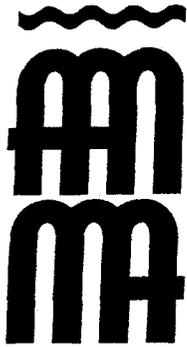


Doobels



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MISSION

To eliminate morbidity
and mortality due to
asthma and allergies
through education,
advocacy, community
outreach, and research.

06/29/2000

FDA Statement re: OTC Asthma and Allergy Medications
Prepared by Nancy Sander, President

Good afternoon. I am Nancy Sander, President of the nonprofit patient education organization, Allergy and Asthma Network • Mothers of Asthmatics, Inc. based in Fairfax, VA. The organization receives one third of its funds from family donations, one third from government, medical and pharmaceutical manufacturer sponsored educational grants, and one third from charitable giving campaigns.

I am here on behalf of our membership, families affected by allergies and asthma. AAN•MA opposes OTC status of asthma medications for the following reasons:

Fifteen people die of asthma every day. Asthma is a serious, potentially life-threatening condition that requires careful, individualized treatment and monitoring by skilled primary and specialty care physicians. While the incidence of asthma is projected to double by the year 2020, there is no explanation or plan for halting it.

In 1996, when FDA was considering OTC status for albuterol and cromolyn sodium, AAN•MA posed the question to our members, is this a good thing? An overwhelming majority said no. They valued the importance of physician monitoring and strategic planning to reduce or eliminate suffering. They said OTC status would eliminate prescription co-pay. Their solution, change their medication to a different prescription. Their fears were not unfounded.

For example, in 1996, OTC Primatene Mist cost more than twice the most expensive long acting bronchodilator on the market - Serevent. And one puff of Primatene Mist lasted 20 minutes as compared to two puffs of Serevent lasting 12 hours. By the way, our members asked FDA to remove Primatene Mist from the OTC market.

Asthma, whether mild, moderate, or severe, has the potential to drown its victims in their own mucus and inflammatory cells. Therefore, because asthma is not an OTC disease, please restrict treatment options to those prescribed by our physicians.

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considerable
In the case of allergies, however, we do have patient experience with existing OTC antihistamines, nasal sprays, and eye drops. Today's OTC antihistamines are predictable, ^{but} they can cause drowsiness as can ^{other} cough and cold preparations sold OTC. Though it may seem on the surface that placing non-sedating prescription antihistamines on the OTC market is a rather seamless idea, AAN•MA sees conflicts and concerns.

An estimated 85 per cent of patients with asthma also have allergies. Allergies range in severity from mild to moderate and severe. When children suffer with allergic rhinitis and sinusitis, allergic conjunctivitis, and associated chronic cough, they don't have the choice of seeing a physician or selecting their own treatment from the broad range of available OTC products. Most OTC purchase decisions are made reading the back of the box or asking a store clerk for advice. The child becomes the at home experiment as parents leave the store arms laden with anyone's guess of what will work.

Poorly managed allergies in childhood are a precursor to developing asthma. Chronic allergic rhinitis and sinusitis, for example, can lead to malformed teeth and facial bones. Chronic ear infections, secondary to allergies, can cause temporary hearing loss resulting in learning difficulties later in a child's life.

Many third world countries sell all medications directly over the counter to anyone who can pay for them. However, convenience and accessibility has never eliminated or reduced morbidity or mortality of allergic diseases. Availability of a medication never insures it will be used correctly or for the proper length of time.

We process nearly 100 inquiries a day from patients and families. In 15 years, not one has requested OTC status for asthma or allergy medications. In the state of Oregon, allergy patients must now pay for immunotherapy, a treatment that must be administered in the physicians office up to 8 times a month. At \$10 and \$15 each, the patient increasingly bears the burden of trying to breathe. OTC status of these medications will not make their lives easier. The patient and physician relationship is the most cost effective and efficient means of delivering medical treatment in our country.

Please do not dilute the importance of physician interaction in our asthma and allergy care by reducing these diseases to OTC status. Please do not increase our out-of-pocket health care costs to manage our very costly disease by approving OTC status for asthma or allergy medications.