

1990s trial gave early danger signs for asthma drugs

25 November 2012, by John Fauber

The troubled history of asthma drugs known as long-acting beta-agonists goes back to the 1990s when a large clinical trial in Great Britain of the GlaxoSmithKline drug Serevent produced disturbing results.

In that 16-week trial of 25,000 [asthma patients](#), 12 people getting the drug died of [asthma](#) and respiratory causes, compared with only two in the [control group](#) who took a standard medication, according to a 1993 paper.

In addition, there were 193 hospitalizations or life-threatening events related to asthma and respiratory causes in the users of the new drug, compared with 102 in the other group.

The serious concerns raised in the first trial of Serevent, also known as salmeterol, led to a second large study of the drug several years later in the United States.

That trial was halted by [GlaxoSmithKline](#), in part because of excess deaths among African-Americans.

Researchers had hoped to study 60,000 people in the trial, but only 26,000 people had been enrolled when it was stopped in 2003.

A 2006 paper that detailed the results of the U.S. trial noted there were 37 asthma and respiratory related deaths in those receiving salmeterol, compared with 14 among those on usual [asthma medication](#) who also got a placebo.

Among African-Americans getting salmeterol, 15 died of asthma and respiratory causes during the 28-week study period, compared with only three who got a placebo.

It is not known why African-Americans may be more vulnerable to the effects of salmeterol. One theory involves genetic variations in cells in the

lungs.

Long-acting beta-agonists are inhaled drugs that are sold as single agents. They also can be combined in an [inhaler](#) with a steroid.

The leading beta-agonist/steroid combination product is Advair, sales of which have topped \$4 billion a year since 2007, according to the market research firm IMS Health.

Another long-acting beta-agonist, Foradil (formoterol) also is available as a single-agent and as the combined product Symbicort, made by AstraZeneca.

In an email, GlaxoSmithKline spokeswoman Karen Collins said studies consistently have shown that Advair provides better overall asthma control than just an inhaled corticosteroid, including improvements in lung function, symptom control and less use of short-acting rescue inhalers.

She said both Advair and Serevent have improved asthma care.

"These medicines are used by millions of people worldwide and in the vast majority of people treated, they are well tolerated," she said.

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