TESTIMONY OF

Colin Chiles
Director, State Government Relations
Mylan Inc.

Good morning. Thank you for the opportunity to speak with you today.

My name is Colin Chiles and I am the Director of State Government Relations for Mylan Inc. Mylan is a leading U.S. based manufacturer of generic and specialty medications. We have facilities in eight states, as well as Puerto Rico, and provide generic medicines in more than 150 countries and territories worldwide.

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 previously known.[2]

We support SB 611 which will ensure that Oregon schools are well prepared in the event of a student experiencing an anaphylactic reaction at school and commend you for also including entities with trained personnel, such as summer camps and after school programs, in this legislation.

Schools nationwide have made efforts to reduce exposure to allergens in the school environment—a critical first step in managing the risk of life-threatening allergic reactions. While practicing allergen avoidance is imperative, accidental contact can still happen, which is why it is important that epinephrine auto-injectors are accessible.

Over the past two years, there have been tragedies at schools around the country that resulted in the death of a student from anaphylaxis from exposure to an allergen. Deaths in Illinois (in 2011) and Virginia (in 2012) resulted in significant attention to the issue and much discussion on how to best address it. At least 10 other states are currently considering legislation similar to the legislation we are here to support today.

A Mylan subsidiary, Mylan Specialty, markets and distributes one of several epinephrine auto-injectors in the United States. Mylan Specialty has long-standing relationships with a number of leading patient advocacy organizations, working closely on educational and awareness efforts relating to food allergies and anaphylaxis. We look forward to working with this committee, the Legislature and school officials as you work to address this important issue.

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, giving affected individuals more time to seek additional emergency medical treatment.[6]

Common side effects of epinephrine may include upset stomach, vomiting, sweating, dizziness, nervousness, weakness, pale skin, headache and shaking. Although uncommon, some side effects can be serious. These include difficulty breathing and pounding, fast, or irregular heartbeat. [6]

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.[7] Failure to administer epinephrine early in the course of treatment has been repeatedly implicated with anaphylaxis fatalities.

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]

The Illinois Legislature passed legislation to allow schools to stock epinephrine auto-injectors for use in response to an anaphylactic emergency. The new Illinois law allows school nurses to administer an epinephrine auto-injector to a student regardless of whether the student has been previously diagnosed if the nurse believes the student is experiencing an anaphylactic reaction. The law further allows other school personnel who are designated in a student's individual health plan to administer an epinephrine auto-injector to that student.

The Virginia, Maryland and Louisiana Legislatures passed legislation last year that will require schools to stock epinephrine auto-injectors for use in response to an anaphylactic emergency. School nurses and other trained personnel are authorized to administer epinephrine auto-injectors to any student who they believe is experiencing an anaphylactic reaction.

Massachusetts addressed this issue more than a decade ago following the deaths of two students while Missouri and Kansas passed legislation more recently. Georgia passed legislation in the past session to allow school personnel to administer epinephrine auto-injectors, Rhode Island passed legislation to allow school bus drivers and monitors to administer epinephrine auto-injectors.

To our knowledge, every state, including Oregon, now allows students who have been prescribed an epinephrine auto-injector to bring their auto-injector to school although the rules may vary among school districts. Unfortunately, some children who are at risk have never been diagnosed and do not know they could be subject to an anaphylactic reaction. Massachusetts compiles a report each year of administrations of auto-injectors in the schools. According the Massachusetts Department of Public Health, a survey conducted in 109 Massachusetts school districts from 2001 to 2003 evaluating the

use of epinephrine for anaphylaxis management in schools, found that up to 24% of anaphylactic reactions occurred in individuals who were not known by school personnel to have a prior history of life-threatening allergies. This number is particularly disturbing.

Mylan is committed to working with states on this going forward. That is why I am pleased to have the opportunity to speak with you today. We learned through our discussions with Massachusetts and Illinois officials that cost of epinephrine auto-injectors presented a challenge to school budgets. As a result, we created a program to provide up to four free epinephrine auto-injectors per school year, upon qualification, which includes having a valid prescription, to public and private kindergarten, elementary, middle and high schools in the U.S.

