**TESTIMONY OF**

Colin Chiles
Senior Director, State Government Relations
Mylan Inc.

Good afternoon. Thank you for the opportunity to speak with you today. My name is Colin Chiles and I am the Senior Director of State Government Relations for Mylan Inc. Mylan is a leading manufacturer of generic and specialty medications with operations in seven U.S. states and a provider of generic medicines in more than 140 countries and territories worldwide. A Mylan subsidiary markets and distributes one of several epinephrine auto-injectors currently available in the United States.

Food allergies, which can sometimes lead to a life-threatening allergic reaction, or anaphylaxis, are a large and growing public health problem.[1,3] Today, an estimated one out of 13 children in the U.S. has a food allergy, a considerably higher number than previous estimates.[2] And, food allergens are only one type of the allergens that can cause anaphylaxis.

Unfortunately, over the past several years, there have been several high profile anaphylaxis-related tragedies around the country in schools and outside of schools. Deaths in Illinois (in 2011), Georgia and Virginia (in 2012), California, Texas and New York (in 2013) resulted in significant attention to the issue and much discussion on how to best address it.

In 2013 Nevada passed legislation to require stock epinephrine auto-injectors in schools and to permit trained school personnel to administer them in an emergency. Today, 46 states have school access laws similar to Nevada's law.

Although there is limited data on anaphylaxis, the numbers we do know are very concerning:

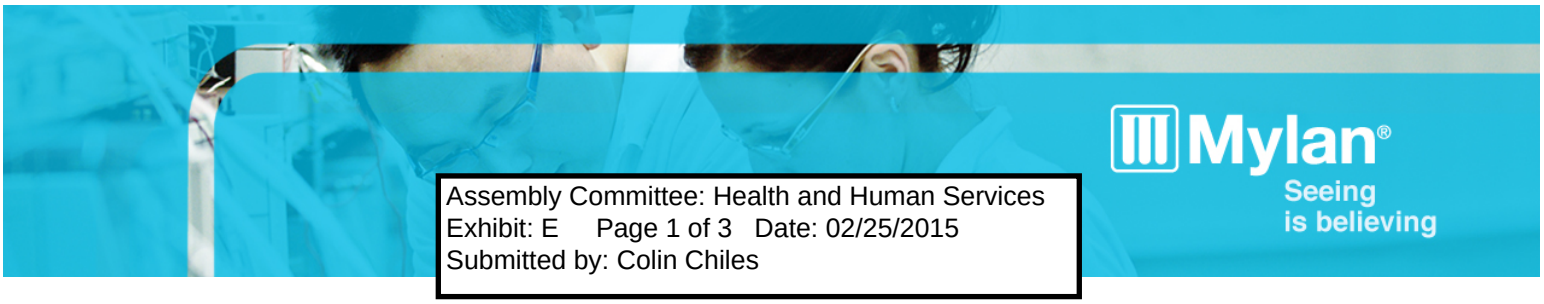
- Massachusetts compiles a report each year of administrations of epinephrine auto-injectors in their schools. According to the Massachusetts Department of Public Health, a survey conducted in that state's schools found that 24% of anaphylactic reactions occurred in individuals who were not known to be at risk of life-threatening allergies.

- Nearly 6 million or 8% of children in the U.S. have food allergies (~ one in 13).[2]

- 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.[10]

- Food allergens account for 30% of fatal cases of anaphylaxis.[7]






Assembly Committee: Health and Human Services
Exhibit: E Page 1 of 3 Date: 02/25/2015
Submitted by: Colin Chiles

- Anaphylaxis results in approximately 1,500 deaths annually.[11]

Nevada has made great strides to address this issue, but more can be done to ensure the state is better prepared in the event that Nevada children or adults experience an anaphylactic reaction for the first time or in a public location. Schools were a very important first step in addressing anaphylaxis. AB 158 will build upon Nevada's school access law and expand access to this critical medication.

AB 158 would expand access and allow colleges and universities, summer camps, sports arenas, restaurants, recreational parks and other places where children and adults could come into contact with potentially life-threatening allergens to stock epinephrine auto-injectors and allow trained personnel to administer them in emergencies.

Anaphylaxis can happen in many different places and prompt recognition of signs and symptoms of anaphylaxis is crucial. If there is any doubt, it is generally better to administer epinephrine.[7] Failure to administer epinephrine early in the course of treatment has been repeatedly implicated in anaphylaxis fatalities. The more rapidly anaphylaxis develops, the more likely the reaction will be severe and potentially life-threatening. This is why increased access is so important.

