

TESTIMONY OF

Fawn Barrie on behalf of Mylan Inc.

Thank you for the opportunity to speak with you today.

My name is Fawn Barrie and I represent 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

Mylan supports 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. Mylan looks 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 and learned through discussions with Massachusetts and Illinois officials that cost of epinephrine auto-injectors presented a challenge to school budgets. As a result, Mylan 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. Mylan 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

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.
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

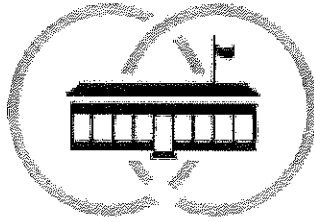


- community. *J Allergy Clin Immunol*. 2005;115(3):575-583.
9. Neugut AI, Ghatak AT, Miller RL. Anaphylaxis in the United States: an investigation into its epidemiology. *Arch Intern Med*. 2001;161(1):15-21.
10. Branum AM, Lukacs SL. Food allergy among children in the United States. *Pediatrics*. 2009;124(6):1549-1555.
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



DATA HEALTH BRIEF: EPINEPHRINE ADMINISTRATION IN SCHOOLS
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)

This annual data health brief documents the epidemiology of epinephrine administration for the treatment of life threatening allergic reactions or anaphylaxis in Massachusetts schools. The American Academy of Allergy, Asthma and Immunology defines anaphylaxis as a collection of symptoms affecting multiple systems in the body. Common signs and symptoms may be a combination of hives, swelling (of any body parts), stomach cramps, throat tightness or closing, difficulty breathing, faintness or loss of consciousness and others. The most dangerous symptoms include breathing difficulties and a drop in blood pressure or shock, which are potentially fatal. Common examples of potentially life-threatening allergies are those to food, stinging insects, medications, latex, environmental and others and reactions to those allergens may be mild, moderate, or severe. Epinephrine (adrenalin) is the first drug that should be used in the emergency management of an individual having a potentially life-threatening allergic reaction. It is recommended that epinephrine be given at the start of any reaction occurring in conjunction with exposure to a known or suspected allergen.¹

After administering epinephrine, all Massachusetts schools are required to complete a standard form, *Report of EpiPen® Administration*, and submit it to the Massachusetts Department of Public Health (MDPH), School Health Unit. Reporting of epinephrine administration in all public and nonpublic schools became mandatory in November 2003 under 105 CMR 210, the Regulations Governing the Administration of Prescription Medications in Public and Private Schools.

This annual data report demonstrates findings consistent with previous reports:

- **The majority of the epinephrine administrations were administered by school nurses (92%)**
- **The numbers of individuals who had a life threatening anaphylactic event without a previous allergy history remains high (25%)**

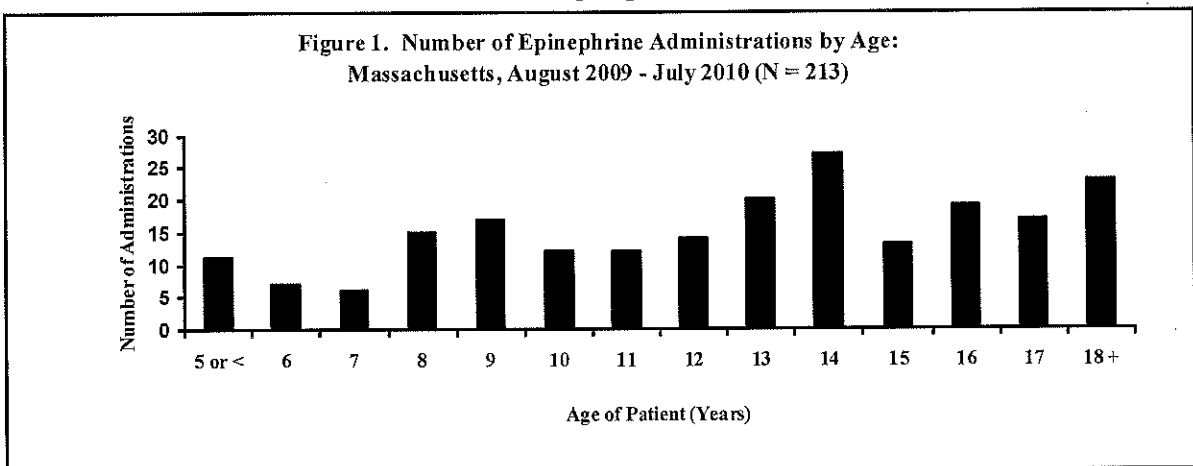
¹ Position Statement: Anaphylaxis in schools and other child-care settings, American Academy of Allergy, Asthma and Immunology, J Allergy Clinical Immunology 1998; Vol.102, No. 2, 173-175.

