

Points of Testimony

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1. Edward Kerwin, MD is an Allergy Asthma and Clinical Research Physician specializing in the treatment of Asthma and COPD patients. Dr. Kerwin has acted as a principal investigator on over 300 clinical trials of new inhaled medications for Asthma and COPD, including some 50 trials studying new HFA (Hydrofluoroalkane) inhalers used to replace older CFC (Chlorofluorocarbon) inhalers. Dr. Kerwin is an independent physician, and is not an employee of any pharmaceutical company, but performs research for many pharmaceutical companies.
2. Asthma is a common condition affecting up to 10% of children and 6% of adults in the U.S. COPD affects up to 10% of U.S. adults and elderly patients. Acute Bronchitis is an acute lung infection of the airways (medical term “Bronchioles”) caused by viral or bacterial infections. All of these conditions cause episodes of airway muscle spasm and mucous plugging leading to acute, sometimes severe narrowing or obstruction of airways and inability to breathe. Acute exacerbations of asthma, COPD and bronchitis are common, occurring as frequently as daily in susceptible patients. Patients with “bronchospasm” require quick or immediate treatment with “rescue bronchodilator” medicines, generally given as inhalers, designed to provide near immediate relief to the airway blockages and obstruction typical of asthma, COPD and acute bronchitis.

3. Asthma, COPD and Acute Bronchitis can occur in the middle of the night, on weekends, during hikes, picnics, excursions, or camps far from cities. Severe Asthma flare-ups and COPD/ Bronchitis flare-ups can cause critical, sometimes progressive shortness of breath that can lead to death and very severe distress if untreated. Asthma especially is allergy and exercise triggered. Picnicking near a hay field, visiting relatives with cats, cleaning a moldy basement or dusty carpet can trigger severe life-threatening asthma flare-ups. Exercise also triggers flares. These generally require immediate treatment, usually with 2-4 puffs of a rescue bronchodilator given within minutes of the onset of airway obstruction. Death from asthma can occur within as little as 20 minutes (due to hypoxia, or starving for air) if asthma and bronchospasm are not rapidly treated.
4. Every patient with Asthma and COPD should carry with them a rescue bronchodilator (such as albuterol HFA inhaler or epinephrine CFC inhaler) per Guidelines of U.S. and Global Asthma and COPD organizations.
5. Since Acute Asthma, Acute COPD and Acute Bronchitis are potential medical emergencies requiring immediate treatment, *over-the-counter therapies can play a key life-saving role* when patients have a flare-up.
6. Another similar emergency condition is acute bee sting anaphylaxis, or food, shrimp or peanut anaphylaxis, or acute allergy to penicillin or another drug. In all these cases there are readily available over-the-counter medicines, Benadryl (diphenhydramine), other antihistamines, (cetirizine, loratidine, fexofenadine), decongestants like Sudafed (pseudoephedrine available OTC in some states), and other rescue-relief medicines that patients can give themselves within minutes in an emergency.

7. This is a key point. Patients have a fundamental right to self-treatment, to try to heal or treat themselves in whatever ways they can, before they resort to the expense and inconvenience of seeing a doctor. This is a fundamental part of American values and American self-reliance, what we might call the Pioneer American Spirit; Americans have a right to treat themselves first and foremost with whatever remedies are available. We would never have settled the Midwestern, Southern, or Western U.S. without this spirit. Many Americans today in Montana, Colorado, California, Idaho, Arizona, Michigan, Wisconsin, Alabama, Georgia, Oregon, etc., live on rural ranches and farms miles from any doctor or hospital. Americans have a fundamental right to treat ourselves, at least with initial emergency first aid treatments. This is who we are.
8. Historically 60-100 years ago asthma was fortunately rare, and was notoriously difficult to treat. Patients smoked asthma cigarettes with anti-cholinergic medicines. They downed theophylline pills and teas, breathed in steam and struggled to take showers, trying to ease their breathing. These were truly the “dark ages” of asthma care. And many Americans died if their severe asthma did not resolve.
9. For 49 years, through four generations, over-the-counter rescue breathing medicines have been readily available OTC to Americans with Asthma or COPD or Bronchitis flare-ups. Primatene Mist (CFC) was released in about 1963. Other brands of inhalers and pills containing epinephrine have also been available over-the-counter to any person without a doctor’s appointment for nearly 50 years.
10. Only now as of December 31, 2011, has the U.S. EPA and FDA banned pharmacies in the U.S. from selling Primatene Mist (CFC) or any other inhaled epinephrine products.

