

## **ISSUE:**

### **Food and Drug Administration's (FDA) proposal to move ASTHMA drugs from Prescription to Over-The-Counter (OTC) status.**

In late March, 2012, FDA held two days of hearings proposing to move a range of prescription drugs to OTC status. These include drugs for asthma among other classes of drugs (diabetes, migraines, high blood pressure and high cholesterol). In doing so, FDA is planning to reclassify these prescription drugs to OTC.

## **BACKGROUND:**

OTC drugs are defined as drugs that are safe and effective for use by the general public without seeking treatments by a health professional. Generally, OTC drugs have to be used primarily to treat a condition that doesn't require the direct supervision of a doctor and must be proven to be reasonably safe and well tolerated. There is a great potential for poor outcomes when patients with persistent asthma are not followed by a physician properly trained to manage this condition. *Over 4,000 Americans die preventable deaths from asthma each year*, and half of those would be categorized as having mild asthma. Even mild asthma needs to be managed by a physician. Physician management has dropped the death rate from 5,000 to 4,000 in the last 10 years after 2 decades of increases.

While patients might be able to access these drugs more quickly without visiting their doctor or allergist, this policy assumes patients, insurance companies, and state and federal governments would save money by reducing overall costs. However, this would shift the cost to a patient's out-of-pocket expense. Studies have shown that high out-of-pocket expenses often prevent patients from either taking their drugs or taking them properly.

### **Allergists and Immunologists are concerned and are opposed to moving current prescription asthma drugs to OTC status for the following reasons:**

- Asthma is a life-threatening disease and approximately 4,000 people die each year in the US from Asthma.
- There may be incorrect diagnosis, delay in seeking proper medical care, adverse reactions, dangerous drug interactions, incorrect administration, incorrect dosage, over-dosage, abuse, and/or incorrect treatment.
- Patients taking more than one drug may experience harmful side effects as there may be serious drug interactions.
- Easier access to drugs for asthma patients vis-à-vis OTC for patients, is **NOT** the answer to our nation's health care.

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A diagnosis of Asthma requires taking an extensive patient history and patient examination—including listening to a patient’s lungs and lung function studies. The National Institutes of Health’s (NIH), National Heart, Lung & Blood Institute (NHBLI), in 2007, issued *Guidelines for the Diagnosis & Management of Asthma*. These guidelines focus attention and resources on six (6) priority messages that reinforce extensive clinical practice recommendations vital for asthma control and high quality patient-centered care. These evidence-based guidelines change lives for the better and include:

- **Use of inhaled corticosteroids to control asthma**
- **Use of written asthma action plans**
- **Assessment of asthma severity**
- **Assessment of and monitor asthma control**
- **Scheduled follow-up visits**
- **Control environmental exposures**

Even with numerous educational programs and countless dollars spent by our specialty societies and industry on programs geared to specialists, primary care providers, pharmacists, and patients, the guidelines are not being implemented for most asthma patients. Following these guidelines save lives. When left to their own choice, patients usually select the wrong asthma medications – inhaled beta agonist instead of inhaled corticosteroids – to control symptoms. The FDA has issued a boxed warning about asthma deaths and the use of long-acting beta agonist. Removing healthcare providers from the equation is a dangerous step backwards.

In addition, during the FDA hearings, it became known that this proposal would include patients going to “kiosks” and filling out questionnaires and/or using “Apps” by which patients would be directed to use various OTC drugs. To our knowledge, there is not any asthma “kiosk,” “App,” or questionnaire by which a diagnosis and treatment plan could be made. Nor are we aware that this technology has been tested.

## **RECOMMENDATIONS:**

**1. Congress should hold hearings on the FDA proposal to move asthma and other drugs to OTC status. Such hearings should explore the safety and effectiveness of such a move, patient adherence to OTC recommendations, patient outcomes, and the status of “Kiosks,” “Apps,” and other technologies.**

**2. Oppose FDA’s proposal to move asthma drugs OTC.**

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