



## Council for Responsible Nutrition

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NCCAM Draft Strategic Plan

CRN<sup>1</sup> Comments

CRN will focus comments on Strategic Objective 1: Advance Research on CAM Pharmacological Interventions.

In the United States CAM natural products or CAM pharmacological interventions are the most commonly used category of CAM. Consumers encounter the majority of CAM natural products as dietary supplements and, therefore, the dietary supplement industry is a key stakeholder in the overall mission of NCCAM. CRN is supportive of NCCAM's proposal to apply greater focus and research priority setting in specific areas where dietary supplements show promise in addressing important public health needs.

In the context of limited resources, it is imperative that NCCAM increases support for basic science and mechanistic studies of dietary supplements to better inform the design of clinical efficacy studies. Large clinical efficacy studies are extremely expensive and should not be initiated without insight to biological effect and the potential to measure biological effect via biomarkers, or surrogate markers relevant to the hypothesis. To the extent that resources allow, NCCAM should explore supporting the identification

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<sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. Our 70+ manufacturer and supplier members agree to adhere to voluntary guidelines for manufacturing, labeling and marketing and CRN's Code of Ethics. Learn more about us at [www.crnusa.org](http://www.crnusa.org).

and validation of biomarkers and surrogate end points of disease. In the absence of validated biomarkers as surrogates for disease, study outcomes must assess the disease endpoints directly, rendering assessment of the effects of CAM therapies on disease risk extremely lengthy and costly. Having the ability to rely on surrogate endpoints dramatically improves the feasibility of human trials, both in terms of duration and total cost.

The CAM research community would also benefit from the development and validation of biomarkers that reflect health and wellness. Consumers report one of their primary reasons for using CAM therapies, including dietary supplements, is to maintain and promote health; yet no validated biomarkers of health or wellness exist to allow for the evaluation of the intended effect on consumers. Validated biomarkers of health and wellness would help address a significant challenge faced by CAM researchers and strengthen the research capacity for the entire CAM research community.

CRN is fully supportive of the continued emphasis on product integrity for dietary supplements used as CAM pharmacological interventions. NCCAM's Product Integrity Policy is of paramount importance to ensure that studies are reproducible. CRN supports continued efforts to develop and improve methodology for characterizing and analyzing CAM pharmacological interventions. On page 28 of the NCCAM Draft Strategic Plan, NCCAM identifies that there are a relatively few incentives for private-sector investment in CAM research. We acknowledge that there are limited opportunities to establish intellectual property protection for most CAM natural products such as vitamins, mineral and botanicals and that this creates a disincentive to invest in large clinical trials. However, the dietary supplement industry invests significant resources and has, subsequently, developed extensive expertise in the area of dietary supplement product integrity. NCCAM has stated that it cannot pursue its mission in isolation and has identified collaboration with other NIH institutions, national and international scientific and professional organizations, national governments, and the World Health Organization as instrumental in reaching its goals. CRN opines that NCCAM will also benefit from collaboration with the dietary supplement industry on issues related to product quality and integrity. The industry possesses vast knowledge related to product procurement and ensuring the identity, purity, quality, strength, and composition of the product. Where appropriate, CRN encourages continued collaboration with the dietary supplement industry to help ensure that high quality product is selected for studies on CAM pharmacological interventions. Further, dietary supplement trade associations, including CRN, are well positioned to be instrumental in facilitating NCCAM's collaboration with the supplement industry.

The NCCAM draft strategic plan cites that limited information exists regarding the safety profile for CAM natural products, including data about interactions with prescription drugs. The current evidence base that is used to inform consumers and health care practitioners about supplement-drug interactions and drug induced nutrient depletions is alarmingly deficient. CRN encourages NCCAM to support research in this area to help identify clinically relevant interactions and discourage the current practice of using assumed pharmacological theory, incomplete case studies, and other unreliable information as evidence of a supplement-drug interaction. NCCAM may also consider supporting systematic analysis of the current evidence base for potential interactions pertaining to dietary supplements and drugs with high use. Such an effort directly supports NCCAM's mission as it relates to defining the safety of CAM natural products and their potential to improve health by accurately identifying potential risks and benefits from interactions. The relatively high incidence of use for both dietary supplements and prescription medication (as compared to incidence of use for other CAM therapies) justifies giving the topic of interactions a high priority.

CRN strongly advocates that optimal health is obtained through a combination of healthy habits such as healthy diet, exercise, stress management, and the responsible use of dietary supplements. Data suggest that supplement users also engage in other health seeking behavior, such as regular exercise and visiting with their doctors, and they do so at higher frequency than those not taking supplements<sup>2</sup>. Clinical studies that attempt to isolate one aspect of healthy behavior overlook the potential combined effect of healthy behaviors. CRN is pleased to see NCCAM's recognition of the complexity of studying CAM in real-world settings and supports efforts to develop better tools to investigate multi-component interventions' influence on patient outcomes.

In Health,

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

D. MacKay, ND

VP, Scientific and Regulatory Affairs

Council for Responsible Nutrition

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<sup>2</sup> 2009 CRN Consumer Survey on Dietary Supplements