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Drug Injury Watch

Prescription Drug Side Effects News and Information from Attorney Tom Lamb

FDA Report Says Popular Asthma Drugs Serevent And Advair May Have Deadly Side Effects For Some Children

Monday, November 26, 2007

November 2007 Advisory Panel Meeting To Consider Safety of These Glaxo Drugs As Well As Novartis' Foradil

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

An [October 24, 2007 FDA staff report about Serevent \(SUBJECT: 1-year Post-Pediatric Exclusivity Postmarketing Adverse Event Review\)](#) concluded that this inhaled beta-2 agonist asthma drugs as well as Advair "may have an unfavorable risk-benefit ratio" for children's asthma.

The October 2007 FDA staff report was prepared in advance of a meeting of an advisory panel of pediatricians later this week being convened to consider the safety of Serevent and Advair (made by GlaxoSmithKline PLC), both of which contain the active ingredient salmeterol, as well as another asthma drug, Foradil (made by Novartis AG



and marketed in the U.S. by Schering-Plough Corp.), which contains the active ingredient formoterol.

In relevant part, for this asthma drug safety report FDA staff reviewed their adverse event reporting system database and found nine cases, including five deaths, in children under age 16 years in the 13 months since Serevent was approved for use in children.

To put this latest development into context, we provide some background from our earlier coverage of the issue of whether Serevent, Advair, and Foradil are unsafe drugs:

- ▶ [In November 2005 the FDA issued a MedWatch alert regarding Serevent, Advair, and Foradil](#) to inform doctors and patients that the use of use of these inhalation powders containing long-acting beta 2-adrenergic agonists ("LABA") may increase one's risk of severe asthma episodes and death.
- ▶ [In March 2006 GlaxoSmithKline finally agreed with the FDA to revise a "black-box" warning on Advair and Serevent](#) to further heighten awareness of an increased risk of death associated with salmeterol, but Novartis refused to take similar action as regards Foradil and formoterol.
- ▶ [In June 2006 the *Annals of Internal Medicine* published the findings of a new analysis of 19 previous studies concerning Serevent, Advair, and Foradil.](#) The authors of that study were so concerned about their findings they suggested that Advair possibly should be taken off the market after estimating that Advair "may be responsible" for as many as 4,000 of the 5,000 asthma-related deaths each year in the United States.

Some more general contextual information is provided by *Wall Street Journal (WSJ)* reporter Jennifer Corbett Dooren in her November 23, 2007 article, "[Asthma Drug Safety Review Needed for Children, FDA Says](#)":

- ▶ While clinical studies have showed all three drugs [Serevent, Advair, and Foradil] are successful at controlling asthma in the vast majority of patients, some have showed that salmeterol can cause severe -- and sometimes fatal -- asthma attacks in a small group of patients. Asthma is a chronic disease that causes narrowing of the airways and affects 22 million Americans, including about 6.5 million children.
- ▶ National treatment guidelines recommend low-dose, inhaled corticosteroids for routine management of the disease along with an inhaler, or so-called rescue medication, to manage attacks. The guidelines recommend that drugs like Serevent, Advair and Foradil should only be used as add-on therapy in patients 12 and older whose asthma isn't controlled by corticosteroids.

This November 23 *WSJ* article also summarized the October 2007 FDA report's findings about the deaths of children using Serevent or Advair and, thereafter, it went on to present the GlaxoSmithKline response to this data:

- ▶ A review of pediatric deaths possibly associated with Serevent from 1994 through 2007 showed 23 deaths, the FDA said, with 14 of the cases being reported as being caused by asthma exacerbation or a worsening of the condition. The agency noted that some patients will experience asthma exacerbations even when receiving appropriate therapy. A review of deaths possibly linked to Advair showed 15 pediatric deaths from 1999 through 2007.
- ▶ GlaxoSmithKline said it believed Serevent and Advair were appropriately labeled to reflect the safety profile of the products. The company also said "salmeterol continues to exhibit a favorable safety profile in pediatric subjects and the safety profile is similar to that seen in adults."

Lastly, from a November 23, 2007 *Bloomberg* article, "[Glaxo's Asthma Drugs May Harm Children, U.S. FDA Staff Says](#)", we learn that:

- ▶ Global revenue for Serevent and Advair rose 12 percent to \$6.13 billion last year, making the medicines the second-best-selling in the world behind Pfizer Inc.'s cholesterol drug Lipitor.

According to that same *Bloomberg* article, this level of sales makes Serevent and Advair "the company's biggest-selling medications".

We will watch for guidance from the FDA's pediatric advisory committee following its November 28, 2007 meeting to discuss the safety of Serevent, Advair, and Foradil. Of course, we await further comment from GlaxoSmithKline, also.

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