During the 2009-2010 school year, 164 schools (156 public schools in 106 school districts, as well as 8 private schools in 7 cities and towns) reported 225 administrations of epinephrine for the treatment of allergic reactions in schools.

- All six regions of the state reported epinephrine administration. The MetroWest region reported the greatest number of administrations (31.7%), whereas the Boston region reported the fewest (4.0%).
- While most school districts reported only one administration of epinephrine, 40 public school districts reported more than one. Ten public school districts reported five or more epinephrine administrations during the school year.

Characteristics of Individuals Receiving Epinephrine

- Of the individuals receiving epinephrine, 198 (or 90%) were students; 20 (9%) were staff members; and 3 (1%) were visitors (the status of 4 was not reported). Figure 1 shows the age distribution of all individuals who received epinephrine.



Data Source: Report of EpiPen® Administration forms.. Age was not reported for 12 patients.

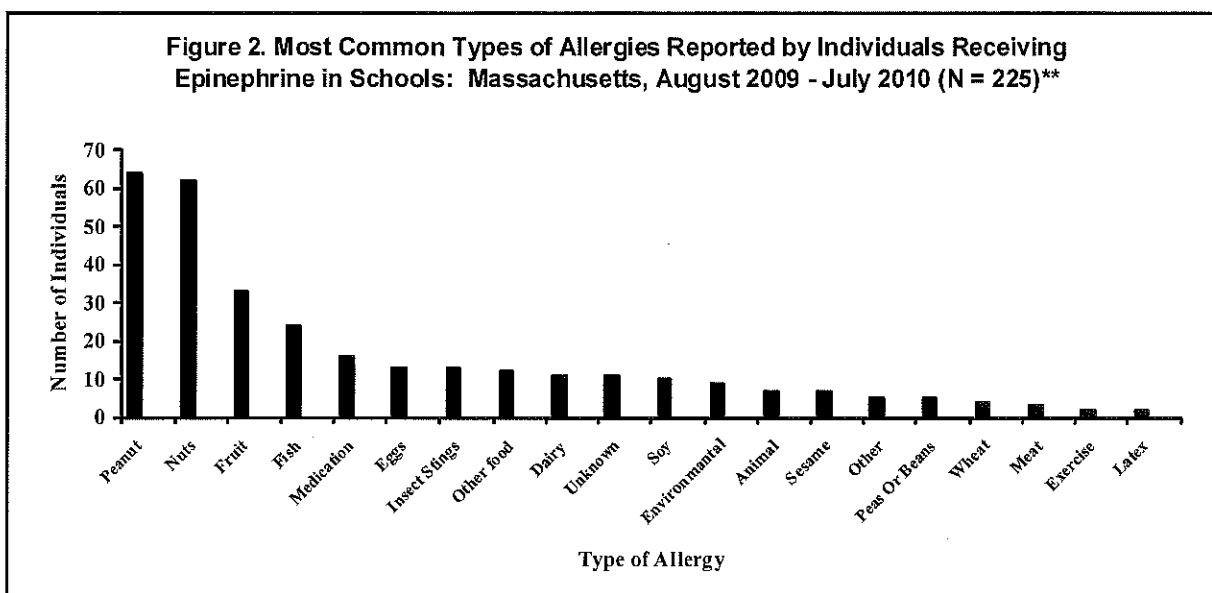
Of the 189 students who received epinephrine, 52% were female and 48% male.²

- The most frequently reported allergies were peanut and nut allergies (Figure 2).³

² The gender of 9 students was not reported.

