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VP and General Counsel
Amphastar Pharmaceuticals, Inc.
US House of Representatives
Energy and Commerce Committee
Energy and Power Subcommittee

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I am Jason Shandell, Vice President and General Counsel, for Amphastar Pharmaceuticals, Inc., the parent company of Armstrong Pharmaceuticals, Inc.

Amphastar believes in placing people before profits and therefore we are grateful to the Members and staff of the Energy and Commerce Committee for their assistance in helping us to distribute the remaining units of Primatene[®] Mist. We strongly believe that allowing patients to have access to Primatene[®] Mist is better than leaving it to expire in a warehouse in California.

History:

Primatene[®] Mist, an epinephrine inhaler with CFC as propellant, was developed by Wyeth Labs in 1967. Amphastar purchased the rights to market the Primatene[®] Mist brand from Wyeth in July 2008.

Primatene[®] Mist is approved “for temporary relief of occasional symptoms of mild asthma”.

There are at least 2-3 million loyal Primatene[®] Mist users.

This drug was manufactured by Armstrong Pharmaceuticals Inc. since 1984 until August of 2011. Once our allocated CFC to produce Primatene[®] Mist was exhausted, we stopped manufacturing the product on August 12, 2011 and shut down Armstrong's manufacturing facility plant in West Roxbury, Massachusetts.

When we purchased the Primatene[®] Mist brand in 2008, we knew that Primatene[®] Mist would be going off the market and that there were technical challenges in creating a CFC free epinephrine inhaler, referred to as Primatene[®] HFA. We accepted the challenges and were confident that a CFC free Primatene[®] HFA could be developed. In fact, we have developed Primatene[®] HFA in our Canton Massachusetts facility and continue to proactively work with the FDA to address their questions and requirements in order to bring the CFC free Primatene[®] HFA to market. We hope to submit an NDA for Primatene[®] HFA in the fourth quarter of this year. Primatene[®] HFA, like Primatene[®] Mist, is an epinephrine inhaler, but with HFA as the propellant,

When the Final Rule was published in the Federal Register in November 2008, requiring the termination of the sale and distribution of Primatene[®] Mist as of December 31, 2011, Armstrong warned the regulatory decision making parties "...that removing OTC epinephrine from the market and attempting to switch patients to prescription medications will, in Armstrong's view, have significant costs and health consequences, which can be avoided by extending the effective date to allow time for a non-ODS OTC epinephrine product to be developed before the current product is phased out." "ODS" is an acronym for Ozone Depleting Substance.

Today:

Because Primatene[®] Mist was removed from the market on January 1, 2012 there is NO over the counter inhaler for asthmatic patients on the US market. An individual who previously used

Primatene[®] Mist must now see a doctor to obtain a prescription for Albuterol and then have it filled, at four to five times the cost of Primatene[®] Mist (approximately \$20.00 versus \$108.75 to \$111.59). We have received thousands of inquiries from users of Primatene[®] Mist who are desperate for availability of an OTC inhaler. Unfortunately, these inquires have also cited two possible deaths because of the lack of an OTC inhaler.

Our Efforts:

Last fall, we engaged Venable Law firm to assist us in requesting from the EPA, Enforcement Discretion on Primatene[®] Mist. Former Congressman Bart Stupak has been our lead counsel in working with the EPA.

After meetings with the EPA, two written Requests for Enforcement Discretion, with supporting government studies and documentation, were submitted last December to the EPA to allow for the sale of the remaining units of Primatene[®] Mist based on public health and economic interests. The public health interest is growing since the untreated or undertreated asthma patient population is largely comprised of the uninsured, economically disadvantaged, black and Hispanic communities, including a large number of women and children.

Without Primatene[®] Mist, those asthmatics who have no insurance or have no prescription albuterol available may have to seek care in emergency rooms and experience longer hospitalizations when experiencing asthma symptoms such as shortness of breath, and they do not have Primatene[®] Mist available Over the Counter.

The company's request for enforcement discretion was denied by the EPA on December 30, 2011 citing that it would not be in the public interest to allow the sale of the remaining units of Primatene[®] Mist.

The EPA has granted Enforcement Discretion on three occasions over the past 10 years after a Final Rule had been published for low sulfur gasoline, lead abatement certification, and Texas Low-Emission Diesel under the Texas State Implementation Plan.

