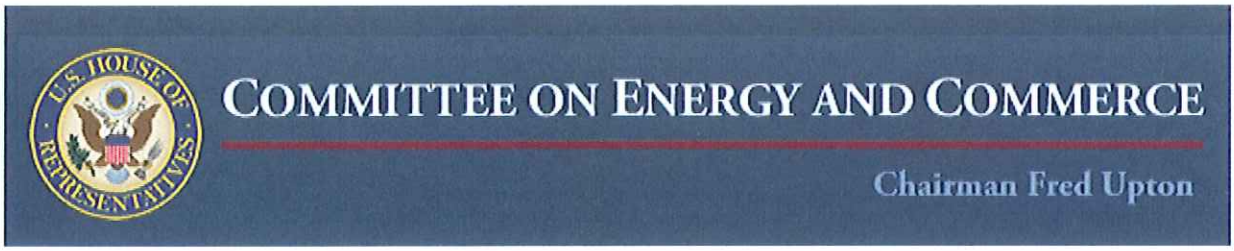

ASTHMA INHALERS RELIEF (AIR) ACT

MYTH VS. FACT

MYTH: ***This bill rolls back the Clean Air Act.***

Fact: Nothing in this bill amends the Clean Air Act or any existing regulation.

MYTH: ***This bill is inconsistent with the Montreal Protocol.***

Fact: The Montreal Protocol allows for "essential uses" of ozone depleting substances. One of their most important essential uses under the treaty has been as a propellant in asthma inhalers. In fact, two prescription-only brands of CFC-inhalers are available in the U.S. today. Only the over-the-counter inhaler was banned.

MYTH: ***This bill will harm the environment.***

Fact: FDA has said this inhaler represents a "fraction" of one percent of all CFC emissions worldwide. The small fraction of one percent of all CFC emissions will not reduce or slow our environmental progress.

MYTH: ***These inhalers are not necessary for public health.***

Fact: FDA approved these inhalers for over-the-counter access to relieve symptoms among asthmatic patients. There is no other asthma medication available to relieve symptoms in an emergency without a prescription or an emergency room visit.

MYTH: ***These inhalers are not safe.***

Fact: Asthma can be life threatening. FDA has approved this medication for over-the-counter use to relieve asthma symptoms not just once, but 22 times, in response to the manufacturer's supplemental applications over the years. Safe use of the product is described on the FDA-approved label.

MYTH: ***Congress should not second-guess the FDA and EPA.***

Fact: This bill is necessary to ensure that a potentially life-saving inhaler that has relieved asthma sufferers for over 40 years is hands of patients who need it, not held in storage because

of agency bureaucrats. FDA approved the use of the inhalers to ease breathing for asthma patients. FDA supported phase-out of the inhalers when an alternative was anticipated, but an alternative has not yet been approved for sale.

MYTH: ***This is a windfall for the manufacturer.***

Fact: The manufacturer has committed to donating to charity any revenues from inhaler distribution. As the result of the ban, the manufacturer had already removed inhaler revenues from its business planning. The manufacturer is trying to address the needs of the patients that have contacted them seeking product access.

MYTH: ***There are other, safer, better alternatives available.***

Fact: There are no effective alternatives readily available without a prescription. The Primatene Mist inhaler has been effective as an emergency rescue inhaler for over 40 years, approved by FDA to ease breathing for asthma patients by reducing spams of bronchial muscles. The only alternatives are available by prescription and cost 2-3 times more, and require a doctor or hospital visit.

MYTH: ***Medical professionals/patient advocates don't support use of Primatene Mist.***

Fact: FDA approved Primatene Mist for two uses: "Temporarily relieves shortness of breath, tightness of chest, and wheezing due to bronchial asthma" and "Eases breathing for asthma patients by reducing spasms of bronchial muscles." FDA has completed 21 approvals after the original approval in 1967, the most recent approval in 2004. According to the manufacturer, thousands of patients have written in to express concerns about the ban. Within the medical community, experts like Dr. Kerwin support patient access to Primatene Mist as an emergency therapy.

MYTH: ***Patients can get help to pay the extra costs of substitute inhalers.***

Fact: For low income patients, paying for doctor visits and expensive inhalers is not realistic. Furthermore, physicians and emergency rooms are not always available in rural areas or during non-business hours. In some parts of the U.S., the nearest hospital may be located far from patients needing emergency relief.

Myth: ***The remaining inventory will be only a temporary fix and will confuse the public.***

Fact: Temporary relief is important for Primatene Mist users waiting for the replacement product to be approved for sale. Temporary relief might be all that is needed to bridge the gap.

MYTH: ***"No Action Letters" are rarely issued by EPA and this situation doesn't justify it.***

Fact: EPA issue these letters routinely, including in the context of its Montreal Protocol allocation rulemakings for allocations of CFCs, HCFCs, and methyl bromide, and also in the context of its Boiler MACT rulemakings. It makes no sense for EPA to threaten enforcement actions against sellers and distributors of this product that has been providing relief to asthmatics for over 40 years, for no environmental benefit whatsoever.

MYTH: ***There are no technical barriers to making an alternate non-prescription inhaler.***

Fact: In 2008, FDA said Dec. 31, 2011 was enough time to develop a Primatene Mist replacement. Whatever the reason –technical or otherwise – the replacement has not yet been approved for sale, and existing stocks of inhalers can help bridge the gap.

MYTH: ***This is not fair to other manufacturers whose inhalers were banned.***

Fact: The focus of this bill is on what will help patients today. If EPA denied waiver requests in the past, that shouldn't be a reason to deny asthmatics relief now.