



LEAH VUKMIR

STATE SENATOR

Senate Committee on Health and Human Services Public Hearing, May 20, 2015 Senate Bill 139

Vice-Chairman Moulton and committee members, thank you again for taking the time to meet today and hear about two worthwhile bills that I have authored. I am very pleased to present Senate bill 139 this morning along with Representative Edming.

Anaphylaxis, caused by a bee sting or a food or drug allergy can be a very real threat to the health or life of a Wisconsin citizen. Luckily, there is a safe and simple solution, epinephrine auto-injectors. Given what a powerful remedy epinephrine auto-injectors provide, this bill seeks to make them more readily available to the public in a variety of settings including camps, colleges, universities, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment and sports arenas.

If adopted, these bills would allow medical professionals to prescribe an epinephrine auto-injector in the name of one of the previously mentioned entities. That college, sports arena, restaurant or other entity would be able to acquire and maintain a supply of epinephrine auto-injectors that would be under the control and oversight of a trained employee. Trained employees or agents of the entity would then be able to provide or administer epinephrine auto-injectors to an individual they believed was experiencing anaphylaxis.

I previously authored a similar bill that dealt with the use of epinephrine auto-injectors in schools last session that ultimately became Act 239. The impact of Act 239 on our state has been positive. A little later you will hear from one manufacturer of epinephrine auto-injectors who will be able to tell you about the thousands of epi-pens they have provided to Wisconsin schools that are making our schools and students safer.

In addition to protecting Wisconsinites against Anaphylaxis, these bills also provide protection from civil liability for Good Samaritans at a variety of different points in the process – from those prescribing the epinephrine auto-injector to the entity maintaining the supply to the employee or agent who provides or administers the epinephrine auto-injector.

While I think this bill is a good start, I have been made aware of a few concerns and I have worked with Representative Edming to draft two amendments that I hope will improve the bill further. Specifically, the Restaurant Association and the Wisconsin Athletic Trainers Association raised concerns regarding legal protection to entities that choose not to take advantage of this new law and to respect the scope of medical professionals respectively, I believe these are both good changes and I hope your committee will give these amendments consideration in the future.

Thank you for your time and consideration, and I would be happy to answer any questions committee members might have.

STATE CAPITOL
P.O. BOX 7882 • MADISON, WISCONSIN 53707-7882
(608) 266-2512 • FAX: (608) 267-0367



JAMES W. EDMING

STATE REPRESENTATIVE • 87TH ASSEMBLY DISTRICT

DATE: May 20, 2015
RE: Testimony on 2015 Senate Bill 139
TO: The Senate Committee on Health and Human Services
FROM: Office of Representative James W. Edming

Thank you for holding a hearing on Senate Bill 139 and allowing me to testify in favor of this legislation.

Senate Bill 139 is a bill that permits epinephrine auto-injectors to be stored and administered at public places where someone could come in contact with an allergen. This bill expands upon last session's Wisconsin Act 239, which allows epinephrine auto-injectors to be prescribed to schools. The bill is intended to provide more access to life saving epinephrine auto-injectors when an individual is experiencing anaphylaxis. Similar legislation has already passed in a number of other states, including Florida, Oregon, and Rhode Island.

Allergens could be present at camps, colleges, restaurants, and sports arenas. Under the bill, health care professionals would be permitted to prescribe epinephrine auto-injectors to these places. Employees at these facilities would be required to complete a training program before they could administer the device in an emergency situation. The bill also provides liability protection to the public place, the epinephrine auto-injector administrator, and the health care professional.

In recent years, there has been an increase in anaphylaxis. These allergic reactions can occur rapidly and without warning. It is estimated that 1 in 13 children¹ and 1 in 20 adults² are at risk for anaphylaxis in the United States. Many times, an anaphylactic reaction occurs in the absence of a known allergic trigger, which could result in death.

During this type of medical emergency, it is critical for people to utilize epinephrine auto-injectors. This bill will provide those experiencing anaphylactic shock with additional access to these epinephrine auto-injectors, which could potentially save lives. In a time where allergies are on the rise, it is vital to have greater availability to treatment in response to these life-threatening emergencies.

Thank you for your time and attention and I ask that you support this legislation. I would be happy to answer any questions.

1. <http://pediatrics.aappublications.org/content/128/1/e9.full.pdf+html>
2. [http://www.jacionline.org/article/S0091-6749\(13\)01302-X/pdf](http://www.jacionline.org/article/S0091-6749(13)01302-X/pdf)

PROFESSIONAL FIRE FIGHTERS OF WISCONSIN, INC.

