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REPORT
112–673

ASTHMA INHALERS RELIEF ACT OF 2012

SEPTEMBER 14, 2012.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 6190]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6190) to direct the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

H.R. 6190, the "Asthma Inhalers Relief Act of 2012," was introduced by Representative Michael Burgess, M.D. on July 25, 2012 (together with Representatives Barton, Carter, Matheson, Pitts, and Ross). The legislation would direct the Administrator of the Environmental Protection Agency (EPA) to allow for the distribution, sale, and consumption of remaining inventories of chlorofluorocarbon (CFC) epinephrine inhalers. These inhalers were banned in the U.S. as of December 31, 2011, pursuant to the Montreal Protocol on Substances that Deplete the Ozone Layer and Title VI of the Clean Air Act, for the purpose of reducing emissions of ozone depleting substances into the air.

Key provisions of this bill would:

- Direct the Administrator of EPA to allow for the distribution, sale, and consumption of remaining inventories of CFC epinephrine inhalers, commonly known as Primatene Mist;
- Direct the Administrator of EPA to refrain from taking any enforcement action against any distributor or seller of such inhalers on the basis of any Federal law implementing the Montreal Protocol; and
- Require the Administrator of EPA to issue a No Action Assurance Letter to any requesting distributor or seller stating that the agency will not initiate such an enforcement action.

BACKGROUND AND NEED FOR LEGISLATION

Epinephrine inhalers containing CFCs, most commonly marketed as Primatene Mist, have been sold in the U.S. without physician's prescription as an over-the-counter (OTC) medicine to provide relief of asthma symptoms for over 40 years. As of December 31, 2011, the manufacture and sale of these inhalers has been banned for the purpose of reducing emissions of ozone depleting substances into the air pursuant to the Montreal Protocol on Substances that Deplete the Ozone Layer and Title VI of the Clean Air Act. Prior to the ban, the Food and Drug Administration (FDA) estimated 1.7 million to 2.3 million consumers purchased approximately 4.5 million such inhalers annually. There is a remaining inventory of over one million such units currently in storage at the manufacturer's facility, and the legislation would allow for distribution, sale, and consumption of this remaining inventory. The legislation would sunset on August 1, 2013.

Statutory and regulatory background

The Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) is an international environmental treaty designed to reduce emissions of ozone-depleting substances into the atmosphere by limiting the production and consumption of those substances. CFCs are included among the listed ozone-depleting substances. The treaty entered into force in 1989, and to implement the treaty, Congress amended the Clean Air Act in 1990 to add Title VI which is administered and enforced by the EPA.

Under the treaty and Clean Air Act Title VI, the use of CFCs has been phased out in the United States, subject to certain exemptions including for essential uses. One of the most important essential uses of CFCs has been as a propellant to deliver therapeutic medicine into the respiratory system of patients who use metered-dose

inhalers (MDIs) for the relief of respiratory symptoms caused by asthma and chronic obstructive pulmonary disease. For decades, OTC CFC epinephrine inhalers were exempt from the phaseout of CFCs.

In 2008, however, the FDA, in consultation with EPA, removed the essential-use designation for such inhalers and prohibited their sale as of December 31, 2011. In its rulemaking, FDA concluded that there are no substantial technical barriers to formulating epinephrine as a product that does not release ozone-depleting substances. FDA also concluded that while the availability of a replacement product was not necessary for the agency to remove the essential use designation, a December 31, 2011, phaseout date would give sufficient time for the development of a non-CFC formulation of epinephrine MDIs and the processing of an application for new drug approval. FDA also concluded at that time that the costs associated with removing OTC epinephrine MDIs from the market the rule could range from $180 million to $1.1 billion annually measured in 2007 dollars due to increased physician visits, more expensive medicines, and increased emergency room visits and hospitalizations.

