NATIONAL CONSUMERS LEAGUE

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October 10, 2003

The Honorable Tommy Thompson
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

On behalf of the National Consumers League (NCL), I wish to bring to your attention a serious matter pending before the Food and Drug Administration [Dockets 98P-0610 and 02P-0163]. Please see enclosed copy of a letter dated March 6, 2003, which NCL sent to each member of the Senate HELP Committee, expressing our concerns about the potential dangers inherent in forced over-the-counter (OTC) switches of prescription drugs.

As we indicated in the enclosed letter, "The potential elimination of a prescription option for consumers will shift costs from health plans back onto consumers, substantially increasing consumers' out-of-pocket costs for use of these particular, and necessary, treatments."

Mr. Secretary, forced OTC switches will precipitate a dangerous situation for consumers to face: self-medicating for conditions that could be potentially more serious, as well as negotiating how to accommodate a dramatic increase in out-of pocket costs for what had been typically covered prescription drugs.

We hope that, by bringing this matter to your attention, American consumers will not be put in the position to make such dire choices with regards to their health. Thank you for your time and consideration.

Sincerely,

LINDA F. GOLODNER
President

LFG:dm
Enclosure

NCL 100 YEARS CONSUMER ADVOCACY National Consumers LEAGUE

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March 6, 2003

The Honorable Judd Gregg, Chairman
Senate Committee on HELP
SH-835 Hart Senate Office Building
Washington, DC 20510

Dear Senator Gregg,

The National Consumers League (NCL) is a private, nonprofit advocacy organization representing consumers on marketplace and workplace issues. NCL is the nation's oldest consumer group, has members in every state, and has a longstanding interest in healthcare issues

We are writing today to urge you to conduct hearings to ensure that the U.S Food and Drug Administration (FDA) continues its long standing policy of providing sufficient time for post market surveillance of drugs introduced in the marketplace. The FDA policy has been not to approve a switch of a prescription drug to OTC status until there is sufficient marketing experience as a prescription product, typically at least five years, to ensure that patient and public health will not be adversely impacted. The purpose of this practice is to ensure that a drug has had sufficient use under physician supervision in a large population to enable potentially serious adverse reactions and side effects to materialize and be detected before a drug is approved for self-medication and OTC sale. Reactions that may occur due to chronic or repeated exposure only can be uncovered over a substantial period of time. Clinical trials required for initial product approval do not involve sufficient numbers of patients (typically less than 2,000) or any chronic or repeated exposure to evaluate low-incidence events or latent events, no matter how serious. While such limited studies may well establish a degree of safety and efficacy and a favorable risk/benefit ratio for patients under direct physician supervision, it is essential that additional experience be acquired before physician oversight and attention to potential side effects is removed.

On April 15, 2002, WellPoint Health Networks (WellPoint), in a highly unusual move, filed a citizen petition requesting that FDA switch the prescription nonsedating antihistamine Clarinex® to over-the-counter (OTC). Previously, WellPoint asked FDA to move the entire category of prescription only nonsedating antihistamines to OTC status. NCL is concerned that such a broad-based switch may not be in the interests of consumers. We are concerned both about the health and safety of allergy and asthma sufferers as well as the economic consequences to consumers. Of primary concern is the detrimental impact that such action could have on patient care and the physician-patient relationship. Specifically, this action could affect physician oversight and diagnosis of patients who may have comorbid conditions such as asthma, other serious allergies, and other untreated chronic respiratory conditions.

NCL is also troubled that various elements of the current labeling for these products include special dosage recommendations for patients with decreased renal function, cautions against overdosage, and recommendations to physicians about patients with conditions other than allergy. NCL believes that an OTC switch may result in chronic continuous use by some patients with a drug that has only gone through clinical trials and has not been in the marketplace long enough to determine its safety as an over-the-counter medication. Another concern is drug-to-drug interaction between OTC antihistamines and other OTC medications, including antacids.

Finally, a major consequence of a switch to OTC status would affect the cost of treatment for many consumers with allergies and asthma and to a health care system where medical conditions may be left undiagnosed, untreated, or under treated particularly at a time when asthma and allergy rates are increasing significantly. There are a variety of nonsedating antihistamines available today and they all have quite different effectiveness and safety profiles. They were approved individually, not as a class. NCL believes that OTC status for these products must be considered individually, at the appropriate time in each product's marketing history, not on a class basis. If FDA accepts WellPoint's petition, it would represent a troubling and serious shift in current agency policy and would set a dangerous precedent. In the wake of several recent high-profile market withdrawals when serious adverse events were detected shortly after FDA approval, NCL believes the FDA must place patient safety first

NCL is very concerned with profound consequences to consumers' ability to treat allergies if these drugs are forced by FDA to move OTC. FDA's recent approval of Claritin® for OTC sale at the request of its manufacturer provides consumers with an important choice of self-medicating. This choice will enable allergy sufferers to optimize their treatment with nonsedating antihistamines and permit those who require further physician contact for the treatment of their condition to do so. The action of switching these products OTC as well as the decision by many HMOs and major insurers to remove all nonsedating antihistamines from their formularies or to place Rx nonsedating antihistamines in high-copay categories in the wake of Claritin's OTC availability jeopardizes the choice for consumers and potentially severs important patient-physician dialogue. The potential elimination of a prescription option for consumers will shift costs from health plans back onto consumers, substantially increasing consumers' out-of-pocket costs for use of these particular, and necessary, treatments.

Finally, it is simply not within the scope of FDA's mission to unilaterally manage such a significant shift in national policy on prescription versus OTC availability of drug products. NCL urges your committee to conduct an oversight hearing into FDA's policies and actual practices in considering requests to switch individual drugs and/or whole families of drugs from prescription to OTC status.

Very truly yours,

LINDA F. GOLODNER
President

LFG:dm