³ Since those with multiple allergies reported more than one allergen, the total number of allergies reported is greater than the number of cases.

Figure 2. Most Common Types of Allergies Reported by Individuals Receiving Epinephrine in Schools: Massachusetts, August 2009 - July 2010 (N = 225)**



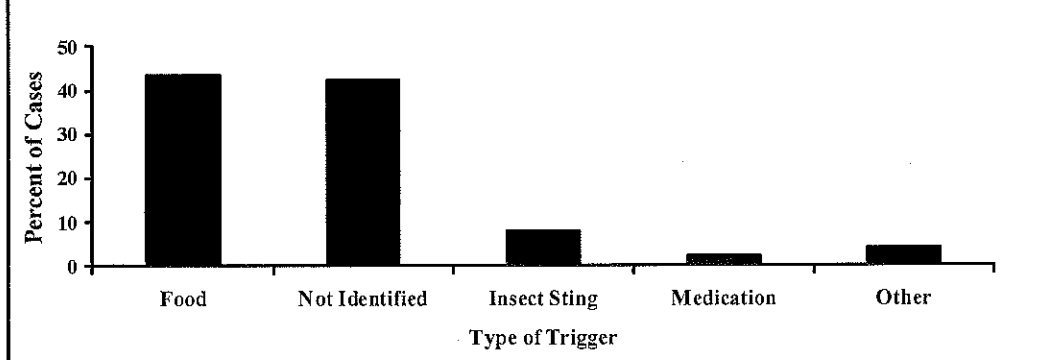
Data Source: Report of EpiPen Administration forms.

- 64 individuals receiving epinephrine (28%) reported having multiple allergies.
- In 57 cases (25%), the individual receiving epinephrine was not known to have an allergic condition at the time of the anaphylactic event. For these individuals, it was a first time event.

Characteristics of Allergic Reactions

- Food was believed to be the cause of 43% of the reactions (Figure 3).
- In 42% of the cases, the allergen that triggered the reaction was not identified (Figure 3) (both for first time events and those with previous known allergies).
- Reported symptoms involved multiple organ systems such as the skin, gastrointestinal, respiratory, cardiovascular, or neurological. In 79% of the cases the symptoms reported involved the respiratory tract, such as a tightness of the throat, wheezing, shortness of breath, or difficulty swallowing. A little over one-half of the cases (60 %) involved symptoms related to the skin such as hives, itchy skin or facial swelling. Gastrointestinal symptoms such as nausea or oral "tingling" were reported in 34% of the cases. Neurological symptoms such as "light headedness" or feelings of anxiety were reported in 11% of the cases, and cardiovascular symptoms such as tachycardia were reported in 4% of the cases.
- Symptoms most frequently developed in the classroom (45%). Other locations included the cafeteria (14%), health office (9%), playground/outside/recess (7%), the gymnasium (3%), and various other locations both inside and outside the school building. In 92% of the cases, epinephrine was administered in the health office.

Figure 3. Triggers of Allergic Reactions Reported by Individuals Receiving Epinephrine in Schools, Massachusetts, August 2009 - July 2010 (N=224)



Data Source: Report of EpiPen® Administration forms. In 1 case, the trigger was not reported.

- The majority of epinephrine administrations (92 %) were performed by the school registered nurse. In 3% of cases, epinephrine was administered by unlicensed personnel such as teachers, coaches, administrators and parents. All had been appropriately trained in the administration of epinephrine. Another 1% were administered by LPNs. In less than 1% of cases, epinephrine was administered by an Emergency Medical Technician.
- In 3% of the cases, students self-administered the epinephrine. The students who self-administered were between 10 and 18 years of age.
- After the development of symptoms, epinephrine was administered in 10 minutes or less 66% of the time (Range: 0 - 150 minutes).⁴

