

# IHPM

INSTITUTE FOR HEALTH AND PRODUCTIVITY MANAGEMENT

August 1, 2003

Mark B. McClellan, MD, Commissioner  
Food and Drug Administration  
14-71 Parklawn Bldg.  
5600 Fishers Lane  
Rockville, MD 20857

RE: FDA's consideration of forcing prescription non-sedating antihistamines over the counter; docket #98P-0610

Dear Dr. McClellan,

As a non-profit research and development organization dedicated to establishing the value of employee health as a business asset, the Institute for Health and Productivity Management (IHPM) is concerned that the FDA is bowing to the requests of managed care companies by considering a switch of prescription non-sedating antihistamines to over-the-counter status. IHPM strongly believes such a switch would negatively impact employee health, workplace productivity, consumer costs and the patient-physician relationship.

A forced switch would actually shift the cost of allergy medications from insurers to consumers, compromise the quality of patient care and increase the already high indirect costs of allergies to employers. Because our Institute regards all aspects of employee health as affecting work performance, we're specifically concerned about how an OTC switch would affect employees and their employers.

A 1999 study published in the *American Journal of Managed Care* estimated that 3.4 million workdays are lost yearly due to allergies, and estimates of lost wages are more than \$150 million per year. Additionally, allergies were found to be the most prevalent medical condition among 4.1 million insured employees surveyed for a 2000 study conducted for us by the MEDSTAT Group.

In our own work with employers and providers in the field, we have documented significant lost productivity from allergies (e.g., studies with employer members of the Nevada Health Care Coalition, St. Joseph Heritage Healthcare in Orange County, CA, and International Truck and Engine Company). Allergies impact the ability to sleep restfully and be productive at work—to perform a broad range of functions needed to perform jobs safely and effectively.

**98P-0610**

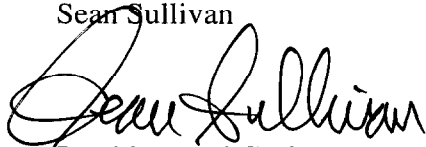
**CSZ**

Finally, we agree with the medical experts who have previously stated that physicians play a vital role in choosing the best and safest medication for their patients, as well as monitoring and educating patients who suffer from allergies. The nearly 36 million Americans who suffer from seasonal allergies each year cannot be expected to know the appropriate drug selection, therapy and dosage, nor monitor the effects of allergy medications without the involvement of their physicians. It should be up to the physicians to determine the proper treatment for their patients' allergy symptoms, not the managed care companies or the FDA.

The domino effect from an over-the-counter shift is simple: a lower quality of life and increased out-of-pocket costs for employees would lead to lost productivity for employers because workers either forgo medication or use cheaper sedating products that interfere with job safety and performance.

IHPM urges the FDA to proceed with caution and heed the numerous concerns being raised by physicians, patients and employers about a forced shift of prescription NSAs to OTC status.

Sean Sullivan

A handwritten signature in black ink that reads "Sean Sullivan". The signature is written in a cursive, flowing style.

President and CEO  
Institute for Health and Productivity Management  
Scottsdale, AZ

*IHPM works with all the major stakeholders in health care for this purpose -- employers, providers, health plans, insurers and employees -- to assemble and analyze databases; develop and refine key metrics and measurement tools; organize pilot projects to build the business case for health and productivity; and carry the message and the evidence to all stakeholders. The IHPM operates from offices in Scottsdale, AZ and Richmond, VA. For additional information on the IHPM, visit [www.ihpm.org](http://www.ihpm.org) or [www.healthandproductivity.com](http://www.healthandproductivity.com).*