



Allergy & Asthma Network

Mothers of Asthmatics

Metered-Dose Inhaler Transition

This year, millions of patients with asthma, COPD (chronic obstructive pulmonary disease) and other respiratory conditions face a critical change in lifesaving medications. The problem: Many are not aware of the change or how to safely go about making it.

We seek emergency intervention by Congress to mandate

- **National public, patient and clinician awareness and education campaigns**
- **A program to actively monitor patient progress**
- **Centers for Medicare and Medicaid Services to place HFA inhalers on the lowest co-payment tier to ensure patients can afford their medications**

Overview

For more than 50 years, respiratory patients have relied on metered-dose inhalers (MDIs) that contain CFC propellants, a man-made chemical known to destroy the earth's protective stratospheric ozone layer.

In 1978, the federal government banned CFC use in spray cans (such as aerosol hairspray) as part of an effort to reverse environmental damage. In 1987, the United States signed on to the Montreal Protocol to eliminate use of CFCs worldwide and the federal government began implementing further bans on CFCs.

MDIs were given a temporary exemption from the CFC ban until manufacturers could develop safe and effective non-CFC MDIs. That time has come for albuterol inhalers. After December 31, 2008, it will be unlawful to manufacture, sell or distribute albuterol MDIs made with CFCs. We now have four distinct non-CFC alternatives.

The federal mandate to eliminate CFCs in medications charged the U.S. Food and Drug Administration with approving alternate medications and removing CFC MDIs from the market. The Environmental Protection Agency was ordered to manage and phase out use of CFCs in all U.S. products.

But no federal mandate was issued to inform patients the transition was happening, provide education for medical professionals and patients, monitor the impact of the transition on patient health outcomes and care, or provide financial assistance for higher priced drugs.

This 20-year-old oversight has created potentially serious health issues for more than 40 million people affected by respiratory disease.

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Patients and medical professionals need to know that

- Inhalers are changing and why
- The change is mandatory
- There are important decisions to make about treatment options that require thoughtful consideration of the patient's medical history and current respiratory health status
- CFC and HFA metered-dose inhalers are distinctly different
- HFA MDIs cost significantly more than generic CFC MDIs, which may present a barrier to effective health care
- HFA MDIs are not interchangeable – one HFA medication cannot be substituted for another without a new prescription, and HFAs cannot be substituted for a CFC inhaler without a new prescription
- Patient assistance, medication discounts and rebate programs are available from pharmaceutical manufacturers

The absence of a medically responsible transition protocol leaves patients with life-threatening conditions exposed to health risks beyond their ability to control.

- Many patients have been switched to new medications at the pharmacy counter – without instructions on how to use HFA MDIs correctly
- Many patients switched at the pharmacy do not know their medication is different until they are home or in the throes of a life-threatening emergency
- Higher out-of-pocket prices and co-pays create a huge financial burden, causing many families to ration MDI use, share one MDI among family members or make choices between medications to breathe vs. medications for other conditions (e.g., mental health, cardiac health, diabetes)
- Health insurance plans force patients to switch to the HFA MDI on their formularies – a decision based on cost, not which medication works best for patients or is recommended by prescribers
- Some pharmacies dispense to patients HFA MDIs other than what was prescribed for them

More than 40 million respiratory patients in the U.S. are affected by this medication change. Exactly how many are already using non-CFC MDIs or are even unaware of the need to switch medications is unclear. Market data suggest that 5 million respiratory patients have yet to make the transition to HFA bronchodilators. The consequences of inaction include needless suffering and anxiety, missed work days, hospitalizations, emergency department visits . . . and death.

Patients across the country just want to breathe. With education and access to effective medications, they can.

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Frequently Asked Questions About the Inhaler Transition

Albuterol inhalers containing CFC propellants – the medication used by millions of Americans living with asthma, COPD and other respiratory conditions – will no longer be available after December 31, 2008. Patients need to know why the change is happening and what they should do next.

What is CFC?

