

5/9/2001

Dear FDA Advisory Committee,

As President of Allergy & Asthma Network Mothers of Asthmatics, a nonprofit patient education and advocacy organization dedicated to eliminating death and suffering due to allergies and asthma, thank you for this opportunity to oppose OTC status for nonsedating antihistamines.

Since 1985, AANMA has enjoyed excellent working relationships with numerous pharmaceutical and device manufacturers, however, the manufacturers of the medications in question have provided financial support for AANMA-developed projects and services totaling less than \$50,000.00 over the last year. We have no financial interests in any of the companies represented in this issue.

AANMA opposes OTC status for nonsedating antihistamines. Asthma and allergies are serious, potentially life threatening conditions which require medical diagnosis and strategic management. The average consumer does not possess the necessary skills to safely select and use appropriate allergy care.

Furthermore, chronic rhinitis – what many people dismiss as hay fever or a little allergy – can lead to sinusitis and trigger asthma or bronchitis. Therefore, identification and elimination of offending allergens is the first line of treatment, not over-reliance on nonsedating antihistamines.

With OTC status for these medications, consumers lose the strategic plan for treating and preventing symptoms with the least invasive and most effective therapies. Only a physician can determine if intranasal corticosteroids, nasal washes, or nonsedating anti-histamines are appropriate. Only a physician can diagnose and treat a sinus infection that developed because the patient tried the self-medication route initially and failed.

We are concerned about poly-pharmacy issues and patient literacy issues as well. Is it really possible to ensure that all people with allergies, which includes 15 million with asthma triggered by allergies, will be able to use these medications wisely and safely without any guidance from physicians and nurses?

AANMA surveyed 1200 members and nonmembers via email. While the results are not scientific, we found overwhelming concerns best summed up by this statement made by Sharon G.: Insurance companies are trying to find ways to save themselves money. If these drugs are put out over-the-counter, we the consumer will have to pay full price and not just a \$5 or \$10 deductible. What

will be next? Self help allergy testing kits and allergy shots you can give at home? Allergies are serious, especially when asthma comes into play. Drug interactions will become more prevalent. We're not doctors. It will get too confusing.

Making informed medical decisions is becoming increasingly confusing as it is, and increasing the number of allergy medications on the OTC market will not relieve this problem, especially for the elderly who must juggle multiple medications and are particularly vulnerable to potential dangers of unwanted interactions and side effects.

Most responders saw a move to OTC status for nonsedating antihistamines as another attack on the sanctity of the physician and patient relationship: "Insurance companies already exert too much control over decisions providers make and unfortunately much of those decisions are based on the financial needs of the company vs. the best course of treatment for the patient."

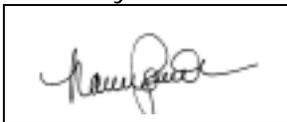
But not all responders opposed OTC status. Some saw the move as positive; it would make the medications easier to obtain and they'd see their doctor less as a result. Most believed there was a strong probability that many people would misdiagnose the symptoms and use the incorrect medication for their symptoms.

Others were uncertain...they simply did not have enough experience to judge. But as one person wrote: "When I was on OTC medicines before allergy testing, I became addicted to a nasal spray and couldn't breathe without it. It took a long time to get that cleared up."

Who does it benefit most for OTC status of nonsedating antihistamines? Insurers or patients? We don't see patients clamoring for OTC status of nonsedating antihistamines. Who will be the likely victims? Insurers or consumers who have no lawyers, consultants, and financial analysts?

There is no health related reason for patients, physicians or insurers to push for OTC status for nonsedating antihistamines.

Sincerely,

A rectangular box containing a handwritten signature in cursive script, which appears to read "Nancy Sander".

Nancy Sander
President and Founder