

# THE ALLERGY & ASTHMA CLINIC

Andrew C. Engler, M.D.

290 Baldwin Avenue, San Mateo, California 94401

(650) 343-4597 FAX (650) 343- 3402

[www.theallergyclinic.com](http://www.theallergyclinic.com)

NEWSLETTER

March 2010

## **FDA Raises New Concerns About Several Commonly Used Asthma Medications**

On Feb. 18, 2010, The Food and Drug Administration (FDA) issued new recommendations on how inhaled medications called Long-Acting Beta-Agonists (LABAs) should be used to treat asthma. The drugs affected by FDA's announcement include Serevent (generic name: salmeterol), Foradil (formoterol) Advair (salmeterol and fluticasone) and Symbicort (formoterol and budesonide).

LABAs help people with asthma or a lung condition called chronic obstructive pulmonary disease (COPD) breathe easier. They are also used for exercise-induced bronchospasm, which is a type of asthma that is triggered by vigorous physical activity.

"Although these medicines play an important role in helping some patients control asthma symptoms, our review of the available clinical trials determined that their use should be limited, whenever possible, due to an increased risk of serious asthma exacerbations and death," says Badrul Chowdhury, M.D., director of FDA's Division of Pulmonary and Allergy Products.

### **Why do people use LABAs?**

LABAs improve breathing by relaxing the muscles of the airways to allow more air to flow into and out of the lungs. LABAs are typically inhaled through the mouth into the lungs.

LABAs are available as single ingredient products, or in combination with a corticosteroid medication. For asthma, LABAs are available by prescription in dry powder inhalers or metered-dose inhalers.

LABAs are called long-acting because their effects usually last for at least 12-hours.

### **Why is the FDA Taking This Action Now?**

Despite the benefits of LABAs in helping many people with asthma and COPD breathe easier, FDA's analyses indicate there is an increase in the risk of severe exacerbation of asthma symptoms in some patients with asthma that use a LABA compared to patients with asthma that do not use a LABA. Because of this risk, FDA wants to make sure LABAs are used appropriately in patients with asthma.

### **What are the key points people should know about the safe use of LABAs in patients with asthma?**

The key points are:

- \* The use of LABAs for asthma is contraindicated without the use of an asthma controller medication such as inhaled corticosteroid. Single-ingredient LABAs should only be used in combination with an asthma controller medication; they should not be used alone.

- \* LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications.

- \* LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication (without a LABA).

- \* Pediatric and adolescent patients who require the addition of a LABA to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA to ensure compliance with both medications.

### **What Does This Mean for Me and My Family?**

At this point in time, it is generally agreed by medical experts that the immense benefits these medications give most patients outweigh their risks. However, in a very small but significant number of patients, severe side effects have occurred and thus, for every patient, we must balance the potential risk and benefit. The FDA is urging more frequent monitoring of patients on these medications and we will therefore comply with their request, in accordance with the guidelines set forth by both the American Academy and the American College of Allergy, Asthma and Immunology, which recommend "stepping up" or "stepping down" therapy as necessary to optimize the patient's clinical outcome.

When you meet with Dr Engler or one of our Nurse Practitioners, we will want to carefully assess your lung function, review how you are doing and decide together, whether using one of these medications is still the best choice for you. When possible, we will want to try to decrease the dose of the medication you are taking while at the same time, making sure that your allergies and asthma stay under the best possible control.

If allergy immunotherapy has been recommended (or if you are already taking this treatment), we will want to make sure your treatment is on schedule since medical research has confirmed that successful treatment with allergy immunotherapy usually decreases the need for allergy and asthma medication use.

Please do not hesitate to contact us if you have any questions. We are here to help you and your family feel and breathe better.