CFC is the acronym for chlorofluorocarbon, an ozone-depleting propellant banned in 1987 by the Parties to the Montreal Protocol, an international treaty signed by nearly 200 countries committed to restoring earth's protective stratospheric ozone layer.

What is the connection between CFCs and metered-dose inhalers (MDIs)?

CFCs have been used as propellants in MDIs for more than 50 years.

How does the Montreal Protocol impact CFC use in MDIs?

MDIs were temporarily exempt from the CFC ban until manufacturers could develop, test, produce and distribute suitable alternatives. That time has come. After many years of research and development, an alternative propellant – hydrofluoroalkane (HFA) – was identified.

What are the similarities and differences between MDIs made with CFCs and HFAs?

CFC and HFA inhalers look similar on the outside but are quite different on the inside.

- **HFA MDIs have a softer spray.** The speed at which the medication exits the canister is slower in HFA inhalers, making it easier to inhale the medication correctly. Some patients have commented that force of the HFA propellant is not strong enough to “push open” their airways during an attack. However, it is the correct inhalation technique, not the force of the propellant, that determines how well the medication works. The force of a CFC or HFA inhaler spray does not “push” or “force” the airways open.
- **HFA MDIs have different cleaning requirements.** HFA MDIs need to be cleaned more frequently than CFC MDIs. The HFA medication tends to clog the exit port of the plastic actuator more quickly than CFCs. This prevents medication from reaching patient's airways, which may explain why patients report HFA inhalers aren't working.
- **HFA MDIs have different priming requirements.** Priming (spraying multiple doses into the air) loads the correct dose of medication inside the inhaler. Each HFA inhaler has different priming instructions – how many sprays are needed and exactly when the medication requires priming – which can be quite different from CFC priming.

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- **HFA MDIs offer more treatment options.** In the past, all brand and generic albuterol CFC MDIs were virtually identical. Now there are three uniquely different formulations of albuterol HFA inhalers plus a levalbuterol HFA inhaler. Although these four MDIs are in the same class of medications – called short-acting bronchodilators – and are used when patients are coughing, wheezing or short of breath, Food and Drug Administration (FDA) officials confirm that each is distinctly different from the others. Some people may find that one HFA inhaler works better for them than another.
- **HFA MDIs cost more than generic CFC albuterol MDIs.** HFA MDIs are not simply copies of CFC MDIs with new propellants. The inhaler transition required a complete overhaul of the MDI manufacturing process. Companies had to find a new propellant safe for use in humans, develop new technologies, retool machinery, use new inactive ingredients . . . then test products for safety and efficacy before submitting them to FDA for approval.

No generic HFA MDIs are currently available. This translates to higher out-of-pocket expenses for many patients, even those with prescription drug coverage. Some patients find their insurance plan limits their access to only one brand of HFA. Some patients report the pharmacy dispenses an HFA MDI other than the one the doctor prescribed.

Pharmaceutical companies are providing financial assistance to patients in the form of rebates, discounts and coupons and patient assistance programs.

When will CFC MDIs go away?

Most pharmaceutical manufacturers got out of the business of making CFC MDIs long ago. You may be surprised to see how many non-CFC MDIs there are! Take a look at our Asthma Inhalers poster online at www.aanma.org/MDITransition to see what's available today.

Now that non-CFC alternatives are available, the Food and Drug Administration and Environmental Protection Agency must enforce the ban on albuterol CFC MDIs. After December 31, 2008, it will be unlawful to make, sell, distribute or give away albuterol CFC MDIs. Other MDIs made with CFCs will be eliminated as alternative medications become more available – there are specific patient safety criteria by which these decisions are made.

It is important for patients to schedule an appointment with their medical care providers, discuss treatment options and select a non-CFC MDI alternative – *before* they find themselves in the throes of an asthma episode. They should also receive an individualized written asthma action plan detailing ways to improve lung function and quality of life.

Visit www.aanma.org/MDITransition for more information about the inhaler transition and free educational resources.

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