To: Oregon State Legislature
From: Roberta Lincoln, resident of Salem, Oregon
RE: Support for Senate Bill 611

My name is Roberta Lincoln, and I am here as a citizen of Oregon and more importantly as a parent of a young child with multiple life-threatening (anaphylactic) food allergies. I strongly support Senate Bill 611, and I urge you to support this bill as well.

I am the parent of a 4-year-old special needs child, who will be entering Kindergarten in the Fall of 2013. This bill would not only allow my son to have his Epinephrine and other allergen-blocking medications in his classroom, and readily available, but would also support the training of the teachers who would be responsible for his care. Please allow me to explain why I feel passionately about his bill. When my son was only 6-months of age, he suffered a life-threatening allergic reaction, known as anaphylaxis, to a milk-based baby formula while in care at his licensed daycare center.

Of course, every person's individual experience with anaphylactic episodes is different. However, they are all life threatening, and can mean death within minutes. In our experience, I arrived at my son's daycare center within 5 minutes of the start of his reaction – upon arrival he was unconscious. Emergency responders were on the scene within the following 2 to 3 minutes. My son was rushed to Salem Hospital– a two-mile ambulance ride. He received emergency treatment with multiple epinephrine injections during this ride. And, while he arrived at the hospital in less than 15 minutes from the on-set of his anaphylactic episode, his remained in critical condition – the situation continued to be precarious and unpredictable for the next hour.

At the hospital, the doctors informed me that the safest course of action would be to life-flight my infant son to Doernbecher Children's Hospital. However, his condition was so unstable, and he was so close to death, that the doctors believed there wasn't enough time to air-lift him there -- all we could do was hope that the treatment provided at Salem Hospital would be enough to keep him alive. After it was evident that my son had made it through the most precarious period of treatment, the doctors informed me that had I taken the time to drive my son to the hospital the 2-miles by myself – without the epinephrine treatment he had received in the ambulance -- he absolutely would have perished. Due to the doctors' steadfast efforts, my son survived... and I am grateful for that every day.

Since that incident, however, we have found it crucial to carry two auto-injection epinephrine pens with us at all times, as well as pre-measured Benadryl spoons, and a rescue inhaler. We have had numerous close calls because my son's five anaphylactic allergens do not have to be ingested to do him harm – just the residue alone on a table-top, playground equipment, or other surfaces could bring on another anaphylactic episode. There are also airborne proteins to shellfish (for example, being heated up in the microwave) that have brought on serous reactions that could lead to anaphylaxis.

Therefore, in order to ensure my son is forearmed while outside of my care, his current preschool keeps his emergency kit with him all day, every day. It remains in his classroom while he is there, and they take it with them out onto the playground and on field trips. My son's emergency kit is never more than a few feet away from him, at all times.

