



## Council for Responsible Nutrition

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White House Commission on Complementary and  
Alternative Medicine Policy  
6707 Democracy Boulevard, Room 840  
MS 5467  
Bethesda, MD 20892

To the Commissioners:

The Council for Responsible Nutrition (CRN) would like to thank the Commission for the opportunity to submit comments for consideration in the draft interim report. CRN is a trade association representing more than 110 companies in the dietary supplement industry. The comments will address the following topics: (1) coordinated research to increase knowledge about complementary and alternative medicine (CAM) practices and products, (2) provision of reliable and useful information about CAM that can be made readily accessible and understandable to the general public, and (3) guidance for appropriate access to and delivery of CAM.

First, CRN thanks the Commission for inviting Annette Dickinson, Ph.D., to participate in a panel (Oct.6) that discussed coordinated research. In addition to her comments, CRN asks that the Commission recommend mechanisms that would encourage collaboration between industry stakeholders and federal research agencies. For example, the National Center for Complementary and Alternative Medicine (NCCAM) advisory council should include a representative from the dietary supplement industry, particularly one knowledgeable in botanicals. Based on CRN's observations of NCCAM council meetings, an industry expert could best address the frequent questions that arise about these products. The enthusiastic attendance at the recent (May 14) NCCAM colloquium to explore collaborative opportunities with industry sends a clear message that industry researchers would like to participate in studies funded by the National Institutes of Health (NIH). One obstacle is industry's lack of familiarity with NIH grant mechanisms and application process. A NIH workshop tailored to industry researchers would help resolve this obstacle. Unlike pharmaceutical products, dietary supplements are rarely eligible for patent protection. Currently, there is no incentive for the industry to conduct large and costly clinical trials. Collaboration with federal research agencies would accelerate mutual research agendas and benefit consumers.

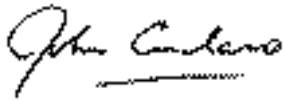
Provision of reliable and useful information about CAM is critically important to consumers and healthcare providers. CRN believes that both NCCAM and the Office of Dietary Supplements (ODS) should do more to inform and educate healthcare providers, scientists and the public. While they can cite outreach and communication efforts, these activities are overshadowed by research operations. Both ODS and NCCAM should be more involved with the media and offer practical and updated information on their websites. Additionally, before large clinical trial results are announced, the funding NIH institute or center should sponsor a media education event to explain the study design and rationale. That way, when results are briefly outlined in a press release or meeting abstract the press would have the proper perspective to frame the study findings accurately. Another concern is publication bias in peer-reviewed biomedical journals. The Commission could propose a meeting of journal editors to solicit recommendations that would increase the acceptance of papers submitted by industry. Additionally, whenever the regulatory status of products is

discussed in a scientific paper, the peer reviewers should include an expert in those regulations. Far too many mistakes and misinterpretations have been published, only to be perpetuated in media reports. The Council of Scientific Editors might be an organization to help with these endeavors.

As outlined in the Findings section of the Dietary Supplement Health and Education Act (DSHEA), Congress found that "legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness." Amendments to DSHEA could compromise consumer access to both products and scientific information. CRN believes concerns about product safety and quality can be addressed through research, self-regulation and government enforcement actions, not new regulations. For example, development of biological assays for standardization of botanical products should be encouraged. The Food and Drug Administration (FDA) should be provided the necessary resources to implement and enforce DSHEA, not as part of a 10-year plan, but in the immediate future. Additionally, the process of authorizing health claims requires serious reconsideration. The current process does not allow reasonable qualified claims that would provide consumers with useful information. Lastly, the Commission should recommend that food stamps be allowed for the purchase of vitamin and mineral supplements.

CRN appreciates the comprehensive work of the Commission and looks forward to the release of the interim report.

Sincerely,

A handwritten signature in cursive script, appearing to read "John Cordaro", with a horizontal line underneath.

John Cordaro  
President and Chief Executive Officer

