

# Breath of Fresh Air

Volume 12, No. 1

Information, news and advice for improving asthma well-being

Summer 2010

## New National Asthma Survey: How Does Your Asthma Compare?



Sometimes if one has to live with a chronic medical condition like asthma, it is helpful to know that you are not alone. Others are going through similar experiences, just like you. In the case of asthma, that would be approximately 22 million other Americans. A random telephone survey of American households conducted between July and September, 2009—called Asthma Insight and Management (AIM)—found that 8% of adults (aged 18 and older) reported having a diagnosis of asthma and having either experienced asthma symptoms in the past year or currently taking medication for their asthma (defined as having “current asthma”). If you add those who previously had asthma but were symptom-free in the last year (6%) and those who had a family member with asthma (31%), then close to half of us have direct experience with living with asthma.

If you had participated in this telephone survey about your asthma, what would you have answered to some of the following questions? The survey results, which are depicted on page 4, give a picture of asthma continuing to have a broad impact on people’s lives, frequently getting in the way of performing usual activities, typically present all year-round but worse in certain seasons, periodically flaring into asthmatic attacks, and impacting how one feels about one’s overall health. The Asthma Insight and Management survey, sponsored by Schering Pharmaceuticals (now part of Merck & Co., Inc.), was similar in design to

one conducted approximately 10 years earlier, called the Asthma in America survey, and had similar findings. Both can be accessed via the Internet: the websites are [www.TakingAIMatAsthma.com](http://www.TakingAIMatAsthma.com) and [www.AsthmainAmerica.com](http://www.AsthmainAmerica.com).

Here are your questions:

- 1) *Overall, how much does asthma interfere with (your/your child’s) life? Would you say it interferes a lot, interferes some, interferes a little, or doesn’t really interfere at all?*
- 2) *How much do you feel that your asthma/health limits what you can do in each of the following areas? Do you feel your asthma/health restricts you—a lot, some, only a little, or not at all in: Daily activities, Sports and recreation; Normal physical exercise; Social activities; and Sleeping?*
- 3) *Would you describe (your/your child’s) asthma as seasonal or does it occur throughout the year?*
- 4) *Have (you/your child) had any SUDDEN SEVERE EPISODES of coughing, or wheezing, or chest tightness, or shortness of breath in the past 12 months? If yes, how often did (you/your child) have these episodes in the past 12 months?*
- 5) *As a result of your asthma/health, how often do you feel: Isolated or alone; Fearful; Depressed or blue; Embarrassed; Angry—often, sometimes, rarely, or never?*

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## Long-Acting Bronchodilators: Why All the Fuss?

In February the U. S. Food and Drug Administration (FDA) issued a “Drug Safety Communication” to healthcare providers and patients about the use of long-acting beta-agonist bronchodilators in the treatment of asthma. What exactly did the FDA advise, and why?

First, about which medications was the FDA speaking? As you probably already know, bronchodilators are medications that relax the muscles surrounding the bronchial tubes, opening them wider for the freer passage

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## Bronchodilators . . . continued from page 1

of air in and out of the lungs. There are available inhaled bronchodilators that act for 12 hours or more, called long-acting beta agonists or LABAs. They are available alone or in combination with an inhaled steroid, as shown in the table below.

Brand Name	Type of Device	LABA	Steroid medication
Serevent Diskus	Dry-powder inhaler	Salmeterol	---
Foradil Aerolizer	Dry-powder inhaler	Formoterol	---
Perforomist*	Solution for nebulizer	Formoterol	---
Brovana*	Solution for nebulizer	Arformoterol	---
Advair Diskus Advair HFA	Dry-powder inhaler Metered-dose inhaler	Salmeterol Salmeterol	Fluticasone (Flovent) Fluticasone (Flovent)
Symbicort HFA	Metered-dose inhaler	Formoterol	Budesonide (Pulmicort)
Dulera HFA	Metered-dose inhaler	Formoterol	Mometasone (Asmanex)

\*Approved for use in chronic obstructive pulmonary disease (COPD), not asthma.

The concern of the FDA derived from their review of all of the data available to them from clinical trials testing the safety and effectiveness of the LABAs. In particular, one large study, called the Salmeterol Multi-center Asthma Research Trial (SMART), carried a lot of weight. In it, approximately 26,000 asthmatic subjects were randomly assigned to receive either a LABA (salmeterol) or placebo, in addition to their usual asthma medications. In the group assigned to receive salmeterol, there were more deaths and more near-deaths *from asthma* than in the group assigned to receive placebo, in both Caucasians and African Americans.