Remaining inventories of Primatene Mist inhalers

There are currently approximately 1.2 million OTC epinephrine inhalers that were not sold or distributed before the ban went into effect. On July 18, 2012, Mr. Jason Shandell, Vice President and General Counsel of Amphastar Pharmaceuticals, Inc., the parent company of Primatene Mist's manufacturer, testified that the manufacturer discontinued manufacture of the inhalers in August 2011 when the company's allocated CFC to produce Primatene Mist was exhausted, has shut down its manufacturing facility plant and is currently storing this remaining inventory at the company's facilities in California. He also testified that the manufacturer has asked both EPA and FDA how to dispose of the inventories, but to date has not received a response.

Need for legislation

There is currently no OTC asthma inhaler available to patients that require relief from respiratory symptoms caused by asthma.[1] Prior to the ban going into effect, the National Association of Chain Drugstores, the National Community Pharmacists Association, other distributors, and the manufacturer submitted requests to EPA for a waiver to allow for the sale or distribution of the remaining inventories without threat of an EPA enforcement action.

On December 30, 2011, EPA declined the manufacturer's request. As a result, patients must now see a doctor to obtain a prescription for an alternative inhaler at significantly higher cost, estimated to be up to four to five times higher, while at the same time remaining stocks of Primatene Mist remain in storage. On July 18, 2012, Mr. Shandell testified that "we have received thousands of inquiries from users of Primatene Mist who are desperate for availability of an over-the-counter inhaler." He also testified that "the un-

[1] The Committee is informed that Nephron Pharmaceuticals Corp. plans to offer an alternative OTC nebulizer product in retail outlets starting in August 2012. Mr. Shandell also testified that an alternative OTC epinephrine inhaler without CFCs is under development and anticipates submitting an application to FDA in the fourth quarter of 2012.

treated and undertreated asthma patient population is largely comprised of uninsured, economically disadvantaged black and Hispanic communities. This includes a large number of women and children. Without Primatene Mist, those asthmatics who have no insurance, they may have to seek care in emergency rooms which can take many hours and cost thousands of dollars."

On July 18, 2012, Dr. Edward Kerwin, Senior Medical Director at the Allergy and Asthma Center of Southern Oregon, testified that Primatene Mist is a "life preserving medicine" for patients who are experiencing a severe asthma attack and do not have access to a doctor or hospital. He further testified that in rural areas, many patients may live distant from either a doctor or an emergency room. He testified that there is no longer any OTC rescue-relief medicine available for those experiencing an acute asthma attack, and that Primatene Mist inhalers play a particularly vital role for low-income asthma patients who cannot afford insurance or the price of both a doctor's appointment and a prescription inhaler.

Dr. Kerwin testified that "Primatene Mist is a first aid situation kind of medicine. The reason it is over-the-counter is that there need to be immediate access, immediate use medicines available to children, poverty-stricken patients, elderly people who have acute airway disease." He stated "We need regular access to emergency medicines." He stated "I live in a rural State. Many patients in southern Oregon live 50 miles from the nearest doctor. That is quite common. Certainly, 100 miles from an emergency room. We believe there is a role for Primatene or epinephrine or any over-the-counter inhaler." He also testified that "even though for 50 years rescue epinephrine has been available OTC to every American, now there is no rescue inhaler that you can get in rural America, in the West, South, Midwest, or Northeast, in inner cities, or for poor or elderly patients with poor mobility."

H.R. 6190—The Asthma Inhalers Relief Act of 2012

H.R. 6190, the "Asthma Inhalers Relief Act of 2012," would direct EPA to allow for the distribution, sale, and consumption of the remaining inventories of over-the counter CFC epinephrine inhalers without penalty, providing temporary relief to asthma patients.

