FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

November 15, 2011

The Honorable Lisa Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator Jackson:

We are writing to express our concerns over asthmatics' access to over-the-counter inhalers. Due to Food and Drug Administration (FDA) regulations and Environmental Protection Agency (EPA) enforcement, on December 31, 2011, consumers will no longer have access to an over-the-counter asthma inhaler used for the relief of bronchial asthma symptoms, such as wheezing, tightness of chest, and shortness of breath. Although prescription inhalers will be available to patients, many individuals rely on over-the-counter inhalers to address acute asthma attacks because of convenience and, more importantly, because of the cost to the consumer.

Primatene Mist is the only over-the-counter inhaler available for individuals who suffer from asthma. We are primarily concerned that the decision to continue with plans to take chlorofluorocarbon (CFC) based over-the-counter inhalers off the market when there is no non-CFC based over-the-counter alternative available could harm patients by severely restricting access to essential medication. Approximately three million people currently rely on this inhaler, which has been available to them in most pharmacies for approximately $20.00. If the ban on the sale of Primatene Mist does go into effect, patient-consumers will be required to pay for doctor visits just to obtain a prescription, and then spend up to three times more than they otherwise would to actually obtain their asthma medication.

We understand that companies are currently developing a non-CFC based over-the-counter inhaler. However, it is unlikely that such an inhaler will be approved by December 31, 2011. To minimize disruption for those that rely on over-the-counter inhalers, we urge you to act promptly to ensure that available inventories of Primatene Mist can continue to be distributed and sold without threat of any enforcement action by the EPA. We request that EPA take all appropriate actions within the agency's authority, including providing assurances that the agency will refrain from any enforcement actions, in order to allow for the continued distribution and

sale in the U.S. of those available inventories after December 31, 2011, and until such time as a non-CFC based substitute over-the-counter inhaler becomes available.

While we understand these actions will not completely address the access issue surrounding the removal of the CFC based over-the-counter inhalers, it could mitigate disruption until a new non-CFC based over-the-counter inhaler is approved. We appreciate your response as soon as possible, and request that you advise us not later than one week after the date of this letter of the actions EPA plans to undertake to address this issue. Should you have any questions, please contact Mary Neumayr of the Committee Staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Joe Barton
Chairman Emeritus

Cliff Stearns
Chairman
Subcommittee on Oversight
and Investigations

Ed Whitfield
Chairman
Subcommittee on Energy and Power

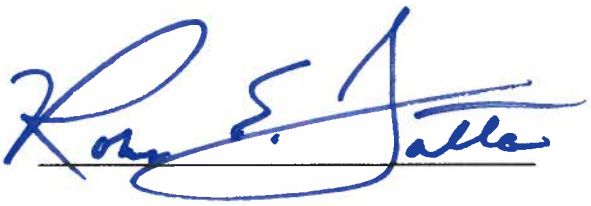
Joseph R. Pitts
Chairman
Subcommittee on Health

Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing,
and Trade

Michael C. Burgess
Vice Chairman
Subcommittee on Health

Marsha Blackburn
Vice Chairman
Subcommittee on Commerce, Manufacturing,
and Trade

H. Morgan Griffith
Member



cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Frank Pallone, Jr., Ranking Member
Subcommittee on Health

Signatories

Fred Upton
Cliff Stearns
Joseph R. Pitts
Michael C. Burgess
H. Morgan Griffith
Robert Latta
Pete Olson

Joe Barton
Ed Whitfield
Mary Bono Mack
Marsha Blackburn
Cory Gardner
Phil Gingrey