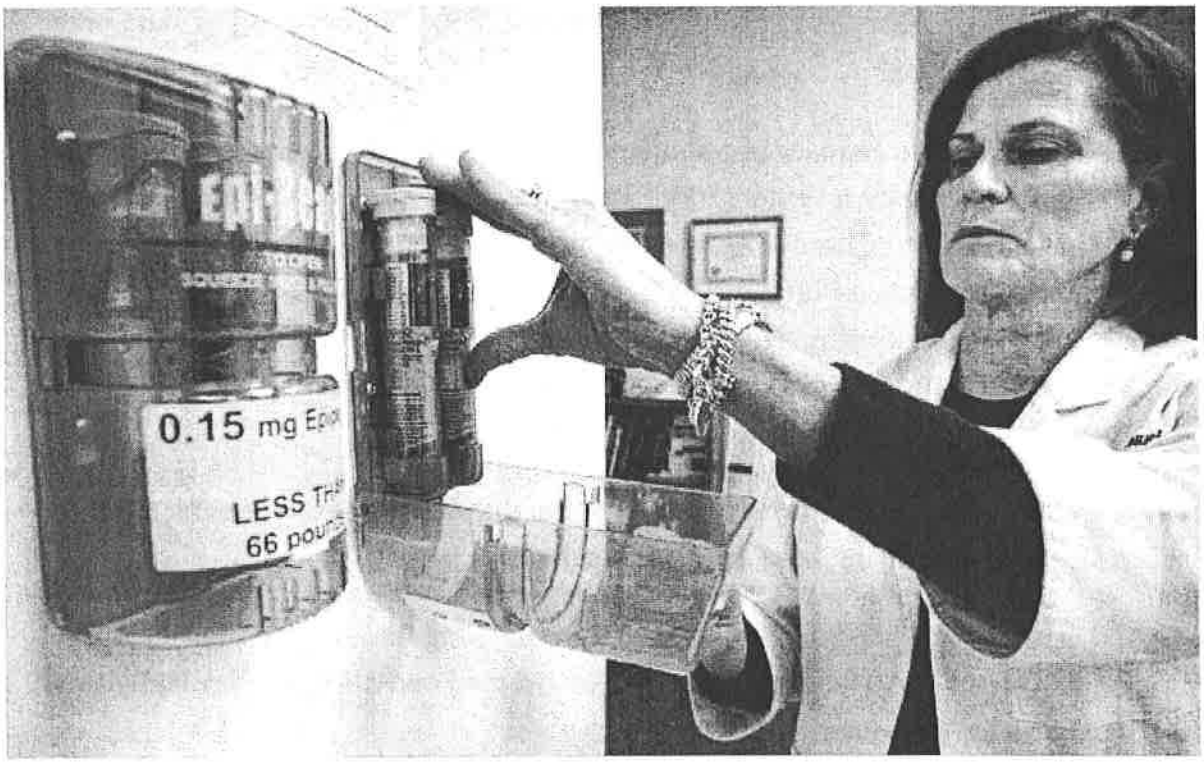
When and if he comes into contact with any of his anaphylactic allergens upon starting public school this coming Autumn, my son might have a 10-15 minute window, or less, for full emergency care – including the transport to Salem Hospital. If his epinephrine pens are stored in a nurse's office at the other end of his school, it would certainly mean his death. Having trained staff readily available (to include regular teachers and substitute teachers) – and having my son's medicine on hand at all times -- could absolutely mean the difference between his life or his death. I implore you to pass this bill in order to save not only his life, but the lives of all other children in Oregon with known or not-yet-identified allergies. Make the epinephrine pens readily available – don't require they be stored away in a "safe place". With anaphylaxis – it's a matter of minutes... please help teachers succeed in saving our kids' lives. Please, I beg you, pass this bill.

Thank you for considering my testimony in your decision-making. Again, I implore you to support and pass Senate Bill 611.

The New York Times

Business Day

Tiny Lifesaver for a Growing Worry



Karen Kasmauski for The New York Times

Diane Voelker, a school nurse in Virginia, with EpiPen kits. Virginia requires its schools to have such devices on hand.

By KATIE THOMAS

Published: September 7, 2012

It has become an all-too-familiar story in schools across the country: a child eats a peanut or is stung by a bee and suffers an immediate, life-threatening allergic reaction known as anaphylaxis.

Enlarge This Image

Jay Paul for The New York Times

Laura Pendleton's daughter Amarria Johnson, a first grader from Chesterfield, Va., died after having a severe reaction at school

If parents and school authorities know about the allergy and a doctor's prescription is on file, a nurse can quickly give an injection of epinephrine, saving the child's life.

But school nurses in many districts face an agonizing choice if a child without a prescription develops a sudden reaction to an undiagnosed allergy. Should they inject epinephrine and risk losing their nursing license for dispensing it without a prescription, or call 911 and pray the paramedics arrive in time?

After a 7-year-old girl died in January in a similar case in Virginia, the state passed a law that allows any child who needs an emergency shot to get one. Beginning this month, every school district in Virginia is required to keep epinephrine injectors on hand for use in an emergency. Illinois, Georgia and Maryland have passed similar laws, and school nurses are pushing for one in Ohio. A lobbying effort backed by Mylan, which markets the most commonly used injector, the EpiPen, made by Pfizer, led to the introduction last year of a federal bill that would encourage states to pass such laws.

Mylan has also lobbied state legislatures around the country directly and is passing out free EpiPens this fall to any qualifying school that wants them.

"When a child is having an anaphylactic reaction, the only thing that can save her life is epinephrine," said Maria L. Acebal, the chief executive of the Food Allergy and Anaphylaxis Network. "911 doesn't get there fast enough."