7 NORTH PINCKNEY STREET, SUITE 200, MADISON, WI 53703-2840

PHONE: (608) 251-5832 / EMAIL: PFFWOFFICE@PFFW.ORG

MEMBER OF INTERNATIONAL ASSOCIATION OF FIRE FIGHTERS

MEMBER OF WISCONSIN STATE AFL-CIO



MAHLON MITCHELL
STATE PRESIDENT

MICHAEL WOODZICKA
STATE VICE-PRESIDENT

STEVE WILDING
STATE SEC. / TREAS.

Testimony of Mahlon Mitchell, President Professional Fire Fighters of Wisconsin On Senate Bill 139 Before the Senate Committee on Health and Human Services May 20, 2015

Thank you Madam Chair and committee members for giving me the opportunity to testify on this bill today. The Professional Fire Fighters of Wisconsin (PFFW) support public access and use of auto-injector epinephrine administration along with emergency medical treatment to treat life-threatening allergic reactions. If used correctly, the only reason to administer epinephrine for a severe allergic reaction is because the person is in a potentially life-threatening condition. According to a 2014 study published in The Journal of Allergy and Clinical Immunology, nearly half (49%) of patients experienced anaphylaxis outside of their homes.

A severe allergic reaction, or anaphylaxis, can lead to respiratory distress, cardiovascular collapse, or death. Emergency epinephrine works to alleviate these symptoms by relaxing the muscles in the airways and tightening the blood vessels. Those affected by anaphylaxis can decompensate quickly and there are no contraindications to the administration of epinephrine in a life-threatening, severe allergic reaction. The affected person's only chance may be the rapid administration of epinephrine, on that point we agree. It's what comes next that we are also concerned about.

In being consistent with public access defibrillation and CPR, it is critical to activate the 911 system and to ensure that EMS is dispatched after the administration of epinephrine. Even when everything is done correctly, the person who moments before was in a life-threatening medical emergency and then administered a very strong drug, can suffer such severe side effects as chest pains and heart arrhythmias.

The National Institute of Health states: "Epinephrine injection helps to treat serious allergic reaction but does not take the place of medical treatment. Get emergency medical treatment immediately after you inject epinephrine. Rest quietly while you wait for emergency medical treatment."

One epinephrine auto injector manufacturer states: "The epi auto-injector is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after use." Another epi auto-injector company states that after injection "Get emergency medical help right away."

911 should be activated as soon as possible for many other reasons besides the side-effects of the epinephrine or the original medical even to begin with. Research reported in The Journal of Allergy and Clinical Immunology shows that up to 20% of patients need more than one dose of epinephrine to

alleviate symptoms. Additionally, since the civilian administering the epinephrine may have little or no training in the practice of medicine, there could be numerous other medical emergencies that could be causing the patient's symptoms.

The NIH and the largest manufacturers of epi pens recommend immediate notification of 911 as soon as possible with patients having a severe allergic reaction. The PFFW asks that the legislature ensure and require that EMS be called as soon as possible when treating a patient that would, will, or did receive pre-EMS epinephrine. We think a friendly amendment to this bill would accomplish that goal.

I'd be happy to answer any questions Committee members may have.

TESTIMONY OF

Dan Lubowitz
State Government Relations
Mylan Inc.

Thank you for the opportunity to speak with you today. My name is Dan Lubowitz and I represent Mylan Inc. Mylan supports SB 139 and urges the support of this committee.

Mylan is a leading manufacturer of generic and specialty medications that currently provides medicines in more than 140 countries and territories worldwide. A Mylan subsidiary markets and distributes one of several epinephrine auto-injectors available in the United States.

Food allergies, which can sometimes lead to a life-threatening allergic reaction, or anaphylaxis, is a large and growing public health problem.^{1,3} Today, an estimated one out of 13 - approximately 6 million - children in the U.S. has a food allergy.² Approximately 1 out of 20 adults have a food allergy. And, food allergens are only one type of the allergens that can cause anaphylaxis. Insect stings, medicines and latex are also known to cause anaphylaxis in some people.

Unfortunately, over the past several years, there have been several high profile anaphylaxis-related tragedies around the country in schools and outside of schools. Deaths in Illinois (in 2011), Georgia and Virginia (in 2012), California, Texas and New York (in 2013) and Minnesota (in 2014) resulted in significant attention to the issue and much discussion on how to best address it.

- Studies done in school settings show that between 20 and 55 percent of anaphylactic events occurred in individuals who were not previously known to have an allergy.⁴
- Anaphylaxis to food allergies alone results in approximately 90,000 emergency department visits each year in the U.S.⁵
- Anaphylaxis results in approximately 1,500 deaths annually.⁶

Wisconsin law allows schools to stock epinephrine auto-injectors and to permit trained school personnel to administer them in an emergency. Today, 47 states have similar

school access laws. More than 55,000 schools nationwide – including 1,291 in Wisconsin - are stocking epinephrine auto-injectors received through a program offered by Mylan that provides free auto-injectors to schools.