11. Let me make this clear. As of January 1, 2012, there are no OTC rescue asthma medicines in U.S. pharmacies whatsoever. There are none.
12. So if you have an acute bee sting allergy in the forest, or at night, or in the inner city, or as an elderly person in your home, you can still get Benadryl, Zyrtec, Claritin or Allegra at any local 7-11 store or gas station.
13. But if you get an acute asthma flare-up on a hike in rural America, in the inner city, at night or on a weekend, you are out of luck. Maybe you can get an immediate doctor's appointment within 20 minutes.... As my teenage son would say, good luck with that. Maybe you are super organized and already have a prescription asthma/COPD rescue medicine like prescription albuterol HFA with you. But we all know that up to half of Americans are not so organized with their healthcare. Maybe you can treat yourself with "dark ages" treatments (see item 8 above). But even though for 50 years rescue epinephrine has been available OTC to every American, now there is no rescue inhaler that you can get in rural America, in the West, South, Midwest, or Northeast, in inner cities, or for poor or elderly patients with poor mobility.
14. You can think of an OTC rescue inhaler like epinephrine inhaler (Primatene Mist) as a *life preserver* for patients with severe flare-ups of asthma, COPD or acute bronchitis.
15. Just as on the *Titanic* or the *Costa Concordia*, people don't think about life preservers until they are drowning. Is it really right to lock up all the life preservers and give the only keys to a ship's doctor or a ship's Captain? As my teenage son says, good luck with that.

16. Rescue inhalers like Epinephrine (inhaled CFC or eventually HFA) should continue to be available over-the-counter to Americans without a requirement for a doctor's visit or a prescription or an ER visit. This is basically a "First Aid" medicine, like a band-aid for a cut, or Benadryl for a bee sting, or a Heimlich maneuver for a choking person. There need to continue to be over-the-counter, fast acting rescue bronchodilators available to Americans in need. They have had these continuously available since 1963. Only in January 2012 did the EPA and FDA prematurely withdraw CFC Primatene Mist inhaler without ensuring that there were alternative OTC rescue inhalers for patients with acute Asthma, COPD and Bronchitis.
17. The EPA and FDA have raided your "First Aid Kit," and removed a key rescue inhaler therapy. An extension on the withdrawal of Primatene Mist (CFC) for two years or 18 months is needed to allow an alternative HFA Epinephrine inhaler to be developed and to be approved for over-the-counter use by all Americans.

Thank you for your attention.

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Summary

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- Asthma, COPD and Acute Bronchitis effect more than 30 million Americans. They cause episodic severe breathlessness requiring the use of rescue bronchodilator inhalers.
- For 49 years Americans have had an over-the-counter (OTC) rescue inhaler alternative, called Primatene Mist (epinephrine) with a chlorofluorocarbon (CFC) propellant. CFC Primatene Mist has been available for four generations of Americans, since 1963.
- The first principal of medicine is that patients have a right to treat themselves, to render first aid, to try to heal their own health before they go to any doctor or ER. This is a fundamentally American value, and how our rural frontiers were settled. Americans have a right to treat themselves through first aid in emergencies.
- OTC Inhaled Epinephrine (CFC) is a lifesaving rescue medicine for acute asthma, COPD, albuterol. This is similar to the role Benadryl plays for bee sting, peanut, or penicillin anaphylactic reactions. Such rescue medicines need to be available over-the-counter. There should be no “locking up” of these life preserving medicines in pharmacies and doctors’ offices. They are needed promptly within minutes, in the middle of the night, in rural areas, in inner cities, by the poor and infirm, by Americans who may have no rapid medical access to a doctor or hospital.
- An 18 month to two year extension of the licensing of OTC Primatene Mist (CFC) inhaler in the U.S. will allow time for a suitable HFA (hydrofluoroalkane) replacement to be developed as an OTC rescue inhaler for Asthma, COPD, and bronchitis patients, available to all Americans.