



Diplomates – The  
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To all CAAC Patients:

## The FDA Expresses Concern that Long-Acting Asthma Drugs Medication May Increase Risk in Asthma

The Food and Drug Administration (FDA) has once again expressed concern about the potential for increased risk of asthma-related side effects from the use of any of the asthma medications containing the long-acting bronchodilators, Serevent and Foradil. These drugs are marketed alone and in combination with inhaled steroids in the products Advair and Symbicort. The FDA looked at whether the use of these drugs increased the risk of asthma-related death, hospitalization, or severe breathing problems resulting in the need for breathing support by mechanical ventilation. These risks appear to be greater in children and among African-Americans. An FDA advisory committee will meet this week to discuss the safety of this class of drugs and whether they should continue to be marketed for use in children and adults.

This is another chapter in an on-going debate at the FDA about the safety of these drugs which have been under review for several years. These drugs already carry the FDA's strongest "black box" warning stating they "may increase the risk of asthma-related death." The FDA pulmonary advisory committee has said the asthma-related deaths are "numerically small" and noted that overall asthma deaths in the U.S. have actually declined since 2000. Furthermore, the FDA pulmonary advisory committee has stated that the drugs have benefits such as improved asthma control and lung function that "are not trivial for patients."

We will continue to monitor this FDA debate as it proceeds. **Do not stop your asthma medication without consulting your physician.** Untreated asthma poses a much greater risk than using long-acting bronchodilators. We encourage you to discuss any concerns that you may have regarding the use of any asthma medication with your allergist.

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