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Testimony of the
American Thoracic Society
before the Energy and Power Subcommittee
of the House Energy and Commerce Committee
Presented by Monica Kraft, MD
President of the American Thoracic Society
Wednesday, July 18, 2012

I am Monica Kraft MD, and I am a professor of Medicine at Duke University and current president of the American Thoracic Society. As both a researcher and a clinician, I have spent most of my professional life dedicated to the diagnosis and management of patients with asthma and I direct the Duke Asthma, Allergy and Airway Center at Duke. It is with this professional and scientific background that I offer to present testimony of the American Thoracic Society on legislation to restore epinephrine inhalers back on the U.S. market place. It is my strongly held view and the view of the American Thoracic Society, that returning epinephrine inhaler to the U.S. market, even for a limited time, would be ill advised.

This view is shared by several other physician organizations including, the American Academy of Allergy Asthma and Immunology, the American College of Asthma Allergy and Immunology, the American Association of Respiratory Care and the National Association for the Medical Direction of Respiratory Care.

As background, asthma is common and potentially life threatening medical condition where the airways of lung are inflamed, severely restricting air flow to the lung. For many people with asthma, it can feel like breathing through a straw. Asthma effects between 5 and 10% of the population, so most everyone knows someone who has asthma. Therefore, over 24.6 million Americans have physician diagnosed asthma, including 7.1 million children. While the majority of asthma patients can and will successfully manages their asthma, every year, people die as a result of asthma attacks.

In the lungs, the airways are inflamed, which means they are red and swollen which can cause them to narrow then and restrict airflow. The focus of asthma treatment is with anti-inflammatory medications, such as inhaled corticosteroids. In addition, medications that cause the airways to widen (bronchodilate) are also used. In more severe asthma, physicians try a combination of other drugs to treat asthma which may include medications to more directly treat allergic symptoms, or in the most severe cases, oral corticosteroids such as prednisone.

Health care professionals play an important role in educating patients about their asthma, including asthma triggers like tobacco smoke, air pollution, and allergens such as pet dander, cockroaches and dust mites, to find the right combination of medications, along with proper drug administration techniques to help people with asthma live full, active lives.

The take away message is that in the majority of cases, asthma can be successfully treated by working with health care professionals to find the right combination of safe and effective medications.

Epinephrine is NOT one of the medications that are considered safe for the treatment of asthma.

Epinephrine

Epinephrine is non-selective bronchodilator. This means that it has effects not only in the lung to bronchodilate but its non-selective nature means it has effects upon other organs such as the heart. Therefore, epinephrine or Primatene® can cause a significantly increased heart rate. This unwanted side effect can lead to cardiac stress and heart attacks in older patients or patients with heart disease.

For years the medical community has recognized the dangerous side effects of epinephrine for the treatment of asthma and has recommended against it use for asthma. In 1999 the American Medical Association 1) urged that warning labels on over the counter epinephrine inhalers be strengthened to warn patients about the dangers of epinephrine use, 2) encouraged FDA to consider removing inhaled epinephrine from the market and 3) requested studies to determine whether the availability of inhaled epinephrine is a risk factor in asthma morbidity and mortality. The American Medical Association again reaffirmed this position in 2009. In addition, we have not seen an increase in asthma death rates since epinephrine has been taken off the market, so I do not believe lack of access to asthma treatment is a reason to put inhaled epinephrine back on the market. Anecdotally, speaking to my colleagues in Emergency Medicine, they have seen fewer severe asthma attacks as they think more patients with asthma are following up with their physicians to get the appropriate care.

Several expert panels have produced recommendations on the treatment of patients with asthma. None of the expert guidelines recommend the use of inhaled epinephrine --like Primatene Mist--to treat asthma. The National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, has issued treatment

guidelines for management of asthma. NAEPP recommends against the use of epinephrine for treating asthma exacerbations stating:

> "Drugs of choice for acute bronchospasm: Inhaled route has faster onset, fewer adverse effects, and is more effective than systemic routes. The less beta2-selective agents (isoproterenol, metaproterenol, isoetharine, and **epinephrine***)* are not recommended due to their potential for excessive cardiac stimulation, especially in high doses. (*emphasis added)*(2)

The American Thoracic Society strongly encourages any patient who is using over the counter medications--like Primatene Mist CFC--to treat their asthma to see a healthcare provider who can help the patient develop an asthma management plan and recommend more effective and safer medications to manage the asthma. Asthma action plans are dynamic plans that help guide a patient on how to manage their asthma on good days, bad days and those days in between. I have attached a sample asthma action plan with my testimony.