Since the EPA did not address the economic factors raised in our original request, we again requested enforcement discretion from the EPA on January 4, 2012. The 2008 Final Rule stated that removing Primatene[®] Mist from the market will cost consumers between \$300 million to 1.1 billion dollars based on 2007 estimates. The cost to the Federal Government and taxpayers for Medicare and Medicaid could run as high as \$75 million dollars in each program.

We have not received a response from the EPA on this subsequent request based on economic concerns.

Amphastar understands that Members of Congress have written to the EPA expressing their concerns about the removal of Primatene[®] Mist from the OTC market and have not received any response from the EPA.

The company has repeatedly asked why Primatene[®] Mist was pulled from the market when two prescription drugs, one of which has an approved, non-CFC replacement on the market, that use CFC as their propellants, have been granted exceptions to the Montreal Protocol to stay on the

market through December of 2013. No one from EPA has ever explained why these two inhalers with CFCs are allowed to remain on the market but Primatene[®] Mist is not.

Primatene[®] Mist had been on the market for almost 50 years with a safe and effective track record. To remove Primatene[®] Mist from the market because it contains CFC with no replacement inhaler jeopardizes the health and safety of the 2-3 million Americans that have relied on this product for many years.

Amphastar believes in putting people over profits and throughout our efforts we have offered to distribute all the remaining units of Primatene[®] Mist as a donation to public health clinics. This offer has been rejected. We are not interested in profiting from the sale of the remaining inventory of Primatene[®] Mist. Therefore, Amphastar commits that it will donate all the net profits from the sale of the remaining units of Primatene[®] Mist to charity. Amphastar believes in its product, Primatene[®] Mist. It should be available in the US OTC market so individuals who are suffering from asthma and depend on this product can enjoy instant relief when they experience asthma symptoms such as shortness of breath. We sincerely believe that there must be a readily available over the counter inhaler for American asthma patients who have difficulty accessing a doctor to obtain a prescription and cannot afford to pay four to five times more for a prescription inhaler.

Please be advised that Amphastar will also be launching an Internet campaign to "Bring Back My Primatene[®]" to get Primatene[®] Mist back on the OTC retail market and available for the millions of Americans who are suffering from asthma and need Primatene[®] Mist.

In closing, let me again thank the Members of this Committee, Chairwoman Mary Bono Mack, Dr. Michael Burgess and Congressman Mike Ross, and your professional staff for holding this

hearing, developing draft legislation to allow the sale or distribution of the remaining units of Primatene[®] Mist, and allowing me to testify on behalf of Amphastar and Armstrong.

In conclusion, our goal is to get the remaining units of Primatene[®] Mist out of the warehouse and in the hands of the American people. The asthmatic population that purchases Primatene[®] Mist believes in our product because it works for them, it is convenient and available without having to see a doctor or they lack adequate health insurance for prescription inhalers. We are concerned about the health of the American people and we will donate to charity all net profits from the sale of the remaining units of Primatene[®] Mist.

Thank You.

SUMMARY

Jason Shandell, Esquire Amphastar/Armstrong Pharmaceuticals

- For almost 50 years, Primatene® Mist is approved “for temporary relief of occasional symptoms of mild asthma. There are 2-3 million loyal Primatene® Mist users.
- Because Primatene® Mist was removed from the market on January 1, 2012 there is NO over the counter (OTC) inhaler for asthmatic patients. Primatene® Mist users must now see a doctor to obtain a prescription for Albuterol and then have it filled at four to five times the cost. We have received thousands of inquiries from Primatene® Mist users who are desperate for an OTC and users cite two possible deaths because no OTC inhaler.
- Two written Requests for Enforcement Discretion were presented with supporting government studies and documentation to the EPA based on public health and economic interests. The public health interest is the growing number of untreated or undertreated asthma patient population which is largely the uninsured, economically disadvantaged, black and Hispanic communities, including a large number of women and children.
- The EPA has granted Enforcement Discretion on three occasions over the past 10 years.
- Amphastar will not profit from the sale of the remaining 1.2 million units of Primatene® Mist and it will donate all the net profits to charity.
- The asthmatic population that purchases Primatene® Mist believes in our product because it works for them, it is convenient and available without having to see a doctor or they lack adequate health insurance for prescription inhalers.
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