

AMERICAN MEDICAL COMMISSION

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March 27, 2003

Mark McClellan, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket # 02P-0163/CP1

Dear Dr. McClellan:

Patient safety, with respect to pharmaceutical medications, must remain a top priority of your agency and its role in the approval of medicines and other medical treatments. With that mission in mind, and on behalf of the American Medical Commission (AMC), we implore you to deny a petition by WellPoint Health Networks to switch the entire class of non-sedating antihistamines to over-the-counter status. To grant WellPoint's profit-driven appeal will undermine the credibility of the FDA at a time when your agency plays such a vital and important in safeguarding the health of the American people.

American Medical Commission is a project of Citizens United, a grassroots advocacy organization dedicated to the traditional American values of limited government, freedom of enterprise, strong families, and national sovereignty and security. American Medical Commission has tens of thousands of members and supporters across the United States. For the reasons that follow we urge you to deny WellPoint's petition.

Non-sedating antihistamines play a vital role in the treatment of allergies and asthma; these newer, non-drowsy medications are allowing young people to attain improved performance in schools and are helping prevent allergy-suffering workers from missing work. But WellPoint's petition poses a dangerous threat to the advances these drugs have allowed. Should FDA approve their petition, WellPoint (along with other major insurers) are expected to quickly delist these drugs from their formularies and direct patients to the new, over-the-counter options available to them.

AMC is concerned that consumers facing these treatment choices without professional guidance may choose cheaper, sedating antihistamines. However, side effects such as sedation can lead to twice the normal risk of a serious injury, according to one study. Current sedating over-the-counter antihistamines contain warnings regarding activities requiring mental alertness, such as driving or operating dangerous machinery.¹

¹ *Annals of Allergy, Asthma & Immunology* 2002; 89:244-250

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HMOs such as WellPoint are convinced that allowing consumers to self-medicate will be safe and effective. But by limiting doctor-patient interactions, WellPoint and other health insurers will instead force consumers to rely on little or no professional advice as the self-medicate to alleviate their symptoms. In the case of antihistamines, this interference in clinical practice could have serious ramifications. Encouraging patients to self-medicate these types of conditions is not appropriate for all allergy and asthma sufferers. Patients who have severe respiratory disease (or chronic allergies) or are at risk of developing asthma, or are prone to drug interactions and complications should be encouraged to have their drug therapy monitored by their physician.²³ This practice could be jeopardized if your agency approves WellPoint's petition.

Commissioner McClellan, the FDA must deny WellPoint's petition to convert non-sedating antihistamines over-the-counter. FDA must not become an unwitting accomplice to WellPoint's attempts to downplay safety concerns in the interests of their bottom line. Do not allow the further exacerbation of the troubling interference HMOs already perpetrate on the doctor-patient relationship. On behalf of American Medical Commission I respectfully ask that you deny WellPoint's petition. Thank you.

Sincerely,


Mary Beth Brown, RN
Director

cc: Karen M. Templeton-Somers, Ph.D
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² *Journal of Allergy Clinical Immunology* 1997; S773, 774, 775