

My name is Michael Parker. I am a physician specializing in otolaryngology—head and neck surgery; practicing in Syracuse, New York. I am here representing the American Academy of Otolaryngic Allergy (AAOA), a specialty medical organization of 2200 physicians who treat ear, nose and throat allergies and other upper respiratory tract disorders. Additionally, as a physician, I participate as a preferred provider and have active contracts with a variety of health care payers, including BC/BS. My experiences both as a physician and as a consultant to Aventis Pharmaceuticals and Schering-Plough, allow me to offer a well-balanced viewpoint.

While representing the AAOA, I am here advocating for the patient's interest. On their behalf, I strongly oppose the proposed shift of second-generation antihistamines from their current status as prescription medications to over-the-counter (OTC) medications.

The Food and Drug Administration is also in the business of advocating for and protecting patients. It is apparent to the membership of the AAOA that a change in the status of second-generation antihistamines to an OTC status would be conflicting with the underlying doctrine of both organizations—to place the patient's welfare first.

As physicians with expertise in managing allergic disease, we feel it is critical to continue to have physicians play an integral role in the diagnostic and therapeutic decision-making process for symptoms of allergies. The differential diagnoses for nasal congestion and a runny nose are widespread—from allergic disease to bacterial infections to malignant tumors. It is important to define the cause of the symptoms before prescribing the therapy.

In Medicine, there are abundant situations in which it is necessary to protect the well-meaning, relief-motivated patient from him or herself. Patient self-diagnosis is not always a simple process, and allergic disease is no exception. By asking the patient to define and treat their nasal congestion or runny nose, you are asking him to differentiate an allergic disease from other disease states such as an acute viral or bacterial infection. The ability to differentiate disease states is a skill that physicians develop after years of education and experience. By allowing these second-generation antihistamines to be dispensed over-the-counter, more and more patients will attempt, or worse, be expected, to self-diagnose and -treat their symptoms—allergic or not.

While antihistamines may easily treat some patients who suffer from simple allergic disease, there are a number of variables that must be considered to successfully manage most patients with allergies. Second-generation antihistamines are clearly superior to OTC preparations with respect to their reduced side effects. This fact actually contributes to an increase in the potential for over-use of this class of drugs. Self-diagnosed patients who treat themselves with second-generation antihistamines inappropriately will find it easier to remain on the drug. For example, if the patient had an upper respiratory viral infection, a condition which should resolve spontaneously, and self-treated with this class of drugs, the patient would perceive success with the drug and continue taking the drug erroneously. This situation already exists with another class of

OTC preparations and indeed results in a disease state from overuse. Rhinitis medicamentosa is a well-documented condition resulting from patient self-diagnosis and prolonged use of topical nasal decongestants.

Utilization of second-generation antihistamines by patients without physician evaluation may also lead to problems of masking diseases or delaying the diagnosis of more serious conditions. Diseases such as acute sinusitis, pathologic obstruction, nasal polyposis, chronic sinusitis, otitis media or asthma can all exist with or without an allergic component. Defining which disease is contributing to which symptom is often difficult for physicians lacking specific expertise in this area. As such, patients self-diagnosing and -prescribing antihistamines can only delay and confuse proper diagnostic and medical or surgical management.

Leaving second-generation antihistamines as prescription medications will assure that allergic disease will be properly diagnosed and managed by physicians. Maintaining the current status will assure that more serious conditions will not go undiagnosed, and that patients will not be medicated inappropriately for diseases they do not have.

I would suggest to you that keeping the physician in the loop is in the patients' best interest. An appropriately trained health care professional is best able to assure that the symptoms of "simple allergies" are not those of a more serious disease, that simple problems do not become serious problems, and that curable diseases are not allowed to become incurable (e.g. a runny nose, improved by an over-the-counter second-generation antihistamine is not allowed to mask a potentially deadly malignant nasal mass).

In exercising its responsibility to protect the patient, the FDA must recognize that it is in the patient's interest to preserve the status of these second-generation antihistamines as prescription medications.

Thank you. I would be glad to respond to questions.