While the legislation is focused on EPA, the legislation expressly provides that FDA will continue to have authority to regulate the inhalers to be distributed should there be any safety-related concerns. In particular, H.R. 6190 provides that the legislation would not in any way limit or otherwise affect the authority of FDA to ensure the safety and effectiveness of CFC epinephrine inhalers. With respect to the safety of these inhalers, FDA's website currently states that these are safe to use.[2]

The legislation would not have any significant adverse environmental impact. In its 2008 regulation, FDA stated that removing these inhalers would reduce CFC emissions by "only a fraction of

[2] On FDA's website, the agency lists questions and answers relating to the Primatene Mist ban. See *http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm080427.htm.* In response to the question "Is it safe for epinephrine users to 'purchase sufficient' amounts of Primatene Mist to use following the phase out date of December 31, 2011?" the website states: "Epinephrine users can use the product after December 31 because the product phase-out only applies to the manufacture and sale of the product after December 31." The website further states that "[i]f you haven't used up your Primatene Mist by Dec. 31, 2011, it's safe to continue using it as long as it hasn't expired."

1 percent of total global CFC emissions." The legislation would also sunset before a separate ban on two other prescription inhalers that use CFCs as a propellant takes effect in December of 2013.

HEARINGS

On July 18, 2012, the Subcommittee on Energy and Power held a legislative hearing on the "Asthma Inhalers Relief Act of 2012," and received testimony from:

- Jason Shandell, General Counsel & Secretary, Amphastar Pharmaceuticals;
- Edward M. Kerwin, MD, Senior Medical Director, Allergy & Asthma Center of Southern Oregon;
- Monica Kraft, MD, Professor of Medicine, Duke University, President, The American Thoracic Society, Director, Duke Asthma, Allergy and Airway Center;
- Chris Ward, MD, Former Chairman, Board of Directors of the Asthma and Allergy Foundation of America; and
- Regina McCarthy, Assistant Administrator for Air and Radiation, U.S. Environmental Protection Agency (Written Statement for the Record).

COMMITTEE CONSIDERATION

H.R. 6190 was introduced on July 25, 2012, by Representatives Michael Burgess, M.D. (together with Representatives Barton, Carter, Matheson, Pitts, and Ross).

On July 18, 2012, the Subcommittee on Energy and Power held a legislative hearing on the "Asthma Inhalers Relief Act of 2012."

On July 18 and 19, 2012, the Subcommittee on Energy and Power met in open markup session and favorably reported the bill to the full Committee by voice vote. No amendments were offered.

On July 31 and August 1, 2012, the Committee on Energy and Commerce met in open markup session. Two amendments were offered but defeated by voice vote.

On August 1, 2012, the Committee ordered H.R. 6190 favorably reported to the House by voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. A motion by Mr. Upton to order H.R. 6190 reported to the House, was agreed to by voice vote. There were no requests for recorded votes.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 6190 directs the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 6190, the "Asthma Inhalers Relief Act of 2012," would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 6190, the "Asthma Inhalers Relief Act of 2012," contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

H.R. 6190—Asthma Inhalers Relief Act of 2012

H.R. 6190 would direct the Environmental Protection Agency (EPA) to allow the distribution, sale, and consumption of the remaining inventories of over-the-counter asthma inhalers that contain chlorofluorocarbons (CFCs) through August 1, 2013. Sales of this type of inhaler have been phased out under the Clean Air Act and the Montreal Protocol, an international treaty to reduce ozone-depleting substances, such as CFCs. (An example of such an inhaler was sold under the brand name, Primatene Mist.)

According to EPA, under this legislation, the agency would end enforcement of the ban on the sale and distribution of inhalers that contain CFCs, but it would continue to verify that such inhalers are not manufactured or imported. CB0 estimates that implementing this legislation would have no significant impact on the federal budget because of the limited amount of EPA resources dedicated to those activities. Pay-as-you-go procedures do not apply to H.R. 6190 because the bill would not affect direct spending or revenues.

This bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Susanne S. Mehlman. The estimate was approved by Peter H. Fontaine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF LEGISLATION

Section 1—Short title

Section 1 provides the short title of "Asthma Inhalers Relief Act of 2012."

Section 2—Distribution, sale, and consumption of remaining inventories of over-the-counter CFC epinephrine inhalers

Section 2 addresses the distribution, sale, and consumption of remaining inventories of over-the counter CFC epinephrine inhalers.

