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F.D.A. Panel Votes to Ban Asthma Drugs

By [GARDINER HARRIS](#)

ROCKVILLE, Md. — A panel of federal drug experts voted on Thursday that the drugs Serevent and Foradil should be banned from use in the treatment of [asthma](#), but the experts said that Advair and Symbicort, which together are far more popular, should continue to be used.

The experts, gathered by the [Food and Drug Administration](#), said that too many doctors used Serevent and Foradil inappropriately and that asthmatic patients were often fooled by their own symptoms and used them incorrectly. Serevent and Foradil widen lung airways but increase the risks of death unless paired with a [steroid](#). The drugs' labels already warn of this risk but half of patients taking the medicines do not get a steroid. Even when patients are prescribed a steroid, many fail to take it.

GlaxoSmithKline, the maker of Serevent, and Novartis and Schering-Plough, the marketers of Foradil, argued that doctors want the freedom to mix and match these drugs with steroids. But Dr. Jesse Joad, a panel member and pediatrician from the University of California Davis Medical Center, said she did not “want to give a drug that is making the disease you're treating worse.”

Dr. John Jenkins, a top F.D.A. official, cautioned that patients should consult their doctor before stopping any asthma drug regimen. And Dr. Jenkins said the agency would consider requiring drugmakers to undertake large studies to assess the safety of Advair and Symbicort, particularly in children.

The drugs' makers rejected the committee's decision to ban Serevent's and Foradil's use in asthma, although each said that it would cooperate with the agency.

Last year, Serevent's sales were \$538 million and Foradil's were \$362 million. Through the first nine months of this year, Advair's sales were \$5.66 billion, and Symbicort's were \$209 million.

Serevent and Foradil are also approved to treat chronic obstructive pulmonary disorders like [emphysema](#). So even if the agency follows the panel's advice, the drugs will remain on the market.

Asthma is caused when airways in the lungs spasm and swell, restricting the supply of oxygen. The two primary treatments are steroids, which reduce [swelling](#), and beta agonists, which treat spasms. Rescue inhalers usually contain albuterol, a short-acting beta agonist.

Serevent and Foradil are longer-acting beta agonists intended to prevent attacks. Used without a steroid, however, these drugs have been shown to increase the risks of more severe attacks. Advair and Symbicort combine longer-acting beta agonists with steroids in a single inhaler.

The expert panel voted unanimously to ban the use of Serevent and Foradil in children, but for adults, it voted 17 to 10 to ban Serevent and 18 to 9 to ban Foradil. It voted unanimously that Advair should continue to be used in asthmatic adults and supported its use in adolescents by 23 to 3 and in children by 13 to 11. Symbicort's use in adults was supported unanimously, while its use in adolescents was supported 20 to 5.

Symbicort is not approved for use in children.

Earlier, some top F.D.A. safety experts recommended that all four drugs should be banned from treating asthma, while other agency experts said the drugs' benefits outweighed their risks.

Like other drug-safety controversies, the debate largely pits those who treat patients against those who study populations. Since the drugs may lead to one death in somewhere from 700 to 4,000 patients, few doctors have seen drug-related deaths, so most focus on their benefits, which allow many of their patients to play sports, go to work or lead normal lives.

Among the drugs' supporters was Anne Dorsey of Baltimore, who described when her 13-year-old son, Julian, nearly died from an asthma attack. Julian spends much of his life in the hospital and is now taking Advair.

"I have to ask you not to let him perish" by banning the drugs, Ms. Dorsey said.

Then Julian stepped to the microphone and in a reedy voice said that Advair had cut the time spent in the hospital in half. "Life got a lot easier," he said, "and without Advair, I don't know what I'd do."

The [American Academy of Pediatrics](#), American Thoracic Society, American Academy of Allergy Asthma and Immunology, and American College of Allergy Asthma and Immunology all support the continued use of the medicines.

Some experts say that although long-acting beta agonists may make patients feel better, they have few concrete benefits that justify risking death.

Dr. Sean P. Hennessy, a panel member from the [University of Pennsylvania](#), called for Glaxo to start a large safety study of Advair. "Given the problems and the nearly \$8 billion in revenue earned from Advair," Dr. Hennessy, "this seems imminently plausible."

Dr. Fernando Martinez, director of the Arizona Respiratory Center at the [University of Arizona](#), said far too many patients whose conditions could be treated adequately with steroids alone were instead receiving Advair or Symbicort, which are riskier and more expensive. Dr. Martinez blamed heavy marketing by Glaxo of Advair instead of Flovent, which contains only a steroid. "In the last two years," he said, "I haven't seen a single ad for Flovent, but I have seen many for Advair."

Stan Hull, a Glaxo senior vice president, said, "That's absolutely not true."

"The reason physicians use Advair over Flovent," he said, "is that Advair has been shown to be superior to Flovent in providing control over asthma."

Doctors face difficult choices with children whose asthma remains uncontrolled with low-dose steroid treatment. If they increase the steroid dose, the risks include stunted growth, [acne](#), greater vulnerability to infections and changes to skin, eyes and bone. If they add a long-acting beta agonist, the risk of death, although small, increases.

The beta agonists, by relaxing bronchial spasms, treat mild symptoms and make patients feel better immediately. Feeling better, these patients may decide against taking the steroids since steroids have few immediate benefits. Indeed, patients prescribed both drugs separately get fewer refills of the steroid than of

the beta agonists. Such patients leave themselves vulnerable to severe attacks and death.

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