MICHAEL C. BURGESS, M.D. 261H DISTRICT, TEXAS

ENERGY AND COMMERCE

SUBCOMMITTEES
HEALTH
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OVERSIGHT AND INVESTIGATIONS
ENERGY AND POWER

JOINT ECONOMIC COMMITTEE

CONGRESSIONAL HEALTH CARE CAUCUS, CHAIRMAN



Congress of the United States
House of Representatives
Washington, DC 20515-4326

WASHINGTON, DC OFFICE: 2241 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515 (202) 225-7772

www.house.gov/burgess

DISTRICT OFFICES:

1660 SOUTH STEMMONS FREEWAY
SUITE 230
LEWISVILLE, TX 75067
(972) 434-9700

1100 CIRCLE DRIVE SUITE 200 FORT WORTH, TX 76119 (817) 531-8454

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President Barack Obama The White House 1600 Pennsylvania Avenue Washington, D.C. 20500

President Obama:

As a lifetime asthma sufferer, I would like to bring to your attention an issue that has been of critical importance to me as well as to millions of asthma sufferers across the country. On January 1, 2012, a common over-the-counter (OTC) emergency asthma inhaler, Primatene® Mist, was forced off pharmacy shelves due to an international treaty agreement known as the Montreal Protocol which bans the use of chlorofluorocarbon (CFC) propellant, an ingredient in Primatene® Mist. Primatene® Mist is the only OTC approved inhaler for asthma symptoms with epinephrine as the active ingredient.

Currently, the Food and Drug Administration (FDA) has under its review a replacement OTC inhaler for Primatene® Mist. While I am concerned over the undue delay in the review of this medication by the FDA, my more immediate concern is over the current lack of any available OTC emergency asthma inhaler. I myself have used Primatene® Mist on numerous occasions where I have found myself in need of an emergency inhaler, and I know other asthma sufferers who have found themselves in the same situation. At present, asthma sufferers who find themselves awake at 2am with an unexpected asthma attack, and who do not have immediate access to an inhaler, are faced with the costly and time-consuming task of rushing to the emergency room for a prescription inhaler, increasing healthcare costs and doing a disservice to asthma sufferers who have long found comfort in knowing that relief could be had with just a short trip to the local drug store.

What is all the more frustrating with this situation is that the OTC version of Primatene® Mist is still available in large stocks, sitting in warehouses, unable to be sold in the U.S. Further, the Environmental Protection Agency (EPA), which has repeatedly espoused its concern over asthma sufferers nationwide, has the ability to grant a waiver to the Montreal Protocol and allow the existing stock of Primatene® Mist to be sold. I have repeatedly approached representatives of the EPA, including Administrator Lisa Jackson and Assistant Administrator Gina McCarthy and asked them to grant such a waiver. While simultaneously pointing their fingers at claiming

the problem lies at the feet of the FDA, they have been unresponsive in answering why the EPA has thus far refused to grant a waiver to allow the existing stock of Primatene® Mist to be sold.

If assisting asthma sufferers and lowering healthcare costs are truly a priority for your administration, allowing the existing stock of Primatene® Mist to be sold to asthma sufferers should be an easy decision. The small amount of CFC propellant used in the remaining stock of Primatene® Mist will hardly have a negative impact on the global environment, especially when weighed against the health benefits of assisting asthmatics suffering from emergency attacks. Indeed, even if not used, the existing stock of this life-saving drug will simply be discarded, allowing the propellant to be emitted into the atmosphere without providing its known benefit to asthma patients. Moreover, this is a finite number of Primatene® Mist inhalers which are at issue, as the company responsible for their manufacture has already switched over to a Montreal Protocol-compliant propellant currently under FDA review.

Because of your stated commitment to helping asthma sufferers and lowering healthcare costs generally, and EPA's refusal to respond to calls to allow the existing stock of Primatene® Mist to be sold, including letters from the Energy & Commerce Committee which have gone unanswered by the EPA, I am writing to you to ask that you direct Administrator Jackson to review this issue and allow Primatene® Mist to be sold until the existing stock is depleted and FDA is able to fully review and approve its replacement. The health and lives of millions of Americans are at risk until this issue can be resolved.

Sincerely,

Michael C. Burgess, M.