SB 139 will build upon Wisconsin's school access law and expand access to this critical medication to day cares, colleges and universities, summer and day camps, restaurants, theme parks and other places where children and adults could come into contact with potentially life-threatening allergens. This legislation would not require any entity to stock epinephrine auto-injectors, but would simply allow it.

Anaphylaxis can happen in many different places; and, prompt recognition of signs and symptoms of anaphylaxis is crucial. Failure to administer epinephrine early in the course of treatment has been repeatedly implicated in anaphylaxis fatalities.⁷ The more rapidly anaphylaxis develops, the more likely the reaction will be severe and potentially life-threatening. This is why this legislation to allow increased access is so important.

Oregon, Florida and Rhode Island passed legislation similar to SB 139 in 2013 and 2014. In 2015, 9 more states (Arkansas, Colorado, Georgia, Indiana, Iowa, Kentucky, Oklahoma, Utah and West Virginia) have had their Governors sign similar legislation into law and Nevada just passed their legislation over the weekend and sent it to the Governor. At least 20 other states are also considering legislation.

Mylan would like to work with you and other interested parties as you consider this important legislation. I am happy to take any questions you may have.

References

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2. Gupta, et al. The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States. *Pediatrics*. 2011; 128: e9-17.
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4. Data on file and Lilliana DeSantiago-Cardenas, L, Rivkina, V, Whyte, S, et. Al. Emergency Epinephrine Use for Food Allergy Reactions in Chicago Public Schools, *Am J Prev Med*. 2015;48(2)
5. 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
6. Clark S, Camargo CA Jr. Epidemiology of anaphylaxis. *Immunol Allergy Clin North Am*. 2007;27(2):145-1463.
7. Lieberman P et al. The diagnosis and management of anaphylaxis practice parameter: 2010 Update. *J Allergy Clin Immunol*. 2010;126(3):477-480.



6117 Monona Drive • Madison, WI 53716 • 608-221-0383 • Fax 608 221-2788

Info@wisconsinnurses.org • www.wisconsinnurses.org

TO: Senator Leah Vukmir, Chairperson and Members of the Senate Health and Human Services Committee

FROM: Gina Dennik-Champion, MSN, RN, MSHA
Executive Director, Wisconsin Nurses Association

DATE: May 20, 2015

RE: Support of SB 139, Supply and use of epinephrine auto-injectors by certain authorized entities

Thank you Chairperson Vukmir and members of the Senate Health and Human Services Committee for holding this public hearing on SB 139 which allows a physician (MD), physician assistant (PA) or an advanced practice nurse prescriber (APNP) to prescribe an epinephrine auto-injector for an entity or organization for use in the event of an individual experiencing an anaphylactic reaction to a known or suspected allergen. We also thank Senator Vukmir for sponsoring this legislative proposal.

My name is Gina Dennik-Champion. I am a registered nurse and the Executive Director for the Wisconsin Nurses Association (WNA). WNA is the professional organization for all registered nurses in Wisconsin, and we are pleased to submit testimony in support of SB 139. WNA advocates for prevention and health promotion that includes a well prepared emergency response and recovery system. Anaphylaxis is a severe, whole-body allergic reaction to a chemical that has become an allergen that can be life-threatening. Anaphylaxis can occur in response to any allergen and the most common causes are drug, food, insect bites/stings and latex.

According to a report in the September 2014 issue of *The Journal of Allergy and Clinical Immunology*, E. Jerschow and colleagues present temporal trends of fatal anaphylaxis in the United States from 1999 through 2010 and the associations of fatal anaphylaxis with age, gender, race and geographical distribution. Their reported findings that the, "combined prevalence of 0.86 deaths due to anaphylaxis

per million people in the United States. These results indicate that the US has one of the highest prevalence of fatal anaphylaxis in the world.” Food and venom allergies were a common cause of death in the study.”

SB 139 appropriately defines the conditions for those entities and organizations interested in having a supply of epinephrine auto-injectors available. WNA supports an emergency response system that includes competency-based trained and certified individuals with a plan for obtaining a medical evaluation and other treatment as necessary.

WNA also supports SB 139 as it recognizes the use of PAs and APNPs as those health professionals that can prescribe and deliver a supply of epinephrine auto-injectors to businesses, other entities and organizations.

On behalf of WNA, thank you Senator Vukmir for developing this legislative proposal and for scheduling this hearing. We thank those Committee members who are co-sponsoring SB 139 and ask for immediate passage.