Section 2(a) directs the Administrator of the Environmental Protection Agency to allow the distribution, sale, and consumption of remaining inventories of such inhalers, refrain from taking any enforcement action against any distributor or seller on the basis of any Federal law implementing the Montreal Protocol, and issue a No Action Assurance Letter to any requesting distributor or seller stating the agency will not initiate such an enforcement action.

Section 2(b) clarifies that nothing in the legislation should be construed to limit the authority of the Food and Drug Administration, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), to ensure the safety and effectiveness of such inhalers.

Section 2(c) provides the following definitions:

1. "CFC epinephrine inhaler" means any epinephrine inhaler containing CFCs that was manufactured and classified as over-the-counter prior to January 2, 2012;
2. "Federal law implementing the Montreal Protocol" means any provision of Title VI of the Clean Air Act or other Federal law implementing the Montreal Protocol, including the regulation entitled "Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine)" published at 73 Fed. Reg. 69532 (November 19, 2008);
3. "Montreal Protocol" has the meaning given in section 601 of the Clean Air Act.; and
4. "Over-the-counter" means not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.SC. 353(b)(1)) or otherwise not required to be dispensed only upon issuance of a prescription.

Section 2(d) provides that the Act shall cease to be effective on August 1, 2013.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

The bill does not change existing law.

DISSENTING VIEWS

The Montreal Protocol, signed in 1987, is widely recognized as a tremendously successful international environmental agreement that has dramatically reduced the production and use of substances that deplete the stratospheric ozone layer, such as chlorofluorocarbons (CFCs). The Environmental Protection Agency (EPA) regulations implementing the Montreal Protocol prohibit the production and import of CFCs with an exception for essential metered dose inhalers (MDIs). Under the Clean Air Act and its implementing regulations, the Food and Drug Administration (FDA) determines whether a MDI is essential.

On November 19, 2008, FDA issued a final rule removing the essential use designation for epinephrine MDIs containing CFCs. FDA concluded that there are no substantial technical barriers to formulating epinephrine as a product that does not release ozone-depleting substances. At that time, the only remaining CFC-containing epinephrine MDI on the market was Primatene Mist. As requested by Armstrong, the manufacturer of Primatene Mist, FDA set a phase-out date of December 31, 2011, one year longer than was originally proposed in 2007. Primatene Mist was phased-out on December 31, 2011, and it has not been on the market for the past eight months.

Prior to its phase-out, Primatene Mist was the only epinephrine metered dose inhaler available over-the-counter without a prescription. According to Armstrong, the company has between 1.2 million and 1.5 million units of Primatene Mist left in its inventory with a potential market value of between $15 million and $18 million.[1]

The bill directs the Administrator of the EPA to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter epinephrine inhalers containing CFCs manufactured pursuant to essential use exemptions. The term "remaining inventories" is not defined. The bill also prohibits EPA from taking any enforcement action or otherwise seeking to restrict the distribution, sale, or consumption of such inhalers pursuant to the Clean Air Act or any other federal law implementing the Montreal Protocol. In response to any request by a distributor or seller of Primatene Mist, the bill would require EPA to issue a letter to the requesting party stating that EPA will not initiate an enforcement action relating to the distribution or sale of any such inhaler prior to August 1, 2013. Under the bill, these provisions would cease to be effective on August 1, 2013.

The bill's approach raises a number of significant concerns.

First, the bill would overturn an established regulatory framework in order to allow a single manufacturer to sell off its remaining inventory of the CFC-containing inhaler Primatene Mist. FDA has established a clear and open process for determining whether inhalers containing CFCs are essential. Over the years, more than a dozen types of inhalers containing CFCs have been phased-out under this process. The schedules were never changed for these thirteen inhalers, and none of these other manufacturers were allowed to sell off their inventories after the phase-out date. All of these CFC inhalers were phased-out prior to the phase-out of

[1] Letter from Jason Shandell, Vice President and General Counsel, Amphastar Pharmaceuticals, Inc., to Rep. Henry A. Waxman (Jul. 16, 2012).

Primatene Mist. The remaining two CFC-propelled inhalers are scheduled for phase-out at the end of 2013.