The efforts are an acknowledgment of the rising rates of food allergies among children and a handful of deaths from allergies across the country. In many schools, children carry their own epinephrine injectors in their backpacks to use themselves, if they're old enough, or the devices are stored on their behalf in nurses' offices.

The initiative also has a commercial underpinning: It is part of an effort to raise the profile of EpiPen. Over the last two years, Mylan has invested millions of dollars in consumer advertising and hired almost 100 extra sales representatives to help promote the product. EpiPen sales are on track to bring in $640 million this year, a 76 percent increase over last year, according to one analyst.

Heather Bresch, the chief executive of Mylan, said charity and profit should not be mutually exclusive.

"I think this goes to the heart of being able to do good and do well," she said.

Although no one knows exactly why, the rate of food allergies among children appears to be on the rise. One survey found that in 2008, one in 70 children was allergic to peanuts, compared with one in 250 in 1997.

"I don't think it's overdiagnosis," said Dr. Scott H. Sicherer, the author of the report and a researcher at the Jaffe Food Allergy Institute at Mount Sinai Medical Center in Manhattan. "There really seems to be a difference."

A study last year in the journal Pediatrics found that about one in 13 children had a food allergy, and nearly 40 percent of those with allergies had severe reactions. A recent survey in Massachusetts, where schools are permitted to administer epinephrine to any student, found that one-quarter of students who had to be given the drug for a reaction did not know they had an allergy. But in many schools, employees are not allowed to use epinephrine injectors on children who do not have a prescription.

That's what happened in January when Amarria Johnson, a first grader from Chesterfield, Va., developed a severe allergic reaction. Her mother, Laura Pendleton, said Amarria's allergy to peanuts was known, but the school did not have an EpiPen that was prescribed to her. At the time, school employees were not allowed to use injectors that were prescribed to other children.

Another student gave Amarria a peanut during recess, and by the time paramedics arrived, Amarria had stopped breathing and could not be resuscitated, according to the Chesterfield County police. In April, Virginia's governor signed a law that lifted those restrictions and required all schools to carry injectors for emergency use.

Ms. Pendleton said parents could not police everything their child ate.

"You need to have the EpiPens there just in case," she said.

Epinephrine is known as a relatively safe drug, with few adverse effects if the drug is given when it is not needed.

"Our motto has always been in training our staff, if you think epinephrine, you give epinephrine," said Nancy Markley, who oversees the school nurses and health clinics in the Loudoun County schools in Virginia.

Ms. Bresch said schools were just the first step in a plan to make emergency epinephrine injectors more widely available in restaurants, airplanes and other public places, much as external defibrillators are today. Mylan has hired consultants who once worked for the device maker Medtronic when it was trying to make defibrillators more widely available.

"It's a complex undertaking and complicated," Ms. Bresch said. "But I think it's doable."

Ms. Acebal's group has not taken a position on placing injectors in public places other than schools. Dr. Sicherer said the issue became less clear in settings like restaurants, where a waiter might not be able to differentiate between choking, a heart attack or anaphylaxis.

"I think that gets to be a little more controversial about upsides and downsides," he said.

EpiPen commands more than 95 percent of the market for epinephrine injectors and is so dominant that its name has become synonymous with the category itself. But until recently, Mylan did not do much to sell the product. The company acquired the brand in 2007 as part of deal with the German company Merck.

Enlarge This Image

Karen Kasmauski for The New York Times

Diane Voelker, right, a school nurse in Virginia, with her assistant, Beth Little. School nurses in some states are not allowed to use injectors, even in an emergency, unless they are prescribed.

"It became very apparent that there was a lot more we could be doing with EpiPen," Ms. Bresch said, adding that just 7 percent of people at risk for severe reactions carry a prescription for one.

Mylan began working with allergy advocates and lobbying state and federal politicians to enact laws permitting the broader use of EpiPens. Politics are nothing new to Ms. Bresch: she is the daughter of Senator Joe Manchin, Democrat of West Virginia. The company also invested in consumer advertising, spending close to $15 million in the last two years on television commercials and other advertising, according to Nielsen.

Gary Nachman, an analyst for Susquehanna Financial Group, said EpiPen was "extremely important" to Mylan. He estimated that EpiPen would account for $640 million of Mylan's $840 million sales this year in brand-name products, and that sales would continue to grow in the double digits for the next few years.

