



July 30, 2012

The Honorable Ed Whitfield
Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
Washington, DC 20515

The Honorable Bobby Rush
Ranking Member
Subcommittee on Energy and Power
Committee on Energy and Commerce
Washington, DC 20515

Dear Chairman Whitfield and Ranking Member Rush:

On behalf of the undersigned medical and public health organizations, we are writing to express our strong opposition to allowing CFC-propelled over-the-counter epinephrine (Primatene Mist CFC) to return to the U.S. market. Our organizations strongly believe that allowing this product to return to the marketplace is not in the best interests of patients with asthma or the public health.

Over 25 million Americans – including 7 million children – have asthma. Asthma is the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences from chronic disease – accounting for over 10.5 million lost school days in 2008. Asthma costs our healthcare system over \$50.1 billion annually and indirect costs from lost productivity add another \$5.9 billion, for a total of \$56 billion dollars annually. Asthma claims the lives of more than 3,300 Americans each year, or approximately nine people per day.

Fortunately, based in part on guidelines and recommendations from several expert panels, there are effective treatment protocols that include the use of medication that people living with asthma can use to successfully manage their disease. None of the expert guidelines recommend the use of over-the-counter medications--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 recognizing that it has the potential for “excessive cardiac stimulation.”

Our organizations strongly encourage any patient who uses over the counter medications – like Primatene Mist CFC – to treat his/her asthma to seek a healthcare provider who can help the patient develop an asthma management plan and recommend more effective and safer medications to manage the asthma – including products that help prevent asthma episodes.

All pharmaceutical manufacturers have been on notice since 1990 that products containing CFCs would be phased out. Armstrong Pharmaceuticals, the manufacturer of Primatene Mist CFC, has known since 2008 that their product – like others made with CFCs – would also be phased out.

Armstrong Pharmaceuticals already received a one year extension of the transition date from the U.S. Environmental Protection Agency to allow its product to be sold until December 31, 2011.

While other companies and products have successfully transitioned their products, providing for safe and effective medications for people with asthma, the maker of Primatene Mist CFC instead has repeatedly sought to be exempted. Congress should not make an exception for one product – especially one that is not recommended for the treatment of asthma. Moreover, reintroducing this product into the marketplace would only further confuse patients and undermine efforts to transition patients to guidelines-based care for managing their disease.

Our organizations strongly believe Armstrong has had sufficient time to prepare for a final transition date of December 31, 2011. In 2008, the decision was made the CFC propelled inhaled epinephrine should be phased out and our organizations have been working with providers and patients to ensure a smooth and orderly transition process. Congress should not create an exemption for Primatene Mist CFC, but instead work to ensure that all people with asthma are receiving guidelines-based treatment for their disease.

Sincerely,

Alpha-1 Association
Alpha-1 Foundation
American Academy of Allergy Asthma and Immunology
American Academy of Pediatrics
American Association for Respiratory Care
American College of Allergy Asthma and Immunology
American Lung Association
American Thoracic Society
Asthma and Allergy Network/Mothers of Asthmatics
Asthma and Allergy Foundation of America
COPD Foundation
National Association for the Medical Direction of Respiratory Care
National Home Oxygen Patients Association

Cc: The Honorable Fred Upton, Chairman, Energy and Commerce Committee
The Honorable Henry Waxman, Ranking Member, Energy and Commerce Committee