Even though Armstrong was not singled out by the FDA process or required to do anything that other companies were not required to do, the bill would change the rules so that Armstrong could sell off its inventory of Primatene Mist. The bill would directly benefit just one company—Armstrong, the maker of Primatene Mist. For example, the bill could benefit Armstrong by allowing the company to maintain its market share until it can obtain FDA approval for a CFC-free epinephrine inhaler.

Companies that made the necessary investments to develop CFC-free inhalers contend that the bill would unfairly provide special treatment to a single company. The International Pharmaceutical Aerosol Consortium (IPAC), a group of MDI manufacturers, argues: "Granting extraordinary, unwarranted and special treatment to a single company would send an extremely negative signal to the manufacturers that responded to the US Government's call many years ago to be a partner in meeting the Montreal Protocol commitments."[2]

On July 26, 2012, FDA officials briefed Committee members and staff about the phase-out of Primatene Mist. They also raised concerns about overturning FDA's established regulatory process for setting deadlines for the phase-out of inhalers containing CFCs.

Second, the Committee heard testimony and received additional information from a host of medical organizations that putting Primatene Mist back on the market would not be in the interests of patients. At a July 18, 2012, legislative hearing, Dr. Monica Kraft, a professor of medicine at Duke University and President of the American Thoracic Society, testified that "[i]nhaled epinephrine is not a safe drug for the treatment of asthma."[3] She explained that Primatene Mist can "cause a significantly increased heart rate," which "can lead to cardiac stress and heart attacks in older patients or patients with heart disease." According to Dr. Kraft, the American Medical Association twice "encouraged FDA to consider removing inhaled epinephrine from the market." She also testified that "[n]o current clinical practice guideline for the diagnosis and treatment of asthma recommends the use of epinephrine." Dr. Kraft expressed concern that "[p]utting Primatene Mist back on the market—for an indefinite period of time—will send a very confusing message to patients." She explained that many people who suffer from asthma have already transitioned to other, more effective treatments. Chris Ward, who testified on behalf of the Asthma and Allergy Foundation of America, echoed this concern, stating: "Lifting the ban now will lead to confusion."[4]

On July 30, 2012, the American Lung Association, the American Thoracic Society, the American Academy of Pediatrics, the Asthma

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[2] International Pharmaceutical Aerosol Consortium, *Re-introducing CFC-Based Epinephrine (Primatene Mist) in the United States Is Counterproductive to Patient Health and US Policy* (July 2012) (fact sheet).

[3] Dr. Monica Kraft, President of the American Thoracic Society, Committee on Energy and Commerce Subcommittee on Energy and Power, Legislative Hearing on H.R. __, the U.S. Agricultural Sector Relief Act of 2012, and H.R. __, the Asthma Inhalers Relief Act of 2012, 112th Cong. (Jul. 18, 2012).

[4] Chris Ward, Asthma and Allergy Foundation of America, Committee on Energy and Commerce Subcommittee on Energy and Power, *Legislative Hearing on H.R.* __, the U.S. Agricultural Sector Relief Act of 2012, and H.R. __, the Asthma Inhalers Relief Act of 2012, 112th Cong. (Jul. 18, 2012).

and Allergy Foundation of America, and other public health groups wrote to Committee members to oppose the legislation, stating: "Our organizations strongly believe that allowing this product to return to the marketplace is not in the best interests of patients with asthma or public health."[5] These organizations agreed with Dr. Kraft that Primatene Mist is not recommended or considered safe for the treatment of asthma because of the potential of epinephrine to cause excessive heart stimulation.

At the July 26, 2012, briefing for members and staff, FDA officials explained that Primatene Mist was determined to meet the regulatory definition of "safe and effective" in 1967, but the standard of care for asthma has changed considerably over the past 50 years. As a result, physicians and expert guidelines do not recommend Primatene Mist for the treatment of asthma. The FDA officials also raised concerns about patients being confused by the temporary re-introduction of a product that has been off the shelves for eight months.

