

**Comments of  
Gary Slovin/R. Brian Tsujimura/Mihoko Ito  
on behalf of  
Mylan Inc.**

DATE: February 18, 2014

TO: The Honorable David Y. Ige  
Chair, Senate Committee on Ways and Means  
*Submitted Via: WAMtestimony@capitol.hawaii.gov*

RE: **SB 2422 SD 1 Relating to Education**  
**Decision Making Date: Wednesday, February 19, 2014; 9:25 a.m.**

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Chair Ige and members of the Senate Committee on Ways and Means:

We represent Mylan Inc. Mylan is a leading U.S. based manufacturer of generic and specialty medications with operations in seven states, as well as Puerto Rico, and provides generic medicines in more than 140 countries and territories worldwide.

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 and other allergies and anaphylaxis. We look forward to working with this committee, the Legislature and school officials as you address this important issue.

Mylan strongly supports SB 2422 SD1 with amendments. 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, an estimated one out of 13 children in the U.S. has a food allergy, a considerably higher number than previous estimates.<sup>2</sup>

To our knowledge, every state, including Hawaii, 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 their schools. According to 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.<sup>13</sup> This number is particularly disturbing.

Mylan supports SB 2422, SD1. Schools are a critical component in the effort to increase access to epinephrine auto-injectors for those at risk from food and other allergies and we believe that additional protections for students are needed. We have requested, and additional bills have been introduced on this subject matter that specifically relate to allowing schools to stock and administer epinephrine auto-injectors. SB 2700 allows schools to stock and administer epinephrine auto-injectors in schools and we urge you to amend and incorporate it into SB 2422 as well.

Unfortunately, over the past several years, there have been anaphylaxis-related tragedies at schools around the country. 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. Seventeen states signed legislation into law in 2013 that is very similar to SB 2700.

Thirty-one states currently allow (or require) schools to stock and administer epinephrine auto-injectors in schools. Mylan is committed to working with states on this going forward. We learned through our discussions with state officials that the cost of epinephrine auto-injectors sometimes 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 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 30,000 schools have already taken advantage of this program. 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.

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.

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.<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>

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> 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.<sup>5</sup>

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

- 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>

Mylan would like to work with you to ensure that Hawaii schools are prepared to address anaphylaxis so that emergencies do not turn into tragedies. As I already mentioned, Mylan currently offers 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., and we continue to look for additional ways that we can help.

Thank you for allowing us to submit these comments. We would urge the committee to amend SB 2422 SD1 to include the provisions of SB 2700 which provide additional parameters and safeguards for the training of personnel and stocking of epinephrine auto-injectors on school premises.

#### References

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**Comments of  
Gary M. Slovin / Mihoko E. Ito  
on behalf of  
Walgreens**

DATE: February 17, 2014

TO: Senator David Ige  
Committee on Ways and Means  
*Submitted Via [WAMtestimony@capitol.hawaii.gov](mailto:WAMtestimony@capitol.hawaii.gov)*

RE: **S.B. 2422, S.D.1 – Relating to Education  
Decision Making: Wednesday, February 19, 2014, 9:25 a.m.  
Conference Room: 211**

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Dear Chair Ige, and Members of the Committee on Ways and Means,

We submit these comments on behalf of Walgreen Co. (“Walgreens”). Walgreens operates more than 8,200 locations in all 50 states, the District of Columbia and Puerto Rico. In Hawai`i, Walgreens now has 17 stores on the islands of Oahu, Maui and Hawai`i.

Walgreens **supports** S.B. 2422 S.D.1. Anaphylaxis is a life threatening allergic reaction that can occur when people are exposed to an allergen. The availability of an epinephrine auto-injector can be life-saving to a person experiencing this type of allergic reaction.

S.B. 2422 S.D.1 authorizes the prescription and stocking of epinephrine auto-injectors by authorized entities. These entities include locations where allergens may be present including restaurants, sports arenas, and summer camps. The time that is saved by having emergency epinephrine readily available in these situations could be the difference between life and death to a person experiencing anaphylaxis. Walgreens supports this measure because it expands access to a critical drug that can save lives and meet an important public health need.

Thank you for the opportunity to submit testimony on this measure.

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