

## **Breaking News: FDA issues new safety requirements for long-acting inhaled asthma medications called Long-Acting Beta-Agonists (LABAs)**

*The FDA recently issued (2-18-2010) a drug safety communication which can be found on their web site ([www.fda.gov](http://www.fda.gov)) and is referenced in a variety of Google News articles. Dr. Steven Zekowski, Stillwater Medical Group's allergist-immunologist comments:*

Some of this communication is not new; but some of it is new, and, in my opinion, represents a more forceful approach by the FDA. This recent communication is important since it summarizes the data that the FDA has reviewed and reinforces their continued concern about LABA safety. Also, while the FDA believes that this is a real risk, not a statistical aberration, the rate of asthma death is very low. These studies of tens of thousands of subjects show death rates at about 0.1% (one out of a thousand LABA users). It is important to note that this safety communication does not apply to COPD.

**What isn't new?** For a few years these drugs - which include Advair, Brovana, Foradil, Perforomist, Serevent, and Symbicort - have carried a "black box" warning in their FDA mandated product information. This warning has stated that long-acting beta-agonists may increase the risk of asthma-related death. Despite this warning, these drugs are still commonly used by health care providers (including myself) because they greatly help many asthmatic patients. The most recent national asthma guidelines (2007) continue to recommend a combination of inhaled corticosteroids and LABAs as the preferred treatment for adolescents and adults with moderate to severe asthma and for children with severe asthma. LABAs without inhaled steroids should never be used to treat asthma. This is also reiterated in this latest FDA statement.

**What are they saying that is new?** Most importantly, that "LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved." While the FDA has previously said that LABAs should be used only in patients who cannot be controlled with other medications, the phrase "shortest duration" is more restrictive. Asthma guidelines have long emphasized the importance of "stepping down" (decreasing) asthma medications when control is good, but have left it up to the doctor and patient to decide what to decrease first. My initial reaction is that compliance with this directive would mean changing patients from combinations of inhaled steroids and LABAs (Advair, Symbicort) to inhaled steroids alone, once control is achieved. Up until now, step-down options also included decreasing the steroid dose in the combination medication or discontinuing an additional controller medication such as Singulair. Higher doses of inhaled steroids also have potential risks, and additional prescriptions have an economic cost. Also new is the FDA's requirement for the manufacturers of combination drugs to conduct additional testing to evaluate the safety of LABAs combined with inhaled steroids (to determine if these are safer than LABAs alone).

**What should a patient do now?** If you are on a LABA or LABA-steroid combination inhaler, and if your asthma is well controlled, make an appointment with the provider who is prescribing that medication. Perhaps your medical regimen can be taken down a step so that you no longer will need the LABA medication. Only make this change at a face-to-face clinic visit with the prescribing provider or with another provider to whom you have been referred. **Do not decrease or discontinue any asthma medication on your own.**