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

DATE: February 9, 2014

TO: The Honorable Josh Green
Chair, Senate Committee on Health
Submitted Via: HTHtestimony@capitol.hawaii.gov

RE: **SB 2660 Relating to Epinephrine Auto-Injectors**
Hearing Date: Monday, February 10, 2014

Chair Green and members of the Senate Committee on Health:

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.

Schools are a critical component to expanding access to epinephrine auto-injectors for those at risk from food and other allergies, but schools are not the only places where greater access is needed.

Mylan strongly supports SB 2660 which allows entities authorized by the state to stock epinephrine auto-injectors and to allow trained personnel of those entities to administer an epinephrine auto-injector in an emergency. We urge the committee to support this important legislation.

We have all seen the tragic stories about children dying at school after coming into contact with an allergen. But tragedies can occur anyplace where children – or adults – come into contact with food and other allergens.

In 2012, a young boy died from anaphylaxis at a large retail store after eating a cookie with nuts. That same year, a young man died from anaphylaxis after eating in his college cafeteria. A teenage girl died in California last year after eating a treat at a summer camp in California and a young boy died after

being stung by fire ants on a football field in Texas. These are just a few of the cases that have made news in the past few years.

SB 2660 can increase access to epinephrine auto-injectors that could help prevent similar tragedies from occurring in Hawaii. Immediate access to an epinephrine auto-injector could be the difference between life and death for some.

Oregon passed legislation in 2013 to allow entities like restaurants, scout troops, colleges, day care centers and summer camps to stock and administer epinephrine auto-injectors. New Jersey passed legislation in January to allow colleges and universities to stock and administer epinephrine auto-injectors.

New York State allows summer camps, day camps and several other entities authorized by regulation to stock and administer epinephrine auto-injectors. Several other states, including Alaska, California, Florida, North Carolina and North Dakota have programs that allow individuals - such as teachers, scout leaders, tour guides, restaurant employees, daycare 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.

Legislation similar to SB 2660 is also being considered in more than a dozen states this year. SB 2660 is an important step to addressing anaphylaxis from food and other allergens here in Hawaii.

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]

Much progress is being made in the effort to prevent tragedies from food and other allergens. 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, giving affected individuals more time to seek additional emergency medical treatment.[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]

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).[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 entities in Hawaii where children and adults may come into contact with allergens that could cause anaphylaxis are prepared to address anaphylaxis so that emergencies do not turn into tragedies. Thank you for your time and your consideration today.

References

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In reply, please refer to:
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SENATE COMMITTEE ON HEALTH

SB2660, RELATING TO EPINEPHRINE AUTO-INJECTORS

Testimony of David Sakamoto, M.D., M.B.A.
Deputy Director, Health Resources Administration

February 10, 2014

1 **Department's Position:** The Department of Health (DOH) opposes SB2660.
2 **Fiscal Implications:** Costs associated with training or certifying trainers
3 **Purpose and Justification:** This Bill authorizes the prescription and stocking of epinephrine auto-
4 injectors by authorized entities such as restaurants, recreation camps, youth sports leagues, amusement
5 parks, and sports arenas. It also includes provisions for their use. We cannot support this bill because
6 its scope may present situations where the risk of harm may exceed benefit to an individual who appears
7 to be having anaphylaxis.
8 The availability of auto-injectable epinephrine and trained personnel who can provide it and/or
9 administer it in schools can be life-saving. This is because school children may be too young to self-
10 administer auto-injectable epinephrine or may not be allowed to have it on their person due to general
11 safety concerns in the school At least 26 states currently have laws that allow for storage of epinephrine
12 in the school setting.
13 Older individuals outside of the school setting are able to carry their own auto-injectable
14 epinephrine. While the ability to provide epinephrine to someone who has never had anaphylaxis before
15 may help someone who is truly having an anaphylactic event, there is a potentially unacceptable risk for
16 misdiagnosis resulting in harm. An example would be an individual who is choking on food who is

1 mistaken to have a food allergy and anaphylaxis. Additionally, administration of epinephrine in an adult
2 with cardiovascular disease may increase blood pressure and increase risk for stroke. This is much less
3 likely to occur in children.

4 Our comments do not preclude an "authorized entity" from deciding to have auto-injectable
5 epinephrine available or obtaining training for staff to administer it in an emergency. There are likely to
6 be individual circumstances where this would be a good choice, for example, a summer camp for
7 asthmatics. However, we cannot support this bill for all "authorized entities" as it is defined in this bill.

8 Thank you for the opportunity to testify.