

STATEMENT
LINDA F. GOLODNER, PRESIDENT
NATIONAL CONSUMERS LEAGUE
BEFORE THE FOOD AND DRUG ADMINISTRATION
NONPRESCRIPTION DRUGS ADVISORY COMMITTEE AND THE
GASTROINTESTINAL DRUGS ADVISORY COMMITTEE
JUNE 21, 2002

The National Consumers League, America's oldest consumer advocacy organization, is pleased to testify today about the possible switch of Prilosec to nonprescription status. NCL has a long history of providing information and educational materials to consumers so they can safely and effectively use medications, both prescription and nonprescription. I would like to inform the committee that occasionally the League receives financial support from pharmaceutical companies for specific consumer education projects in which we maintain full editorial control. In addition pharmaceutical companies have supported our annual dinner and conferences. These contributions amount to less than one half of one percent of our annual operating budget. NCL did not receive any financial incentive to appear at this meeting.

Many of the 60 million Americans who suffer from heartburn are not satisfied with the current OTC medications available. Making Prilosec, a proton pump inhibitor, available without a prescription would provide more options when self-treating heartburn symptoms. Heartburn is one of those conditions that when you have it, you know you have it. Therefore, we feel that consumers can adequately self-diagnose this condition. If this medication were available over-the-counter, consumers would be able to effectively prevent frequent heartburn with Prilosec without having the trouble or expense of a visit to their physician.

Consumers today are taking a more active role in their health care, including self-

38615PHL - 06 - GOLODNER

diagnosing and self-medicating. NCL is working to help consumers understand what medicines they are taking, why they are taking them, and how to take them safely and effectively. Because of this trend to self-medicate, any medication switched from prescription to nonprescription status must first be found by the FDA to be safe and effective for the OTC market. And if allowed on the market, there should be clear, understandable information, available at point-of-sale and through advertising, for consumers to use that product appropriately and safely.

In order to better understand what consumers know about OTC medications and how they are using them, NCL commissioned a survey on consumer use and attitudes regarding nonprescription medicines. According to the survey, consumers generally have a favorable impression of OTC drugs and use them regularly to treat minor health conditions. But one third of consumers do not **regularly** read the labels of OTC products before purchasing or using them. And one-quarter of those surveyed had some trouble reading and understanding the label. Another one-third of the consumers reported taking more than the recommended dose some or most of the time, while more than one in five consumers take OTC medicines for longer than recommended. These survey results underline the need to use clear, good-sized type on the labels and that specific directions for dose and how long to take the medicine be emphasized on the package, on the label, and in any promotional material.

A recent survey by the National Council for Patient Information and Education (NCPIE), a patient education advocacy group of which NCL is on the board and I presently serve as chair, also found that consumers need to be better informed about using OTC medications appropriately. While the survey found that 95% of the consumers read some portion of the label, they do so selectively. When buying an OTC product for the first time, only a third look for the

active ingredient and one in five seek out warning information. Over a third of the consumers combine nonprescription medications when they have multiple symptoms. On a positive note, the survey also found that the majority of consumers get their information about OTC medications from their health professionals, and that the health professionals were very willing to discuss OTC medication use with their patients. What is clear from these surveys is that consumers need to be better informed when using OTC products, but also that the involvement of health practitioners could increase consumer understanding of OTC use.

If the FDA determines that Prilosec, in 20 milligram doses for 14 days, can be taken safely by consumers without a prescription, we recommend that there be appropriate labeling on the medication to ensure proper use by consumers, including clear information about who should not be taking the medication, especially those who take drugs that would interact with Prilosec. There must be clear label directions on how to take the medication, and a specific list of warning symptoms of when consumers should contact their physician. NCL wants to ensure that consumers seek medical attention if the recommended Prilosec regimen does not relieve their heartburn or if they experience certain symptoms. Clear label warnings and information should help prevent consumers from delaying seeking necessary medical attention. Of course the label should also list possible side effects and encourage consumers to continue to have regular physician visits while taking Prilosec. Consumers should also be instructed to inform their physician that they are taking Prilosec, and to contact their physician or pharmacist if they have any questions about the medication.

NCL recognizes that pharmaceuticals are an important component in assuring good health, however, whether by prescription or over-the-counter they must be taken seriously. Just

because a drug is available from the shelf of a grocery store or discount store, does not make it any more safe than if a doctor prescribed the drug. Physicians, nurses, physicians assistants, pharmacists, and other healthcare professionals play a vital role in ensuring that consumers use their medications effectively, and open communications between consumers and health professionals must be strengthened in order for outcomes to improve. If FDA finds that the safety data supports a switch of a medication from prescription to OTC, NCL supports such a switch if there is appropriate labeling and involvement of health practitioners to increase consumer understanding of the risks and benefits of OTCs.