Pending Legislation

One of the goals of today's hearing is to discuss the pros and cons of enacting legislation to either permanently or temporarily restore inhaled epinephrine for the treatment of asthma to the U.S. market. If the intent of the legislation is to restore a safe and effective asthma drug to the market place, then this legislative effort is mis-informed. Inhaled epinephrine is not a safe drug for the treatment of asthma. The adverse side effects of epinephrine are serious and well documented. No current clinical practice guideline for the diagnosis and treatment of asthma recommends the use of epinephrine. In fact, asthma guidelines specifically recommend against inhaled epinephrine for treating asthma.

If the legislative intent is to provide access to an inexpensive drug for the treatment of asthma, then the legislative effort is laudable, but mis-directed. Inhaled epinephrine's risks outweigh its benefits.

I am also concerned about sending a very confusing message to patients. Physicians, drug makers and retailers have spent a lot of time and effort educating patients about the Primatene Mist transition and treatment alternatives patients have now that Primatene Mist is no longer available. Putting Primatene Mist back on the market – for an indefinite period of time – will send a very confusing message to patients.

Congress should be considering ways to increase patient access to health care professionals who can work with patients to find an effective combination of drugs to control asthma. We should not be abandoning patients with a serious medical condition like asthma to self diagnosis and self medication with less effective drugs that have well known serious side effects.

I hope the committee will keep the view of the American Thoracic Society in mind as it considers legislation on inhale epinephrine for the treatment of asthma. I would be happy to answer any questions you may have.

1) AMA House of Delegates policy H-115.972 (CSA Rep.2 A-99, reaffirmed CSPH Rep. 1 A-09)
2) National Asthma Education Prevention Program– Expert Report 2 (1997) p. 64 figure 3-2.

Asthma Action Plan

For: _____ Doctor: _____ Date: _____

Doctor's Phone Number _____ Hospital/Emergency Department Phone Number _____

GREEN ZONE

Doing Well

- No cough, wheeze, chest tightness, or shortness of breath during the day or night
- Can do usual activities

And, if a peak flow meter is used,

Peak flow: more than _____
(80 percent or more of my best peak flow)

My best peak flow is: _____

Take these long-term control medicines each day (include an anti-inflammatory).

Medicine	How much to take	When to take it
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
Before exercise ❒ _____	❒ 2 or ❒ 4 puffs _____	5 minutes before exercise

YELLOW ZONE

Asthma Is Getting Worse

- Cough, wheeze, chest tightness, or shortness of breath, or
- Waking at night due to asthma, or
- Can do some, but not all, usual activities

-Or-

Peak flow: _____ to _____
(50 to 79 percent of my best peak flow)

First

Add: quick-relief medicine—and keep taking your GREEN ZONE medicine.

_____ ❒ 2 or ❒ 4 puffs, every 20 minutes for up to 1 hour
(short-acting $beta_2$-agonist) ❒ Nebulizer, once

Second

If your symptoms (and peak flow, if used) return to GREEN ZONE after 1 hour of above treatment:
❒ Continue monitoring to be sure you stay in the green zone.

-Or-

If your symptoms (and peak flow, if used) do not return to GREEN ZONE after 1 hour of above treatment:
❒ Take: _____ ❒ 2 or ❒ 4 puffs or ❒ Nebulizer
(short-acting $beta_2$-agonist)
❒ Add: _____ mg per day For _____(3–10) days
(oral steroid)
❒ Call the doctor ❒ before/ ❒ within _____ hours after taking the oral steroid.

RED ZONE

Medical Alert!

- Very short of breath, or
- Quick-relief medicines have not helped, or
- Cannot do usual activities, or
- Symptoms are same or get worse after 24 hours in Yellow Zone

-Or-

Peak flow: less than _____
(50 percent of my best peak flow)

Take this medicine:

❒ _____ ❒ 4 or ❒ 6 puffs or ❒ Nebulizer
(short-acting $beta_2$-agonist)

❒ _____ mg
(oral steroid)

Then call your doctor NOW. Go to the hospital or call an ambulance if:
- You are still in the red zone after 15 minutes AND
- You have not reached your doctor.

