervousness, weakness, pale skin, headache and shaking. Although uncommon, some side effect can be serious. These include difficulty breathing and pounding, fast, or irregular heartbeat.<sup>6</sup>

The more rapidly anaphylaxis develops, the more likely the reaction is to be severe and potentially life-threatening. Prompt recognition of signs and symptoms of anaphylaxis is crucial. If there is any doubt, it is generally better to administer epinephrine.<sup>7</sup>

The NIH-NIAID guidelines also state that antihistamines are not effective in treating the symptoms of anaphylaxis. The use of antihistamines is the most common reason reported for not using epinephrine and may place a patient at significantly increased risk for progression toward a life-threatening reaction.<sup>5</sup>



## What is anaphylaxis? (pronounced an-uh-fuh-lak-sis)

Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure.<sup>1</sup>

## What are the common triggers of anaphylaxis?

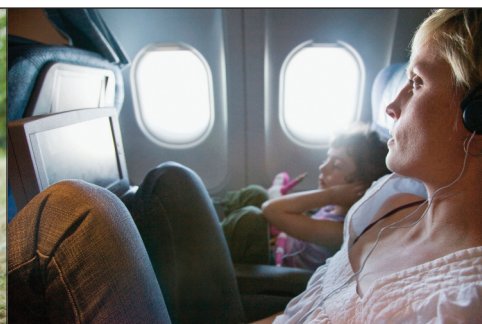
Food, insect venom, medication, and latex exposure<sup>1</sup>

## What are the most common foods to cause anaphylaxis?

Milk, egg, wheat, soy, peanut, tree nut, fish, and shellfish<sup>5</sup>

## Did you know?

- One out of 25 Americans are at risk for anaphylaxis.<sup>8,9</sup>
- Nearly 6 million or 8% of children in the U.S. have food allergies (one in 13).<sup>2</sup>
- The Centers for Disease Control and Prevention report that food allergies result in more than 300,000 ambulatory-care visits a year among children under the age of 18.<sup>10</sup>
- Food allergens account for 30% of fatal cases of anaphylaxis.<sup>7</sup>
- Anaphylaxis results in approximately 1,500 deaths annually.<sup>11</sup>



**EXHIBIT C – HEALTH CARE**  
Document consists of 2 pages.  
Entire exhibit provided.  
Meeting Date: 07-10-12

## IMMEDIATE ACTION IS NEEDED IN SCHOOLS

**On Dec. 20, 2010**, 13-year-old Katelyn Carlson of Chicago, Ill. had a severe allergic reaction to peanut oil from Chinese food ordered for a class party. She was not carrying an epinephrine auto-injector at the time, was rushed to a nearby hospital and was pronounced dead due to anaphylaxis. Even though Katelyn had been previously diagnosed with severe food allergies, she did not have an epinephrine auto-injector on hand to administer. This tragedy caused Illinois to take action. On Aug. 15, 2011, Illinois Governor Pat Quinn signed into law the School Access to Emergency Epinephrine Act, which permits access to undesignated epinephrine auto-injectors in Illinois schools for students who suffer a severe allergic reaction.<sup>12</sup>

A study evaluating the use of epinephrine for the management of anaphylaxis in the school setting found that **24% of anaphylactic reactions occurred in children who did not have a prior history of life-threatening allergies.**<sup>13</sup> This eye-opening statistic speaks to the increasing importance of making epinephrine auto-injectors available and accessible in schools in the event that an anaphylactic reaction does occur.



## Change in schools means

- ☐ Standardizing and implementing guidelines for managing life-threatening food allergies in schools
- ☐ Allowing students to carry prescribed epinephrine auto-injectors and self-administer
- ☐ Allowing schools to maintain a supply of undesignated epinephrine auto-injectors
- ☐ Allowing medical professionals and trained non-medical professionals to administer epinephrine auto-injectors to students with or without a prescription on file
- ☐ Protecting good samaritans who administer an epinephrine auto-injector in an emergency situation
- ☐ Allowing physicians to prescribe epinephrine auto-injectors to an entity, like a school
- ☐ Tracking epinephrine auto-injector administration in schools

## THE NEED FOR EPINEPHRINE ACCESS EXTENDS WIDELY

A first reaction, whether it is from food, an insect sting or medications, may be severe enough to cause death.<sup>3</sup> What if a child's first reaction occurs at a restaurant, on an airplane, on a subway or at a museum? What if it happens in a place where the first responder is not authorized to administer epinephrine or the ambulance does not have epinephrine stocked?

**On Aug. 16, 2011**, 15-year-old Jharell Dillard went to a shopping center in Atlanta, Ga. with his mother and two sisters. While there, he ran outside to grab a cookie from the car. What he thought was simply a chocolate chip cookie turned out to contain nuts, to which he was severely allergic. He immediately went into anaphylaxis, but was not carrying his epinephrine auto-injector. By the time he was airlifted to the local children's hospital it was too late. Jharell was pronounced dead due to anaphylaxis.<sup>12</sup>

## Change beyond schools means

- ☐ Allowing for undesignated epinephrine auto-injectors on forms of public transportation and at camps, restaurants and other public venues
- ☐ Requiring emergency first responders to carry epinephrine
- ☐ Training and authorizing first responders to administer epinephrine auto-injectors

### Action should not have to wait until another tragedy occurs

Laws and policies should ensure that individuals and organizations are fully aware of, enabled and empowered to treat emergency anaphylactic episodes wherever they may occur.



**Mylan Specialty**

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(as of Feb. 15, 2012)