

## [Serevent, Advair, and Foradil: Despite The Increased Risk of Severe Asthma Episodes and Death, Monotherapy Use Continues](#)

### **Numerous Safety Warnings From FDA About These LABA Asthma Drugs Have Seemingly Been Ignored By Patients, According To New Medco Study**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on May 12, 2010; see <http://bit.ly/dtlHOo>)

As some of you may recall, back [in November 2005 the FDA issued a Public Health Advisory regarding Serevent, Advair, and Foradil](#) to inform doctors and patients that the use of inhalation powders containing long-acting beta 2-adrenergic agonists ("LABA") may increase one's risk of severe asthma episodes and death.

The asthma inhalation powders addressed in the November 2005 FDA warning are:

- Serevent Diskus (salmeterol xinafoate inhalation powder), made by GlaxoSmithKline;
- Advair Diskus (fluticasone propionate & salmeterol inhalation powder), made by GlaxoSmithKline; and,
- Foradil Aerolizer (formoterol fumarate inhalation powder), made by Novartis Pharmaceuticals Corp.

Almost four-and-a-half years later, on February 18, 2010, that November 2005 Public Health Advisory about these LABA asthma drugs was updated. From this more recent safety warning, ["FDA Drug Safety Communication: New safety requirements for long-acting inhaled asthma medications called Long-Acting Beta-Agonists \(LABAs\)":](#)

#### **Safety Announcement**

**[02-18-2010]** Due to safety concerns, the U.S. Food and Drug Administration (FDA) is requiring changes to how long-acting inhaled medications called Long-Acting Beta-Agonists (LABAs) are used in the treatment of asthma. These changes are based on FDA's analyses of studies showing an increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients using LABAs for the treatment of asthma (see Data Summary below).

LABAs are approved as single-ingredient products (Serevent and Foradil) and as an ingredient in combination products containing inhaled corticosteroids (Advair and Symbicort) for the treatment of asthma and chronic obstructive pulmonary disease (COPD). They work by relaxing muscles in the airway and lungs. This helps patients breathe easier, and lessens symptoms such as wheezing and shortness of breath. The new recommendations only apply to the use of LABAs in the treatment of asthma.

To ensure the safe use of these products:

- The use of LABAs is contraindicated without the use of an asthma controller medication such as an 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.

- 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.

During the several years between those two FDA warnings, we reported on some of the developments concerning this still-emerging drug safety issue, as seen by this list of articles posted previously on this Drug Injury Watch blog:

1. [GlaxoSmithKline Will Revise "Black-box" Warning On Its Asthma Drugs Advair And Serevent - Novartis, However, Continues To Disagree With FDA About The Need To Change Label On Foradil](#) (3/9/06)
2. [Is Advair Use Causing Asthma-related Deaths?](#) -- Glaxo's Best-selling Asthma Drug May Be Unsafe For Some Users (4/6/06)
3. [Should The Popular Asthma Drug Advair Be Pulled From The Market?](#) -- Study Finds Increased Risk Of Serious Side Effects For A Broad Range Of Users (6/6/06)
4. [FDA Report Says Popular Asthma Drugs Serevent And Advair May Have Deadly Side Effects For Some Children](#)-- November 2007 Advisory Panel Meeting To Consider Safety of These Glaxo Drugs As Well As Novartis' Foradil (11/26/07)
5. [November 2007 FDA Advisory Panel Recommends That Serevent And Advair Get Stronger Warnings About Use By Children](#)-- Some Panel Members Want Serevent Withdrawn From Market; FDA And GSK Say Asthma Drug Recall Is Not Appropriate (11/29/07)

Accordingly, we were surprised earlier today when we saw this May 11, 2010 Medco press release, "[Medco Study: Despite FDA Warnings, Nearly One-Third of Asthma Patients Still Treated with Long-Acting Beta Agonists Without Controller Medications, Increasing Their Risk for Complications and Hospitalizations](#)".

From the May 2010 press release from Medco, we get this introduction to what appears to be a continuing, and potentially fatal, problem:

Nearly one-third of asthma patients are taking long-acting beta agonists (LABAs) alone, and not in combination with other asthma control medications, despite years of warnings from the Food and Drug Administration (FDA) on the risk of worsening asthma symptoms and death associated with this practice. This according to a new study from the Medco Research Institute™ and the Medco Pulmonary Therapeutic Resource Center® (TRC), presented at the 2010 Eastern Allergy Conference and coinciding with National Asthma and Allergy Awareness Month.

For more details, see this clinical research brief from Medco about the new LABA monotherapy-use study: "[Prescription patterns of long-acting beta agonist \(LABA\) monotherapy for patients with asthma](#)".

Our law firm is beginning to investigate death cases involving the use of Advair, Serevent, and Foradil, as well as other LABA asthma drugs. If you or someone you know has a potential case which you would like us to consider, please [send an email to Tom Lamb](#).

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.  
<http://www.DrugInjuryWatch.com>