"This is basically the workhorse for them in their branded business," Mr. Nachman said.

Doug Tsao, a pharmaceuticals analyst for Barclays, said Mylan's efforts in schools had an added benefit.

"When the school nurse uses EpiPen, what does the nurse refer parents to?" he said. "I think that is absolutely part of the motivation."

Two coming events may be giving Mylan pause: in November, Sanofi plans to introduce a rival device, and in 2015, Teva may win approval of a cheaper, generic version of the EpiPen.

Sanofi's product, the Auvi-Q, has a rectangular shape and the added feature of voice instructions to help a user use the device. Teva's product, if approved by the F.D.A., would closely mimic the EpiPen design and, like a generic drug, could be substituted by pharmacists even if doctors prescribed the EpiPen.

Dr. Sicherer said the Auvi-Q had potential advantages over the EpiPen, which is shaped like a felt-tip marker and can be awkward to carry. Sanofi has boasted that the Auvi-Q is shaped like a cellphone and can slip into a pocket. In addition, "it's voice-guided," Dr. Sicherer said. "This is a whole new world."

Ms. Bresch said that because so few people at risk for allergic reactions use EpiPens, there was room in the market for a competitor.

"There's still a lot of people that we need to get to," she said.

Ken Cacciatore, an analyst at Cowen & Company, questioned whether parents would be willing to switch to a different brand in such life-or-death situations.

"Parents may want the real thing," he said.

Food Allergy Facts and Statistics for the U.S.

- Food allergy is a growing public health concern.
- As many as 15 million people have food allergies. [1, 2, 3, 4, 5]
    - An estimated 9 million, or 4%, of adults have food allergies. [2, 3, 5]
    - Nearly 6 million or 8% of children have food allergies with young children affected most. [3, 4, 6, 7, 8]
- Boys appear to develop food allergies more than girls. [5]
- Food allergies may be a trigger for or associated with other allergic conditions, such as atopic dermatitis[9] and eosinophilic gastrointestinal diseases. [10]
- Although childhood allergies to milk[11], egg[12], wheat[13] and soy[14] generally resolve in childhood, they appear to be resolving more slowly than in previous decades, with many children still allergic beyond age 5 years. Allergies to peanuts, tree nuts, fish, or shellfish[15] are generally lifelong allergies.

Food Allergies are on the Rise

- The prevalence of food allergies and associated anaphylaxis appears to be on the rise. [6]
    - According to a study released in 2008 by the Centers for Disease Control and Prevention about an 18% increase in food allergy was seen between 1997 and 2007. [1]
    - The prevalence of peanut allergy among children appears to have tripled between 1997 and 2008. [16]

Top Food Allergens

- Eight foods account for 90% of all food-allergic reactions: milk, eggs, peanuts, tree nuts (e.g., walnuts, almonds, cashews, pistachios, pecans), wheat, soy, fish, and shellfish. [5, 15, 17, 18, 19, 20, 21, 22, 23, 61] Estimated prevalence[9], some based on self-report, among the U.S. population:
    - Peanut: 0.6-1.3%
    - Tree nuts: 0.4-0.6%
    - Fish: 0.4%
    - Crustacean shellfish (crab, crayfish, lobster, shrimp): 1.2%
    - All seafood: 0.6% in children and 2.8% in adults

- Milk and egg: based on data within and obtained outside the United States, this rate is likely to be 1-2% for young children and 0.2-0.4% in the general population.

Managing Food Allergies

Cooking and Cleaning

- A study showed that peanut can be cleaned from the hands of adults by using running water and soap or commercial wipes, but not antibacterial gels alone. In addition, peanut was deaned easily from surfaces by using common household spray cleaners and sanitizing wipes but not dishwashing liquid alone. [24]

- Some studies have shown that most individuals with peanut and soy allergies can safely eat highly refined oils made from these ingredients. However, cold-pressed, expeller-pressed, or extruded oils should be avoided. Talk to your doctor about avoiding oils made from ingredients to which you are allergic. [25, 26, 27, 28, 29, 30]

- Casual exposure, such as skin contact and inhalation, to peanut butter is unlikely to elicit significant allergic reactions. [31, 32]

