

Asthma Drug Health Risks Are Suspected

GlaxoSmithKline said yesterday that Serevent, one of its popular asthma drugs, might pose a risk of death and serious asthma-related illness in some patients.

The company said it was halting the study it had been conducting since 1996 to evaluate Serevent's safety because the study was unlikely to be conclusive. GlaxoSmithKline said it would work with regulators to design further studies to address concerns about Serevent's safety. While the results of the study were not statistically significant, they suggested that people who use Serevent, particularly African-Americans, might be at greater risk for life-threatening attacks or deaths associated with their asthma. People who use Serevent without also taking inhaled steroids to control their asthma may also be at increased risk. The Food and Drug Administration, which issued a statement yesterday about the study, emphasized that the benefits of Serevent for people with asthma continued to outweigh the risks based on current information. The agency said it would meet with GlaxoSmithKline to discuss the findings and was interested in further evaluating whether certain patients might be at greater risk for what it described as rare but potentially serious adverse effects from their use of the drug. "Patients who require significant treatment should not be afraid of using Serevent," said Dr. Lanny Rosenwasser, a professor at the National Jewish Medical and Research Center and the incoming president of the American Academy of Allergy Asthma and Immunology. Previous studies had indicated that Serevent and similar drugs were not successful in controlling asthma alone, he said. "You need another controller medicine," Dr. Rosenwasser said. GlaxoSmithKline makes another asthma drug, Advair, which has the active drug in Serevent. But Advair combines Serevent with a type of inhaled steroid that is recommended by doctors to control the inflammation associated with asthma. While Serevent received regulatory approval in 1994, the food and drug agency said it had received some reports of asthma-related deaths associated with the drug, which prompted the study. Studies had also raised concerns about a class of drug known as beta agonists, which includes Serevent. About 26,000 patients participated in the study, which had been intended to enroll 60,000. Although the preliminary analysis of the study suggested additional risks, they were not statistically significant because of the small number of deaths and other serious effects, said Dr. Kate Knobil, a research physician at GlaxoSmithKline. The company would soon make public the number of these cases, she said, but was still compiling the information. The increased risk appears to be driven by the lack of inhaled steroid use, Dr. Knobil said. Despite medical recommendations that patients use inhaled steroids or some other medication, many patients in the study were not being treated with additional medicine. Less than half, or 47 percent, of the patients used inhaled steroids. Whether or not a patient was using an inhaled steroid was determined by that patient's doctor, not the company. African-American patients were less likely to be using inhaled steroids and were more likely to have a more severe case of the disease, which could partly explain why they were at greater risk for death or other serious problems. But genetics might also play a role, Dr. Rosenwasser said. In addition to asking for further studies, the drug agency might require GlaxoSmithKline to change how it labels the drug or otherwise alert doctors to its risks. Analysts played down the significance of the study while acknowledging that it gives GlaxoSmithKline's competitors some advantage in promoting their own drugs to treat asthma. "It's a little marketing nudge here and there," said Todd Lebor, an analyst with Morningstar Inc. in Chicago. While the asthma franchise, which includes Advair, is important, Mr. Lebor said, it is a small part of GlaxoSmithKline's nearly \$30 billion in revenue. "They don't have a blockbuster portfolio," he said. For the nine months ended Sept. 30, the company sold \$574 million in Serevent, with \$327 million coming in the United States. Advair sales reached \$1.7 billion, of which \$925 million were in the United States.