

*New York Times*

*July 13, 2005*

## **Experts to Consider Withdrawal of Asthma Drugs**

By Denise Grady

A panel of lung experts is being convened today to advise the government on whether three popular asthma drugs should stay on the market or be withdrawn because of safety concerns.

The drugs are Advair and Serevent, made by GlaxoSmithKline, and Foradil, made by Novartis and sold in the United States by Schering Plough. Advair and Serevent contain the same drug, salmeterol; in Serevent, salmeterol is alone, while in Advair it is combined with another medicine. Foradil does not contain salmeterol; its active ingredient is formoterol.

The drugs are inhaled to keep the airways open, preventing asthma attacks. Patients are to take them every day even if they are feeling well. The drugs are different from the inhaled medicines used to treat attacks.

Concerns have arisen about the three drugs, the Food and Drug Administration said, because in a small number of patients they “have been associated with severe asthma exacerbations.”

Advair and Serevent already carry warnings about a study that showed a small but significant increase in deaths among people who added the drugs to their usual asthma treatment: 13 deaths in 13,176 patients who took the drugs, versus 3 in 13,179 who took placebos. Foradil was not part of the study and does not carry such a warning.

Serevent was one of the drugs singled out by Dr. David Graham, a drug agency reviewer who began speaking out in November about what he called the F.D.A.’s inability to protect the public from unsafe drugs.

The meeting today is of an advisory committee of 14 asthma experts who are expected to review the data on the drugs, listen to presentations from the manufacturers and others, and then vote on whether the products should be left as they are, re-labeled or taken off the market altogether.

Spokeswomen for both companies said they would present data showing that the drugs’ benefits far outweighed their risks, and that they should be left on the market.

More than 21 million adults and 8 million children in the United States have asthma. Dr. Erwin W. Gelfand, chairman of pediatrics at the National Jewish Medical and Research Center, a hospital for respiratory diseases in Denver, said that he and many other doctors treating asthma thought the drugs helped many patients.

“There is no doubt,” Dr. Gelfand said. “To my knowledge, when you look at the overall picture from a number of studies there’s not really a danger emerging.”

Advair, sold overseas as Seretide, was the third-best-selling drug in the world in 2004, with sales of more than \$4.5 billion. In the past 12 months in the United States, 17.2 million Advair prescriptions were filled. Serevent’s sales were \$639 million last year, and Foradil’s \$320 million.