Most of the patients in this study were not taking an inhaled steroid. Many physicians believe that the risk from LABAs relates to their use without an accompanying inhaled steroid. They point to the fact that in recent years asthma deaths have occurred less often in the United States while sales of combination medications containing both a LABA and an inhaled steroid have increased. However, based on their review of available evidence, the FDA could not be certain whether a LABA is entirely safe when used together with an inhaled steroid, and so its warning included medication combinations that include both a LABA and a steroid (that is, Advair, Symbicort, and Dulera).

The FDA emphasized four points in its drug safety communication. Based on evidence regarding LABAs used without an accompanying asthma controller, the FDA advised that:

- LABAs should not be used alone; they should be used together with an asthma controller medication, such as an inhaled steroid; and
- Children needing a LABA in addition to an inhaled steroid should use a combination product containing both an inhaled steroid and LABA, to ensure that they take both medications together.

Based on the *possibility* that even when used together with an inhaled steroid the LABAs might put some patients at risk for

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## *Breath of Fresh Air*

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## **Bronchodilators . . . continued from page 2**

dangerous asthmatic attacks, they advised that:

- LABAs should only be used long-term in patients whose asthma cannot be well-controlled on an asthma controller alone (that does not contain a LABA); and
- LABAs should be used for as short a period of time as is needed to achieve asthma control and then, if possible, they should be stopped in favor of an asthma controller medication that does not contain a LABA.

These recommendations pertain specifically to persons with asthma and not to persons with cigarette-smoking related obstructive lung disease (COPD or emphysema).

### **Plans for future studies**

Going forward, the FDA plans to mandate a large-scale research study testing the safety of LABAs when used in combination with an inhaled steroid. In the meantime it has emphasized that in asthma LABAs should be used only when the severity of asthma is sufficient to warrant them. In this circumstance—when asthma is not well-controlled with an inhaled steroid alone—LABAs can reduce symptoms and prevent asthmatic attacks and may *decrease* the risk of death or near-death from asthma. The FDA had the option of having LABAs withdrawn from the market or of advising against their use in asthma. Instead, recognizing how useful they are in achieving asthma control in many people, the FDA urged physicians to use these drugs wisely, not casually. Cautious use of LABAs means their prescription when other medications are insufficient to relieve asthma symptoms and protect against asthma attacks, and then only together with an inhaled steroid (or other asthma controllers).

One other recommendation from the FDA, for both patients and physicians, was that patients be able to recognize warning signs of worsening asthma and to seek prompt medical help when their asthma deteriorates. Remember that the potential danger from LABAs has to do with severe, life-threatening asthma attacks. To protect yourself against such severe attacks, be asthma savvy and have a plan to deal with worsening asthma (see *Breath of Fresh Air*, Vol. 11, No. 2: “In Case of Emergency ...”). Warning signs of an asthma flare include shortness of breath with light activities, frequent need for your quick-acting “rescue” bronchodilator, and decline in your peak flow by more than 20-30% from usual. And part of your plan to deal with worsening asthma symptoms can always include contacting your asthma doctor.



## **News About Asthma**

### **New medication combination**

The Food and Drug Administration (FDA) has recently given approval for a medication, to be called Dulera, which combines a long-acting bronchodilator with an anti-inflammatory steroid in a single inhaler. Combining these two categories of medications has proven to be highly effective in the treatment of asthma. The combination addresses two key elements that cause the airways to narrow in asthma: constriction of the bronchial smooth muscles surrounding the airways, and inflammation and swelling of the walls of the airways themselves. In one inhaler comes a medicine that causes the bronchial muscles to relax (or helps to prevent them from going into spasm in the first place) mixed with a medicine that suppresses the inflammation and mucus production that can plug up the bronchial tubes. Because of the long-duration of action of the broncho-

dilator component, the medication can be administered just twice daily and still provide 24-hour activity. The combination is recommended for treatment of asthma of moderate or greater severity—persons whose asthma does not improve sufficiently with only an anti-inflammatory steroid or leukotriene blocker (such as montelukast [Singulair] or zafirlukast [Accolate]).

Until now there have been two such combination medications available. Advair is the name given to the combination of the long-acting bronchodilator, salmeterol (Serevent), with the anti-inflammatory steroid, fluticasone (Flovent). Symbicort is the name given to the combination of the long-acting bronchodilator, formoterol (Foradil) with the anti-inflammatory steroid, budesonide (Pulmicort).

