

PRESENTATION
OPPOSING THE SWITCH OF FEXOFENADINE HYDROCHLORIDE,
LORATADINE AND CETRIZINE HYDROCHLORIDE TO OTC STATUS DUE TO
SAFETY ISSUES

I have served as a Consumer Representative as well as Member of the Allergenic Products Advisory Committee and therefore have closely followed FDA regulations and regulation changes. The decision regarding these medications is an extremely important one because its outcome will have a ripple effect on the health care of our society.

In order to determine if a drug is a suitable candidate for an OTC switch, various issues involving safety must be considered. A number of these issues are listed as switch principles. One of these principles asks if **“the candidate has been used for a sufficiently long time on the Rx market to enable a full characterization of its safety profile?”**

At the time of Blue Cross’s original petition, fexofenadine (Allegra) was prescribed at a dose of 60mg twice daily. In the year 2000, Fexofenadine was released on the market with a dose of 180 mg once a day. Since it has been scarcely one year since Fexofenadine (Allegra) came on the market at the current dosage, insufficient time has passed to permit accurate characterization of its safety profile for an OTC switch.

A similar principle applies to Loratadine (Claritin). A prescription formula of loratadine for children (ages 2 years to 5 years) was approved only five months ago, in December of 2000, too brief a period for an accurate safety profile for OTC use. However, should the adult dosage of loratadine be approved for OTC use, it is very probable that parents will use the adult dosage “off label “ for their children.

Certirizine (Zyrtec), due to cross reactivity and a recently released pediatric dosage, has also had insufficient time for characterization of its safety profile for an OTC preparation.

It is important to remember nearly ten years had passed before it was realized that there were cardiac side effects with terfenadine when used with other medications. A similar lapse of time occurred before the same problem was discovered with Hismanal, Astemizole. Nor should we forget the recent action taken with PPA (phenylpropanolamine). Caution must be taken in regards to the three drugs listed in the current petition

Another question posed by the Switch criteria is whether or not the **candidate’s safety profile has been defined at high dose**. At the present time, this is not the case with the medications in question and this is definitely not the case when one of the drugs being discussed was released at a higher dose only one year ago.

The use of antihistamines combined with Pseudoephedrine at a high dose of 240mg in a single tablet form for use on a daily basis should raise serious concerns about switching it to an OTC. Since studies have shown that a majority of OTC drugs are used more than once a day, it is possible and perhaps even likely that the public may use the non-sedating medications more than once daily. Concern must also be focused on special population groups such as the elderly as these drugs require dosing adjustments in patients with renal impairment.

In reviewing the FDA/AERS database, it is reasonable to determine that the pharmaceutical companies have not done outcome analysis and that they are not supporting OTC approval. Since the burden of presenting projections for use in an unsupervised OTC setting has been the manufacturer's responsibility, requests for an OTC switch has typically come from the manufacturer. The data currently available on the drugs referred to in Blue Cross's petition is insufficient to provide an adequate safety profile for an OTC switch.

Allergies are more prevalent than ever. In fact, it might be said that we are currently having an allergy epidemic. The important fact to realize is that one form of allergic disease can cause or worsen other symptoms. Recent studies have indicated that up to 90% of asthmatics have allergic rhinitis.

Nowadays, it has been recognized that allergic rhinitis comprises more than the classical symptoms of sneezing, rhinorhea and nasal obstruction. Several studies have shown that allergic rhinitis has a direct relationship with other diseases. In the last decade, an increasing effort has been made to understand the social burden of rhinitis in terms of effects on health-related quality of life. When evaluating the safety of a medication, the quality of life of the patient must also be taken into consideration.

It has been acknowledged in several consensus reports that allergic rhinitis is associated with impairments of daily function at home, at work and in school. The use of an antihistamine is not the simple solution to a more complex management of an allergic condition and related diseases such as asthma, otitis, sinusitis and urticaria.

The management and care of a learned educator is of pivotal importance in the care of these diseases. Because mortality due to asthma is on the rise, we must recognize the importance of good management of allergic rhinitis by physician guided control of the allergic condition. Careful control of allergic rhinitis will have a direct effect on asthmatic patients.

The treatment period of seasonal allergic rhinitis has tremendous variations nationwide. Because plants pollinate ten months out of the year in the state of California, the use of these drugs is more frequent and persistent. This factor provides a different perspective to Blue Cross of California's petition and elevates the need for caution.

What is the worldwide experience of the switch candidate?

Blue Cross' petition bases its safety evidence on a Canadian adverse drug reaction database that combines data from clinical trials with varying methodologies. Further data regarding actual OTC usage is necessary for proper assessment of its safe use without a physician's supervision. Furthermore, contrary to Blue Cross's assumption, the use of non sedating prescriptions is higher in countries where these medications are prescribed by a physician.

An OTC switch in this case will deprive an indigent population of the use of these drugs. If switched to OTC, approximately 10 million patients will not be able to use these drugs. Instead of improving health care we will be jeopardizing patient safety

J. A. Quel, MD, FAAAAI, FACAAI

Executive Director

Hispanic American Allergy, Asthma, Immunology Association (HAAMA)