    - *Note: Casual exposure presents a greater risk to young children who frequently put their hands in their mouths. Depending on the amount of contact and the location of the contact, these reactions are occasionally more serious.* [31, 32]

- Food proteins released into the air from vapor or steam from foods being cooked (e.g., fish, milk) can potentially cause allergic reactions, but this is uncommon and has been noted mainly with fish. Reactions from vapor or steam are similar to what you would expect from pollen or animal dander exposures, for example hay fever or asthma symptoms. [8, 33, 34]

Conventionally Packaged Food Labels

- According to the Food Allergen Labeling and Consumer Protect Act (FALCPA) the major eight allergens must be declared in simple terms, either in the ingredient list or via a separate allergen statement. However, FALCPA does not regulate the use of advisory/precautionary labeling. [35]

    - Note: Advisory/precautionary labeling (e.g., "may contain", "in a facility that also processes") is voluntary. The terms do not reflect specific risks and random products tested for allergens have shown a range of results from none to amounts that can cause reactions. [9, 36]

Dining Away From Home

- Eating away from home can pose a significant risk to people affected by food allergy. Research suggests that close to half of fatal food allergy reactions are triggered by food served by a restaurant or other food service establishment. [37, 38, 39]

- One study looking at peanut and tree nut allergy reactions in restaurants and other food establishments found that reactions were frequently attributed to desserts, that Asian restaurants and take-out dessert stores (bakeries, ice cream shops) were common sources of foods that triggered reactions, and that the food establishment was often not properly notified of a food allergy by the customer with the allergy. [40]

Travel

- Research on self reported reactions occurring on commercial airlines show that reactions to peanuts and tree nuts do occur on airlines via ingestion, contact, and inhalation. Ingestion of an allergen remains the main concern for severe reactions. [41, 42, 43]

Food Allergy Reactions and Anaphylaxis

- The CDC reported that food allergies result in more than 300,000 ambulatory-care visits a year among children under the age of 18. [1]
    - From 2004 to 2006, there were approximately 9,500 hospital discharges per year with a diagnosis related to food allergy among children under age 18 years. [1]
- Even small amounts of a food allergen can cause a reaction. [44, 45, 46, 47, 48, 49]
- Most allergic reactions to foods occurred to foods that were thought to be safe. Allergic reactions can be attributed to a form of mislabeling or cross-contact during food preparation. [37, 38, 39]
- Food allergy is the leading cause of anaphylaxis outside the hospital setting. [50]
    - Every 3 minutes a food allergy reaction sends someone to the emergency department–that is about 200,000 emergency department visits per year, and every 6 minutes the reaction is one of anaphylaxis. [51]
- Teenagers and young adults with food allergies are at the highest risk of fatal food-induced anaphylaxis. [37, 38, 39]
- Symptoms of anaphylaxis may recur after initially subsisting and experts recommend an observation period of about 4 hours to monitor that the reaction has been resolved. [52, 53]
- Individuals with food allergies who also have asthma may be at increased risk for severe/fatal food allergy reactions. [37, 39]
- Children with food allergy are 2-4 times more likely to have other related conditions such as asthma and other allergies, compared with children without food allergies. [1]
- It is possible to have anaphylaxis without any skin symptoms (no rash, hives). [1]
- Failure to promptly (i.e., within minutes) treat food anaphylaxis with epinephrine is a risk factor for fatalities. [37, 38]

Food Allergy Treatment

- There is no cure for food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important measures to prevent serious health consequences. [54]

- Prompt administration (e.g., within minutes of symptoms of anaphylaxis) of epinephrine (adrenaline) is crucial to successfully treating anaphylactic reactions. Epinephrine is available by prescription in a self-injectable device (EpiPen® or Twinject® or Adrenaclick®, depending on local availability). [55]

- There are a number of promising food allergy therapies under study, although none are yet proven for general use.

Food Allergies in School

- Approximately 20-25% of epinephrine administrations in schools involve individuals whose allergy was unknown at the time of the reaction. [56]

- More than 15% of school aged children with food allergies have had a reaction in school. [57, 58] Food allergy reactions happen in multiple locations throughout the school, and are not limited to the cafeteria. Care must be exercised regarding bake sales, classroom parties, and snacks outside of the cafeteria. [39, 59, 60]

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