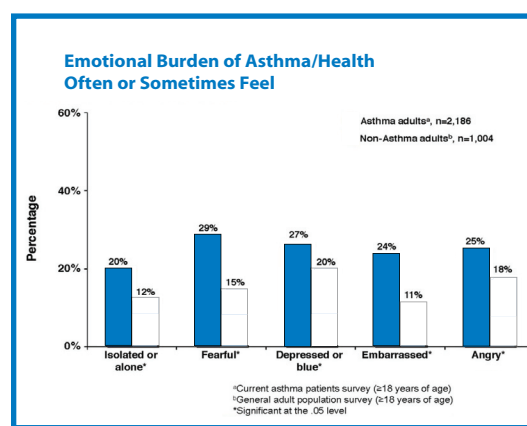
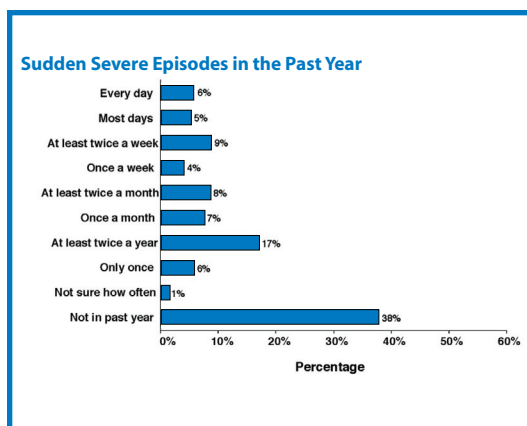
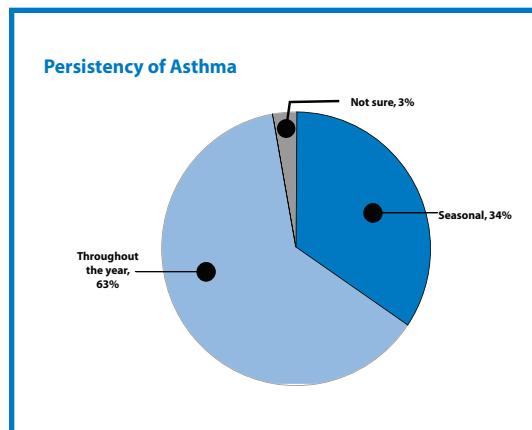
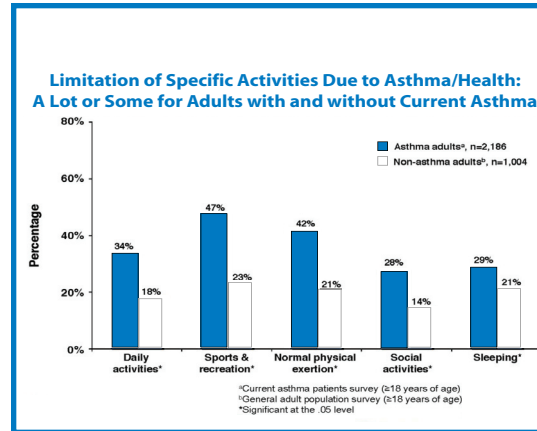
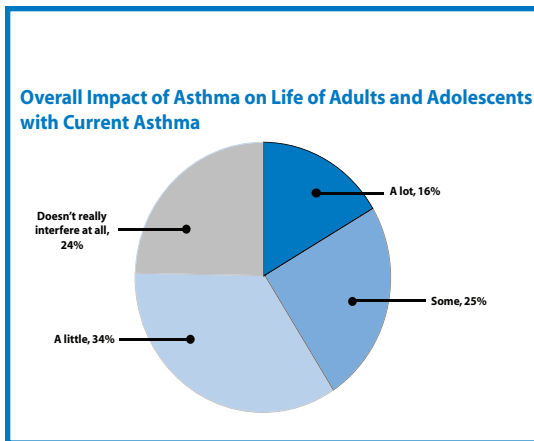
The newly approved Dulera mixes in a single metered-

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## National Asthma Survey . . . continued from page 1

The answers given to these questions by the approximately 2,500 persons with asthma (aged 12 and over) who participated in the AIM study (and by another

approximately 2,000 persons without asthma who were interviewed for the sake of comparison) are shown in the graphs below.



Let's summarize the information in these figures. Forty-one percent of persons with current asthma feel that it impacts their overall health "some" or "a lot." Persons with asthma find that their health interferes with routine activities—including recreation, physical exertion, social activities, and sleep—significantly more often than persons without asthma. Nearly two thirds of persons with asthma experience their disease year-round. Approximately 60% experience a sudden severe episode of asthma over the course of a year,

many with episodes once a month or more often. And compared to persons without asthma, feelings of isolation, fear, depression, embarrassment, and anger are significantly more common among those living with asthma.

The bottom line? For many people living with asthma, we still have a long way to go achieve effective control of asthma . . . and then, someday, to find a cure.



## News about Asthma . . . continued from page 3

dose inhaler the long-acting bronchodilator, formoterol (Foradil), with the anti-inflammatory steroid, mometasone (Asmanex). It will be offered in two strengths, Dulera 100/5 and Dulera 200/5. These numbers refer to the amount of medication in micrograms (1 microgram = 1/1000 of a milligram) delivered in each actuation of the inhaler: 100 or 200 micrograms of mometasone and 5 micrograms of formoterol. The medication is approved for persons with asthma 12 years of age and older in a standard dose of 2 puffs twice daily.

