Office of Dietary Supplements Public Meeting

A Consumer Plan for the Future

May 20, 2005

Alison Rein

Assistant Director, Food and Health Policy
National Consumers League
alisonr@nclnet.org



Presentation Overview

- About the National Consumers League (NCL)
- Concerns about the current dietary supplement environment
- Relevant NCL activities and research Findings
- Recommendations for the ODS Strategic Plan



About NCL

- NCL is the Nation's oldest consumer organization
- Since 1899, the League has been providing government, industry, and other organizations with the consumer perspective on numerous health issues, including food and drug safety
- Through research and education, NCL works to help consumers understand appropriate use of medications and other health care products



The Current Environment

- Public concern about disease prevention and health maintenance, coupled with rising health care costs, has driven consumers to take a more proactive role in their health:
 - > OTC drugs
 - Increased use
 - Number of Rx to OTC switches
 - Dietary supplements
 - NHANES data from 1999-2000 (50%)
 - Functional foods
 - Health claims



The Supplement Environment

- Given this environment, it is more important than ever to remind consumers that supplements can have both beneficial and harmful effects
- Because supplements are often portrayed as "natural," and are available in grocery stores, many consumers automatically assume they are harmless
 - ➤ NCL survey 75% thought "natural" meant "safe"



The Supplement Environment

- Dietary supplements provide consumers with a variety of beneficial self-care options
- They also can cause unwanted side effects, and interact – perhaps seriously – with other products
- Until safety and efficacy data for all dietary supplements are available, consumers will need to rely on the informational tools available through ODS and other trusted resources

The Supplement Environment

- In addition to better safety and efficacy data,
 NCL would like to see the following tools available to consumers:
 - Improved supplement labeling
 - Readable, understandable directions,
 - Possible side effect warnings, and
 - Relevant interactions
 - Medwatch # and web address
 - ➤ The Medwatch program must be redesigned to be more user friendly for patients, not just providers



NCL Research and Education Initiatives

- Responding to the more general need to help consumers use medications safely, NCL convenes SOS Rx
 - A collaborative coalition dedicated to improving outpatient medication safety
 - Over 80 participating organizations, including patient, pharmacy, and provider groups, government agencies, industry, academia, and others
 - Embarking on 4 projects:
 - Targeting high risk drug situations
 - Personal medication record (PMR)
 - Clearinghouse of safe practices
 - Electronic prescribing



NCL Research and Education Initiatives

- Recent survey findings indicate the following:
 - Many patients use dietary supplements, even those taking multiple prescription medications
 - Many of those patients do not communicate adequately with their health care providers about all products they are taking
- This suggests that there is a real need to educate consumers about the importance of perceiving dietary supplements as products that can help, but can also do harm

Targeting High-Risk Drug Situations

- Outpatient medication safety campaign aimed at consumers, caregivers, and providers
- An initial focus of this campaign is on oral anticoagulants (blood thinners), which are highly effective for numerous indications, including stroke and coronary event prevention
- Despite the benefit, these agents are known to interact with numerous drugs, vitamins, supplements, and foods



Most oral anticoagulant patients are taking multiple medications

Rx and OTC Use:	%
Number of prescription medications taken on regular basis:	
1 (anticoagulant only)	2
2-4	23
5-7	35
8 or more	38
Mean number of Rx: 7	
Currently taking Plavix on a regular basis	6
Currently taking aspirin as a blood thinner	37
Currently taking any OTCs on regular basis (not including aspirin)	27
Currently taking vitamins or supplements on a regular basis	46



Gaps in patient education

When your doctor <u>first</u> prescribed your anticoagulant, did he or she:	Yes %	No %	Not Sure %
Tell you about any special dietary considerations you should know while taking this medication	74	21	5
Explain potential interactions between the anticoagulant and other prescription or over-the-counter medication, vitamins or supplements	76	19	5
Explain any side effects you might experience when taking the anticoagulant	78	17	5
Tell you symptoms to watch for and when to seek further care or treatment	79	15	6
Give you clear instructions about how to take the medication	94	4	1
Tell you how often you should have your blood tested	96	2	1
Explain to you why you need to take the anticoagulant	98	1	1

PMR Project

"Consumers should have a role in ensuring that a complete, accurate, and updated list of medications & supplements is available to all of their medical care providers so as to maximize therapeutic benefit and minimize the risk of adverse reactions."

- For this project as well, we have conducted research that points to the need for more emphasis on the potential effects of dietary supplement use
 - ➤ In a survey of over 300 seniors in NJ, we learned that almost 50% take at least one supplement in addition to their prescription regimen
 - Only 60% of these seniors shared this information with their medical providers on a regular basis

The ODS Strategic Plan

- The ODS deserves great credit for working to improve the public's knowledge and understanding of dietary supplements
- NCL is greatly encouraged by the Office's research efforts
 - Program for evidence-based review of dietary supplement efficacy and safety
 - Research focused on interactions both beneficial and harmful – between supplements, foods, drugs, and other dietary supplements

Research Recommendations

- Increase the level of research for consumer awareness, attitudes, and behaviors:
 - Do consumers understand the regulatory differences between drugs and supplements?
 - Are consumers able to comprehend supplement label instructions and claims?
 - What are consumer perceptions of risk regarding the use of supplements?
 - From what types of sources are consumers most likely to get information about supplements?

Outreach Recommendations

- Expand and Improve consumer materials:
 - Standardize web-based formats for supplement fact sheets
 - Create separate CARDS database that is understandable and easily searchable for consumers
 - Distribute dietary supplement safety tips and a PMR template – perhaps as part of the MMA / MTM initiative



Outreach Recommendations

- Expand and Improve consumer directed outreach efforts:
 - ➤ Increase collaboration with trusted government and non-government distribution partners to improve message dissemination
 - Expand efforts to reach vulnerable populations, minorities, and those without web access/low literacy
 - Convene regular meetings with media to educate them about recent ODS (and partner) research initiatives and findings, and help them improve communications of benefits/risks to consumers