Most state laws are unclear in this regard, but we are pleased that more than 20,000 schools have already taken advantage of this program. There have been several cases in schools across the country in which the free epinephrine auto-injectors were used to treat an anaphylactic reaction, underscoring the positive impact of the program. We will continue to work with stakeholders including physicians, allergy advocacy organizations, school officials, school nurses, the American Red Cross and others to learn more about the ways to address potentially life-threatening food allergies and anaphylaxis in the schools.

There are a number of important statistics that have been accumulated with regard to food allergies and anaphylaxis, but I would to mention just four key points here:

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

My colleagues and I at Mylan would like to work with you to ensure that Oregon schools are prepared to address anaphylaxis so that emergencies do not turn into tragedies. As I already mentioned, Mylan currently offers a program to help schools address the cost issue associated with stocking of epinephrine auto-injectors and we continue to look for additional ways that we can help.

Thank you for your time and your consideration today. I would be pleased 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.

Mylan®
Seeing is believing

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 AI, 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

People with Life-Threatening Allergies Need to be Better Prepared

The Issue

There is a growing rate of life-threatening allergic reactions, or anaphylaxis, in the U.S., creating a public health concern and a major safety issue. Estimates indicate that anaphylaxis causes approximately 1,500 deaths annually.[1] Children and adolescents are among those most at risk for anaphylaxis.[2]

Food allergies are the most common cause of anaphylaxis, and the prevalence of food allergies is on the rise.[3,4] Today, food allergies affect an estimated one out of 13 children in the U.S., a considerable increase from previously reported figures.[5]

Schools nationwide have made efforts to reduce exposure to allergens in the school environment—a critical first step in managing the risk of life-threatening allergic reactions. While practicing allergen avoidance is imperative, accidental contact can still happen, which is why it is important that epinephrine auto-injectors are accessible.[4,6]

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[7]

According to food allergy guidelines released in December 2010 by the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), epinephrine is the only first-line treatment in all cases of anaphylaxis (including from food allergies) and should be available at all times for people at risk for anaphylaxis. According to the NIAID guidelines, if experiencing anaphylaxis, a person should use an epinephrine auto-injector and seek immediate emergency medical attention.

Common side effects of epinephrine may include upset stomach, vomiting, sweating, dizziness, nervousness, weakness, pale skin, headache and shaking, difficulty breathing and pounding, fast, or irregular heartbeat.[8]

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 critical.[9] If there is any doubt, it is better to administer epinephrine. Failure to administer epinephrine early in the course of treatment has been repeatedly implicated with anaphylaxis fatalities.[9,10,11]

What is anaphylaxis?
(pronounced a-na-fi-LAX-is)

Anaphylaxis is a life-threatening 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.[2]

What are the common triggers of anaphylaxis?

Foods, insect stings, medications, latex, other allergens or an unknown trigger.[2]

What are the most common foods to cause anaphylaxis?

Milk, egg, wheat, soy, peanut, tree nut, fish and shellfish.[7]

Did you know?

- A 2010 study indicated that anaphylaxis results in 90,000 emergency department visits per year for food allergies alone.[12]
- In 2008 the CDC reported that an 18% increase in food allergy was seen between 1997 and 2007.[3]
- Food allergens account for 30% of fatal cases of anaphylaxis.[4]
- Data on anaphylaxis incidence and prevalence are sparse and often imprecise; however, estimates indicate that anaphylaxis may affect 3 to 43 million Americans. As evidenced by the range provided, more research needs to be conducted.[1]

IMMEDIATE ACTION IS NEEDED IN SCHOOLS

Recent tragedies have brought significant attention to the issue of managing anaphylaxis at school and raised much discussion on how to best address the problem.

Following the deaths of two students a decade ago, Massachusetts became the first state to address the issue of anaphylaxis management at school. A survey conducted in 109 Massachusetts school districts from 2001 to 2003 evaluating the use of epinephrine for anaphylaxis management in schools, found that up to **24% of anaphylactic reactions occurred in individuals who were not known by school personnel to have a prior history of life-threatening allergies.[13]**

On Dec. 20, 2010, 13-year-old Katelyn Carlson of Chicago, Ill. had a life-threatening allergic reaction to peanut oil from Chinese food ordered for a class party. She was rushed to a nearby hospital and pronounced dead due to anaphylaxis. Katelyn had been previously diagnosed with life-threatening food allergies but did not have an epinephrine auto-injector on hand to administer. As a result, on Aug. 15, 2011, Illinois signed into law the School Access to Emergency Epinephrine Act, permitting access to undesignated epinephrine auto-injectors in Illinois schools for students who suffer from a severe allergic reaction.[14]

