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Dockets Management Branch
HFA-305, Food and Drug Administration
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For the past 20 years of my association at Harvard Medical School I have had the honor of training a number of physicians interested in the field of allergy and immunology in my role of Co-Director of the Allergy Fellowship Training Program for which I have been an administrator for the nearly ten years.

I am very disturbed by the decision of the FDA to consider a change in the classification for medications of allergic rhinitis and asthma from prescription status to over-the-counter status.

Although there is no significant mortality associated with allergic rhinitis there is significant disease morbidity. Many patients with allergic rhinitis suffer from concomitant asthma, allergic conjunctivitis, chronic serous otitis media and chronic sinusitis. The availability of non-sedating antihistamines or intranasal corticosteroids as over the counter medications would lure patients with significant allergic rhinitis away from the offices of practicing physicians who are capable of diagnosing these co-morbid conditions often associated with allergic rhinitis. The failure to diagnosis concomitant asthma or chronic sinusitis can lead to significant harm to patients and allow for progression of disease that otherwise would be diagnosed through appropriate intervention occurring in a physicians office.

Close to forty million Americans have allergic rhinitis and associated conditions. Over five million Americans have allergic asthma. The overall economic impact of asthma and allergic rhinitis exceeds 10 billion dollars annually largely related to reductions in work of productivity, the cost of inpatient services for asthma exacerbations and lost time from work and school.

It is highly unreasonable and medically undesirable for patients to be provided greater incentives to self medicate for allergic disease such as allergic rhinitis and asthma. It cannot be expected that patients would understand or recognize the development of co-morbid conditions such as chronic sinusitis and allergic asthma, which may cause significant morbidity if not promptly diagnosed by a physician.

Moving prescription non-sedating antihistamines and prescription intranasal corticosteroids to over the counter status places patients with allergic rhinitis at significant risk simply because it removes from the diagnostic and therapeutic decision the intervention of a well-trained physician.

It is my sincere hope that the FDA will continue to require prescription coverage for non-sedating antihistamines and intranasal corticosteroids in addition to inhaled bronchodilators required for asthma management. The assumption that patients can self medicate for allergic rhinitis and asthma is false. The adverse consequences that will occur to the public related to failure to seek early intervention by a physician for the appropriate diagnosis and treatment of allergic rhinitis and asthma will have a significant adverse impact on public health.

I urge you to maintain prescription coverage for non-sedating antihistamines, intranasal corticosteroids, inhaled bronchodilators and inhaled anti-inflammatory medications for asthma, all of which require the sophisticated training of a medical physician for their appropriate administration. The movement of any of these medications to over-the-counter status could place patients with allergic disease at significant risk and increase morbidity and mortality of allergic asthma.

Sincerely,

Lawrence M. Du Buske, M.D.

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