Potential medication side effects of any beta-agonist bronchodilator include rapid heart beat, jitteriness, and muscle cramps. For the anti-inflammatory steroid, potential side-effects include a yeast infection in the mouth (oral candidiasis or “thrush”), hoarse voice, and throat irritation. Concerns about life-threatening asthmatic attacks related to the use of long-acting beta-agonist bronchodilators are discussed elsewhere in this issue of *Breath of Fresh Air* (“Long-Acting Bronchodilators: Why All the Fuss?”).

### Last of the CFC-containing metered-dose inhalers

One by one, metered-dose inhalers with traditional chlorofluorocarbon propellants (CFCs) have stopped being manufactured and sold. They have been banned because of the environmental harm caused by CFCs and because of the availability of alternative, environmentally-safe propellants, called hydrofluoroalkanes (HFAs). Recently the FDA granted an exemption for continued sale of the CFC-containing quick-acting bronchodilator, pirbuterol (Maxair), with its unique breath-actuated delivery device . . . until December, 2013.

Pirbuterol is a rescue bronchodilator very similar to albuterol (which is contained in the metered-dose inhalers, ProAir, Proventil, and Ventolin, all now with HFA propellants). Like albuterol, it begins to work within 5 minutes, and its effect lasts for approximately 4-6 hours. Pirbuterol (Maxair) is unique in that its metered-dose inhaler device is designed to release a “puff” of medication when triggered by the beginning of a breath in.

With lips around the mouthpiece, one breathes in. The force of the inhalation pulls up a small plastic vane, which then triggers the primed canister to release a dose of medication. The design is meant to optimize the timing between actuation of the metered-dose inhaler and

breathing in the medication. With the usual “press and breathe” metered-dose inhaler, if you breathe in too soon, well before pressing the canister to actuate the inhaler, you’ll have little breath left to pull the medication deep into the lungs. Breathe too late after pressing the canister, and much of the medication has a chance to escape out into the air before you can suck it down into your lungs. The breath-actuated device, called an Autohaler, ensures the release of medication at the start of inhalation.

The Autohaler is only available to deliver pirbuterol (Maxair); other canisters cannot be fitted into the Autohaler. The manufacturer of Maxair reports that it is working to develop an HFA-driven form of pirbuterol.

### FDA approves bronchial thermoplasty for the treatment of asthma

In the last issue of *Breath of Fresh Air*, we reported that an FDA advisory committee had recommended to the full FDA panel that it approve use of the bronchoscopic procedure called bronchial thermoplasty to treat asthma. In April the FDA gave formal approval for its use . . . in selected patients.

Bronchoscopy is a medical procedure in which a thin flexible tube with a tiny camera at its tip is passed through the back of the throat into the trachea (wind-pipe) and its branches, the bronchial tubes. In bronchial thermoplasty, a catheter is passed through the central channel of the bronchoscope and opens after exiting the distal end of the bronchoscope. Once in place inside the bronchial tubes, it is used to transmit radiofrequency energy to the walls of these airways. By heating the bronchial smooth muscle, bronchial thermoplasty is meant to weaken the muscle and reduce its ability to constrict around the bronchial tubes.

Bronchial thermoplasty has been approved for use in persons 18 years of age and older who have persistent, difficult-to-control asthma despite the use of an inhaled corticosteroid and long-acting beta-agonist bronchodilator. It requires at least three bronchoscopy procedures, each treating different areas of the lungs. The risks involve bleeding, partial lung collapse, and asthma attacks complicating the procedures. The benefit is a reduction in the likelihood of subsequent serious asthma attacks. The FDA has mandated a five-year post-approval study of safety and effectiveness of the procedure.



Maxair

## Sharing Your Asthma Stories

We would like to use our asthma newsletter, *Breath of Fresh Air*, as a place where patients and families dealing with asthma can share their experiences and stories of asthma, making it possible for others to learn from what you have already been through.

We would like to publish your story in the next issue (with your name included or anonymously, as you wish). It can be an anecdote, a piece of asthma history, your advice to others, or difficulties that you have had dealing with asthma.

Send us your asthma story—a paragraph or two will suffice. You can send it:

- by mail (Partners Asthma Center, PBB Clinics-3, 15 Francis Street, Boston, MA 02115),
- by e-mail ([asthma@partners.org](mailto:asthma@partners.org)),
- or by fax (617-732-7421, attention: Editor, *Breath of Fresh Air*).

If we print your asthma story, we will send you as thank you a Partners Asthma Center tote bag and mug.

### *Breath of Fresh Air*

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