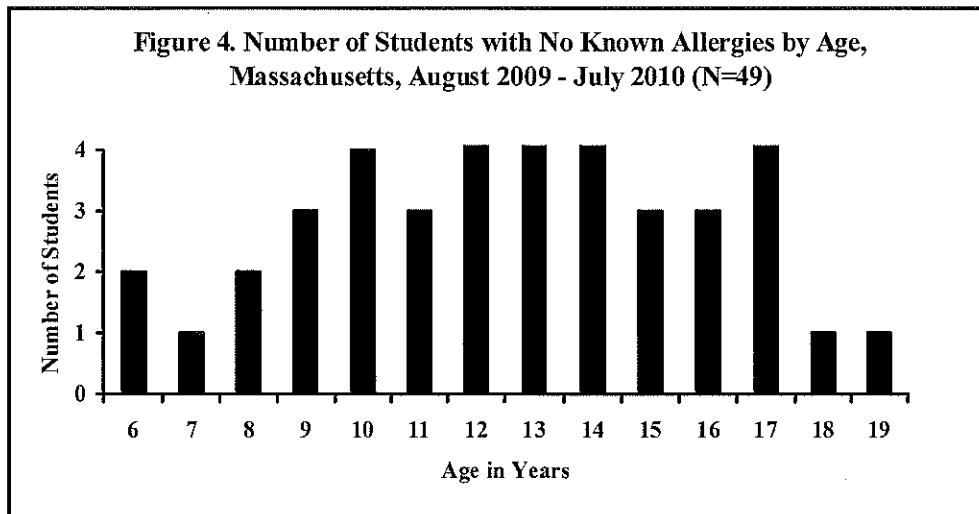
Reasons for delayed administration (≥ 90 minutes):

- In all 3 cases, the student did not have a history of epinephrine use
- In 2 of the 3 cases, the student did not have a known allergy or a history of anaphylaxis
- Of those students with known allergies, 72% had an individualized health care plan (IHCP) in place.
- Of those students with known allergies, 52% had also been diagnosed with asthma.
- Five students were not transported to a medical facility via the Emergency Medical System.
 - In all five cases, the parent made the decision not to transport the student to the emergency room and took the student home. In two of these cases, the student had no known allergies.

⁴ This includes individuals with known and unknown allergic conditions.

Characteristics of Cases Involving Individuals without a Known Allergic Condition

- Fifty-seven cases (25%) involved individuals without a known allergic condition, and 49 of those involved students.
- In cases involving individuals without a known allergic condition:
 - The average age of students was 12.9 years, with a range of 6-19 years (Figure 4).
 - After the development of symptoms, epinephrine was administered in 10 minutes or less 51% of the time (compared to 69% of the time in cases involving a known allergic condition).



Data Source: Report of EpiPen Administration forms.

ONGOING RECOMMENDATIONS TO SCHOOLS

This report has been prepared as a performance improvement strategy to ensure high quality management of individuals with life threatening allergies in the school setting. Based on some of the findings, the following are ongoing recommendations and will be shared with all school nurses:

- Educate parents stressing the importance of sharing their children's information on known allergies with the school nurse and ensure that EpiPens® are available at the school.
- Ensure that all students with life threatening allergies have an individualized care plan.
- Recommend that school staff share any information on their own life threatening allergies with the school nurse to ensure a prompt emergency response should an unintended exposure occur.
- Ensure that all individuals who have experienced a life threatening allergic event are transported via an emergency medical vehicle to an emergency care facility. This

requires education of the parents/guardians, all school staff and emergency medical personnel about the potential for a repeat of the symptoms or a biphasic reaction.⁵

- Ensure that school policy and individual health care plans follow the American Academy of Allergy, Asthma and Immunology position statement that epinephrine is the first drug that should be used in the emergency management of a child having a potentially life threatening allergic reaction.⁶
- Implement the Massachusetts guidelines, *Managing Life Threatening Food Allergies in Schools*. www.doe.mass.edu/cnp/allergy.pdf

⁵ Biphasic reaction or secondary response is a recurrence of symptoms within 72 hours with no further exposure however a continued presence of antigens in the body.

⁶ Position Statement: Anaphylaxis in schools and other child-care settings, American Academy of Allergy, Asthma and Immunology, J Allergy Clinical Immunology 1998; Vol.102, No. 2 , 173-175.