On Jan. 2, 2012, seven-year-old Amarria Johnson of Chesterfield, Va. died at school after she suffered an allergic reaction to a peanut product. She did not have an epinephrine auto-injector on hand and was in cardiac arrest by the time emergency crews arrived and was pronounced dead shortly after. Amarria's death caused Virginia to make a change. On April 26, 2012, legislation requiring Virginia schools to stock epinephrine auto-injectors for use by school nurses and other trained personnel to administer to any student who they believe is experiencing an anaphylactic reaction became law.[14]

These are just a few of the tragic examples that demonstrate why each school should have a comprehensive anaphylaxis action plan,[15,16,17] so that students, teachers and school employees:

- Understand the risk of anaphylaxis
- Avoid allergic triggers
- Recognize the signs and symptoms
- Are prepared with access to epinephrine auto-injectors (two doses)[7]
- Know to seek emergency medical care following administration of treatment

THE NEED FOR EPINEPHRINE ACCESS ALSO EXTENDS BEYOND SCHOOLS

A first reaction, whether it is from food, an insect sting or medications, can happen anywhere and may be severe enough to cause death.[4]

On Aug.16, 2011, 15-year-old Jharell Dillard, who had a life threatening allergy to peanuts, 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 actually contained nuts. He immediately went into anaphylactic shock, and 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.[14]

Change in schools means

- ☐ Standardizing and implementing guidelines for managing life-threatening allergies in schools
- ☐ 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

A number of states have taken action to address anaphylaxis in schools:

- Examples include: Maryland, Virginia, California, Georgia, Illinois, Kansas, Missouri, Nebraska and Massachusetts[14]
- Rhode Island passed legislation to allow school bus drivers and monitors to administer epinephrine auto-injectors[14]
- Texas published statewide food allergy guidelines, making it the 15th U.S. state requiring public schools and open-enrollment charter schools to implement strategies for special care of students with food allergies[14]

Change beyond schools means

- ☐ **Allowing for undesignated epinephrine auto-injectors at restaurants, camps and other public venues, including public transportation**
- ☐ **Requiring all emergency first responders to carry epinephrine and to be trained and authorized to administer epinephrine auto-injectors**

