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November 2007 FDA Advisory Panel Recommends That Serevent And Advair Get Stronger Warnings About Use By Children

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POSTED: Thursday, November 29, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Some Panel Members Want Serevent Withdrawn From Market; FDA And GSK Say Asthma Drug Recall Is Not Appropriate

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

On November 28, 2007 an FDA pediatric advisory panel recommended that the safety warnings on Serevent and Advair needed to be strengthened in order to emphasize the increased risk of hospitalization and death for children using these two asthma drugs from GlaxoSmithKline PLC (GSK).

For some information about the extent of use by children, we get this sales information about Advair and Serevent from a November 29, 2007 article, "[New Warnings Sought For Two Asthma Drugs](#)", published by *The Wall Street Journal*:

Advair, known as Seretide outside the U.S., is Glaxo's biggest-selling drug, with global sales of \$6.1 billion last year. Serevent sales totaled \$538 million. The company estimates 13.3% of Advair and 3% of Serevent prescriptions were for children. According to an FDA analysis of data from Verispan, 779,006 U.S. patients ages 16 or younger got retail prescriptions for Serevent or Advair between April 2006 and March 2007.

With the stage set, we now consider what the experts on this FDA advisory panel had to say about the safety aspect of Serevent (salmeterol). For that we turn to a November 28, 2007 *Reuters* article, "[Glaxo asthma drug needs kid risk warning: FDA panel](#)", by Kim Dixon:

"The data is very troubling because both the increase in hospitalization and in mortality is so different" from what doctors currently believe, said Thomas Newman, an epidemiologist at the University of California, San Francisco, and panel member....

At least two panel members said the data was so convincing that

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Serevent should be pulled from the market. The FDA said it will consider the safety of all drugs in the class, called long-acting beta agonists, at a future meeting....

FDA staffers said no date for the meeting has been set.

Those "other" asthma drugs to be consider at this future FDA meeting would be GSK's Advair and Foradil, made by Novartis AG (NVS) and sold in the U.S. by Schering-Plough Corp.

As for the suggestion that Serevent and Advair should be recalled from the market, this idea was rejected by an FDA official and a GSK representative.

The November 29 *WSJ* article gave us the FDA's apparent position on this issue:

Dianne Murphy, director of the FDA's office of pediatric therapeutics, said, "We don't think it's appropriate to take the drugs off the market" or restrict use to adults only. In 2005, another FDA committee voted unanimously to keep salmeterol on the market.

For the GSK statement we return to the November 28 *Reuters* article:

Kathy Rickard, vice president for respiratory clinical development at Glaxo, said the company believes data shows no increased risk of hospitalization and mortality for Advair and she is not aware of a pending FDA meeting on the issue.

Despite this wishful thinking by GSK that the FDA will not further scrutinize the safety of Serevent and Advair, we anticipate an increasing debate on this issue in the time leading up to the next FDA meeting concerning these allegedly dangerous asthma drugs.

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