DANGER SIGNS
- **Trouble walking and talking due to shortness of breath**
- **Lips or fingernails are blue**

- **Take ❒ 4 or ❒ 6 puffs of your quick-relief medicine AND**
- **Go to the hospital or call for an ambulance _____ NOW!**
(phone)

See the reverse side for things you can do to avoid your asthma triggers.

How To Control Things That Make Your Asthma Worse

This guide suggests things you can do to avoid your asthma triggers. Put a check next to the triggers that you know make your asthma worse and ask your doctor to help you find out if you have other triggers as well. Then decide with your doctor what steps you will take.

Allergens

❒ Animal Dander

Some people are allergic to the flakes of skin or dried saliva from animals with fur or feathers.

The best thing to do:

- Keep furred or feathered pets out of your home.

If you can't keep the pet outdoors, then:

- Keep the pet out of your bedroom and other sleeping areas at all times, and keep the door closed.
- Remove carpets and furniture covered with cloth from your home. If that is not possible, keep the pet away from fabric-covered furniture and carpets.

❒ Dust Mites

Many people with asthma are allergic to dust mites. Dust mites are tiny bugs that are found in every home—in mattresses, pillows, carpets, upholstered furniture, bedcovers, clothes, stuffed toys, and fabric or other fabric-covered items.

Things that can help:

- Encase your mattress in a special dust-proof cover.
- Encase your pillow in a special dust-proof cover or wash the pillow each week in hot water. Water must be hotter than 130º F to kill the mites. Cold or warm water used with detergent and bleach can also be effective.
- Wash the sheets and blankets on your bed each week in hot water.
- Reduce indoor humidity to below 60 percent (ideally between 30—50 percent). Dehumidifiers or central air conditioners can do this.
- Try not to sleep or lie on cloth-covered cushions.
- Remove carpets from your bedroom and those laid on concrete, if you can.
- Keep stuffed toys out of the bed or wash the toys weekly in hot water or cooler water with detergent and bleach.

❒ Cockroaches

Many people with asthma are allergic to the dried droppings and remains of cockroaches.

The best thing to do:

- Keep food and garbage in closed containers. Never leave food out.
- Use poison baits, powders, gels, or paste (for example, boric acid). You can also use traps.
- If a spray is used to kill roaches, stay out of the room until the odor goes away.

❒ Indoor Mold

- Fix leaky faucets, pipes, or other sources of water that have mold around them.
- Clean moldy surfaces with a cleaner that has bleach in it.

❒ Pollen and Outdoor Mold

What to do during your allergy season (when pollen or mold spore counts are high):

- Try to keep your windows closed.
- Stay indoors with windows closed from late morning to afternoon, if you can. Pollen and some mold spore counts are highest at that time.
- Ask your doctor whether you need to take or increase anti-inflammatory medicine before your allergy season starts.

Irritants

❒ Tobacco Smoke

- If you smoke, ask your doctor for ways to help you quit. Ask family members to quit smoking, too.
- Do not allow smoking in your home or car.

❒ Smoke, Strong Odors, and Sprays

- If possible, do not use a wood-burning stove, kerosene heater, or fireplace.
- Try to stay away from strong odors and sprays, such as perfume, talcum powder, hair spray, and paints.

Other things that bring on asthma symptoms in some people include:

❒ Vacuum Cleaning

- Try to get someone else to vacuum for you once or twice a week, if you can. Stay out of rooms while they are being vacuumed and for a short while afterward.
- If you vacuum, use a dust mask (from a hardware store), a double-layered or microfilter vacuum cleaner bag, or a vacuum cleaner with a HEPA filter.

❒ Other Things That Can Make Asthma Worse

- Sulfites in foods and beverages: Do not drink beer or wine or eat dried fruit, processed potatoes, or shrimp if they cause asthma symptoms.
- Cold air: Cover your nose and mouth with a scarf on cold or windy days.
- Other medicines: Tell your doctor about all the medicines you take. Include cold medicines, aspirin, vitamins and other supplements, and nonselective beta-blockers (including those in eye drops).

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For More Information, go to: www.nhlbi.nih.gov

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