In anticipation of the December 31, 2011, phase-out of Primatene Mist, EPA and FDA took a number of actions to inform consumers of the approaching transition. In addition to public and stakeholder meetings convened by the agencies, FDA approved a message for Primatene Mist cartons and containers indicating to consumers that Primatene Mist would not be available after December 31, 2011. Under the bill, after being off the market for over eight months, Primatene Mist would go back on the market, but only for as long as the inventory lasted. Then it would once again disappear from the shelves.

To address concerns about patient confusion and safety, Rep. Pallone offered an amendment at the full Committee markup of the bill. The amendment would have prevented the provisions of the bill from taking effect unless FDA finds that the temporary reintroduction of Primatene Mist is unlikely to cause significant patient confusion and will provide an overall public health benefit. The amendment required FDA to make a determination within 30 days. The amendment was defeated by voice vote.

Third, despite concerns from the proponents of the bill that no over-the-counter asthma inhalation treatment has been available since the phase-out of Primatene Mist, an alternative is now entering the market. On July 19, 2012, at the Subcommittee markup of this legislation, it was revealed that Nephron, a company in Florida, has developed a hand-held, battery-operated atomizer that uses vials of a variant of epinephrine (racepinephrine hydrochloride).[6] The product is a portable, over-the-counter device and is explicitly being marketed as an affordable alternative to Primatene Mist. According to Nephron, the product, called Asthmanefrin, will soon be available nation-wide at Walmart, CVS, and other retail

[5] Letter from 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, and National Home Oxygen Patients Association to Rep. Ed Whitfield and Rep. Bobby Rush (July 30, 2012).

[6] Letter from Lou Kennedy, Chief Executive Officer of Nephron Pharmaceuticals Corporation, to Rep. Kathy Castor (Jul. 17, 2012).

outlets.[7] Under a 1986 FDA rulemaking, simple epinephrine delivery mechanisms like nebulizers or atomizers can be placed on the market without pre-approval by FDA.

Nephron made a significant investment to bring this product to market, relying on the established regulatory regime. The bill's intervention in the market would affect companies that have followed the rules and made investments based on those rules.

To avoid picking winners and losers, Rep. Castor offered an amendment at the full Committee markup of the bill. The amendment would have prevented the provisions of the bill from taking effect if an alternative over-the-counter inhalation asthma treatment is available on the date of enactment. The amendment was defeated by voice vote.

Finally, it is unlikely that the bill would result in the widespread availability of Primatene Mist sought by proponents of the legislation. According to Armstrong, 2–3 million people used Primatene Mist, but fewer than 1.5 million Primatene Mist inhalers remain in Armstrong's inventory. As a result, as many as half of all previous users of Primatene Mist would not be able to obtain even one inhaler if Armstrong was allowed to sell off its remaining inventory. It is unclear whether Primatene Mist would be available nationwide and which pharmacies or drug stores would carry it. Some retailers may opt not to sell inventoried units of Primatene Mist because "Armstrong's inventory of Primatene Mist will expire at varying times between January and August of 2013."[8] Additionally, the inventory would not immediately be available. According to Armstrong, the company would need to move the inventoried units to a subsidiary in order to re-label the units to eliminate the labeling statement that Primatene Mist would not be available after December 31, 2011.[9] Thus, the real effect of this bill would be to provide a regulatory earmark to Armstrong rather than a "rescue inhaler" that would be available in the middle of the night to someone suffering from an asthma attack, as the bill's proponents contend.

For the reasons stated above, we dissent from the views contained in the Committee's report.

HENRY A. WAXMAN
BOBBY L. RUSH
FRANK PALLONE, JR.

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[7] Nephron Pharmaceuticals Corporation, *Nephron Announces Asthmanefrin, an Alternatives to Primatene Mist* (Aug. 20, 2012).
[8] Letter from Jason Shandell, Vice President and General Counsel, Amphastar Pharmaceuticals, Inc., to Rep. Henry A. Waxman (Jul. 16, 2012).
[9] *Id*.