Oregon passed legislation in 2013 to allow a broad range of entities like sports arenas, restaurants, parks and summer camps to stock and train employees to administer epinephrine auto-injectors and Florida and Rhode Island followed suit in 2014. New Jersey and Indiana allow colleges and universities to stock and administer epinephrine auto-injectors. New York, New Hampshire and Ohio allow summer camps and similar entities to stock and administer epinephrine auto-injectors.

In addition, 8 states, including California, Maryland, North Dakota and Alaska, have laws that would allow individuals - such as scout leaders, daycare workers, guides and camp employees – who have completed state approved training programs to obtain and administer epinephrine auto-injectors to others who they believe are experiencing anaphylaxis.

Those laws allow individuals to possess and administer epinephrine auto-injectors, but fall short by not clearly allowing the entities or businesses that employ those trained individuals can stock them. As a result, these laws will never be as effective as AB 158 would be at addressing this issue. Nevada is one of approximately 30 states expected to consider legislation similar to AB 158 this year because it is clear that more can be done.

Forty-six states currently allow (or require) schools to stock and administer epinephrine auto-injectors in schools. Mylan is committed to working with states going forward to expand access beyond schools just as we have worked with states to allow epinephrine auto-injectors to be stocked

Mylan®
Seeing is believing

in schools. Mylan created a program to provide up to four free epinephrine auto-injectors per school year to public and private kindergarten, elementary, middle and high schools in the U.S., upon qualification under applicable state law.

We are pleased that more than 49,000 schools across the country have already taken advantage of this free program including 629 schools in Nevada. There have been a number of situations where schools across the country have used these free epinephrine auto-injectors to treat an anaphylactic reaction, underscoring the positive impact of clear laws around the ability to stock and administer epinephrine auto-injectors and the program.

Much progress is being made in the effort to prevent tragedies from food and other allergens in schools and elsewhere. In the last several months, the American Red Cross launched a training program on anaphylaxis and administration of epinephrine auto-injectors, and the U.S. Centers for Disease Control and Prevention issued voluntary guidelines for managing food allergies in schools.

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.[5] Epinephrine works to relieve the life-threatening symptoms of anaphylaxis, which gives affected individuals more time to seek additional emergency medical treatment.[6]

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.[5]

Mylan would like to work with you as you consider this important legislation. Thank you for your time and consideration today. I am happy to take any questions and to work with the committee and other interested parties as you consider this legislation.

**References**

1. Simons FER. Anaphylaxis. *J Allergy Clin Immunol*. 2010; 125(suppl 2): S161-S181.
2. Gupta, et al. The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States. Pediatrics. 2011; 128: e9-17.
3. Munoz-Furlong A, Weiss C; Characteristics of Food-Allergic Patient Placing Them at Risk for a Fatal Anaphylactic Episode. *Current Allergy and Asthma Reports*. 2009; 9: 57-63.
4. "Data Health Brief: Epinephrine Administration in School." Massachusetts Department of Public Health, Bureau of Community Health Access and Promotion, School Health Unit. August 1, 2009 – July 31, 2010 (School Year 2009-2010).
5. Boyce, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel *J Allergy Clin Immunol*. 2010 Dec:126(6):S1-58.
6. "Epinephrine Injection." MedlinePlus http://www.nlm.nih.gov/medlineplus/druginfo/meds/a603002.html#brand-name-1. Last reviewed on September 1, 2008. Accessed on December 2, 2011.
7. Lieberman P et al. The diagnosis and management of anaphylaxis practice parameter: 2010 Update. *J Allergy Clin Immunol*. 2010;126(3):477-480.
8. Sicherer SH, Simons FE. Quandaries in prescribing an emergency action plan and self-injectable epinephrine for first-aid management of anaphylaxis in the community. J Allergy Clin Immunol. 2005;115(3):575-583.
9. Neugut Al, Ghatak AT, Miller RL. Anaphylaxis in the United States: an investigation into its epidemiology. Arch Intern Med. 2001;161(1):15-21.
10. Branum AM, Lukacs SL. Food allergy among children in the United States. *Pediatrics*. 2009;124(6):1549-1555.
11. Clark S, Camargo CA Jr. Epidemiology of anaphylaxis. *Immunol Allergy Clin North Am*. 2007;27(2):145-1463.
12. According to various news reports.
13. McIntyre CL, et al. Administration of Epinephrine for Life-Threatening Allergic Reactions in School Settings. *Pediatrics*. 2005; 116: 1134-1140

Mylan®
Seeing is believing