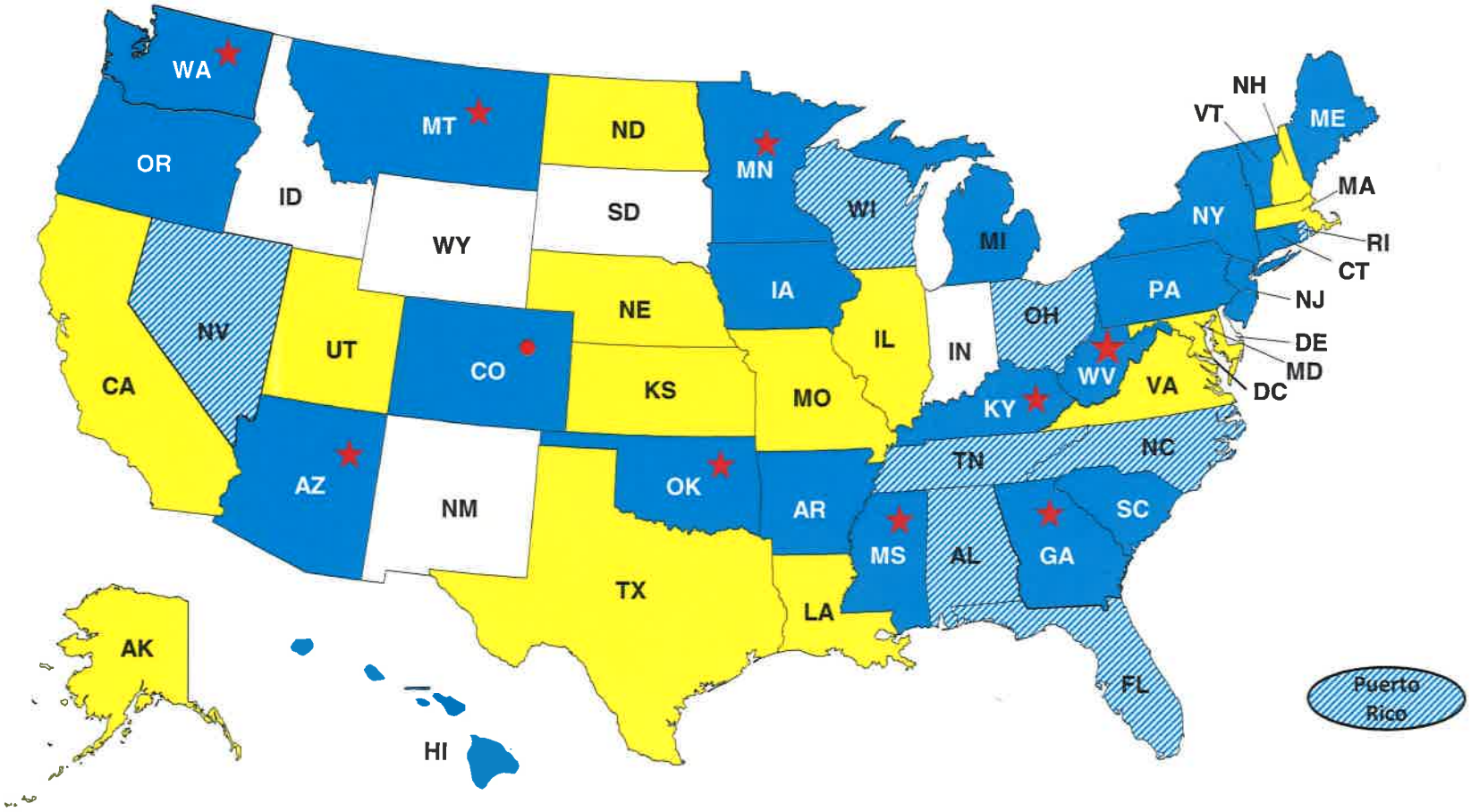
Mylan®
Seeing is believing

(as of Nov. 20, 2012)

References

1. Neugut AI, Ghatak AT, Miller RL. Anaphylaxis in the United States: an investigation into its epidemiology. *Arch of Intern Med.* 2001; 161(1): 15-21.
2. Simons FER. Anaphylaxis. *J Allergy Clin Immunol.* 2010;125(suppl2):S161-S181.
3. Branum, A, Lukas S. Food Allergy among US Children: Trends in Prevalence and Hospitalizations. National Center for Health Statistics Data Brief. 2008: 1-7.
4. Lieberman P et al. The diagnosis and management of anaphylaxis practice parameter: 2010 Update. *J Allergy Clin Immunol.* 2010;126(3):477-480.
5. Gupta, et al. The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States. *Pediatrics.* 2011; 128: e9-17.
6. 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.
7. 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.
8. EpiPen [package insert], Napa, CA: Mylan Specialty, L.P., 2008.
9. Bock SA, Munoz-Furlong A, Sampson HA. Fatalities due to anaphylactic reactions to food. *J Allergy Clin Immunol.* 2001;107(1):191-193.
10. Bock SA. Further fatalities caused by anaphylactic reactions to food, 2001-2006 [letter]. *J Allergy Clin Immunol.* 2007;119(4):1016-1018.
11. Sampson HA, Mendelson L, Rosen JP. Fatal and near-fatal anaphylactic reactions to food in children and adolescents. *N Eng J Med.* 1992;327(6):380-384.
12. 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.
13. McIntyre C, Sheetz A, et al. Administration of epinephrine for life-threatening allergic reactions in school settings. *Pediatrics.* 2005; 116:1134-1140.
14. According to various news reports.
15. Simons FER. Anaphylaxis: Recent advances in assessment and treatment. *J Allergy Clin Immunol.* 2009. 635-636.
16. Sampson HA, Munoz-Furlong A, 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.
17. Sicherer SH, Simons F. Quandaries in prescribing an emergency action plan and self-injectible epinephrine for first-aid management of anaphylaxis in the community. *J Allergy Clin Immunol.* 2005; 116(3): 575-583.

Epinephrine School Legislation Status - 2013



Legislation Introduced - 22	Introduction Expected - 10	Existing law/guideline - 13
★ Passed one chamber - 9	☆ Awaiting Floor Action - 0	● Passed First Committee - 1

Updated as March 19, 2013

Mylan®
Seeing is believing