CRN Comments on the ODS Strategic Plan

March 2009

The Council for Responsible Nutrition (CRN) is the leading trade association representing the dietary supplement industry and was directly involved in development and enactment of the Dietary Supplement Health and Education Act (DSHEA), the legislative initiative that created the NIH Office of Dietary Supplements (ODS). Next year, ODS will have been in existence for fifteen years – long enough to have expanded the scientific study of key nutrients and dietary supplements, and long enough to permit a thoughtful evaluation of what additional strategies might usefully be pursued, to further enhance the ability of ODS to achieve its Congressionally-mandated purposes.

CRN appreciates the opportunity to provide ODS with comments as it proceeds with the development of its 2010 – 2014 Strategic Plan (Strategic Plan)[1]. These comments reflect the collective thoughts and opinions of CRN staff and its membership of over 70 manufacturers, ingredient suppliers, testing laboratories and consulting firms. We trust that these comments will be seen as forthright and sincere, as they both praise ODS for its accomplishments and provide a constructive analysis of its shortcomings. The comments are organized primarily by ODS' main strategic areas, including research support, research tools and outreach followed by comments on ODS' mandate in DSHEA and its advisory role to other government agencies. We are hopeful that these comments will be of assistance to ODS as the strategic planning process proceeds.

As specified by DSHEA, the purposes of ODS are: "(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to

[1] A Report to the Public Office of Dietary Supplements, National Institutes of Health, Fall 2008

improve healthcare; and (2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions."[2] This language very rightly was taken as the basis for the official mission statement of ODS, as follows:

> "The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population."[3]

Scientific research support

DSHEA specified the key duties of ODS, to include supporting and coordinating NIH research and funding relating to the benefits of dietary supplements, compiling scientific research on dietary supplements, and creating a database on dietary supplement research. (See Attachment A for the full text of DSHEA relating to the establishment and role of ODS.) There is no question that ODS has performed admirably in fulfilling its objectives relating to dietary supplement research. Fifteen years ago, many scientists at major universities would have shied away from research dealing with herbs and other botanicals, while today there are half a dozen ODS-funded Botanical Research Centers at leading universities. Fifteen years ago, serious discussions of dietary supplement usage patterns and potential health benefits were rare at scientific meetings, while today such discussions are a routine component of research conferences.

[2] 42 U.S.C. § 287c-11(b)
[3] http://ods.od.nih.gov/about/about_ods.aspx

ODS has excelled in the area of supporting scientific research in large part because of its focus on partnering with the various NIH institutes and with other research institutions including Federal entities such as USDA, CDC, and NIST as well as numerous universities in every region of the country. The four webinars organized by ODS in February 2009 to provide opportunities for discussion of current programs and future research needs turned out to be an impressive display of the wide-ranging influence ODS enjoys within the research community and the degree to which the office and its staff are valued, not only as sources of funding, but also as sources of expertise and as partners in collaboration. ODS is congratulated for skillfully multiplying its limited resources through engagement with partners such as these. Such efforts must definitely continue and even be expanded if resources permit.

One area of expansion that ODS should consider addressing from a research perspective is healthcare savings. It is important to assess whether, and to what extent the use of dietary supplements leads to reductions in healthcare spending, presumably by reducing the risk of chronic disease. Ultimately, public health recommendations involving dietary supplements will be tied to healthcare and associated costs. Therefore, it would be both useful and prudent for ODS to apply its expertise in identifying research gaps for the purpose of understanding if, why and how dietary supplement use can benefit the healthcare system.

<u>Research tools and evaluation.</u>

ODS has also been active in sponsoring evidence-based reviews through the Agency for Healthcare Research and Quality (AHRQ). As currently defined, evidence-based reviews focus heavily on evidence from randomized, controlled trials (RCT) and give relatively little credence to other scientific evidence, including well-conducted observational studies. While RCTs are

needed to establish causality between intake of a substance and an outcome(s) of interest, many of the large, highly publicized RCTs published in recent years may not have been adequately designed to assess nutrient effects. In contrast, most have assessed nutrients using a drug-like model. Although experts in the field of nutrition science have been openly critical of this approach, and justifiably so[4], none have as yet offered an alternative approach with comparable rigor to that established for the classic RCT. Future ODS-funded research involving dietary supplements should be less reductionist in nature and more holistic and integrative. For example, future studies should examine the combination of dietary supplement use combined with other modalities (such as behavior change) with assessment of multiple outcome measures (since nutrients affect all cells and tissues in the body). The main target outcome could be, for example, a global index of health or wellness which would be comprised of multiple individual outcome measures of efficacy (or safety as the case may be). We recommend that ODS investigate the potential for implementation of adaptive trials[5] for assessing chronic disease risk reduction. In such trials data are analyzed on an interim basis and used to dictate the future course of the trial. This approach can utilize biomarkers to identify responders and non-responders and in theory would require fewer subjects to achieve statistical significance, and thus vastly lower the cost of such trials. We recognize there are serious challenges to utilizing adaptive trials including issues related to unblinding and bias, and their high level of complexity. However, we believe this approach is still worth investigating.

The whole topic of evidence-based reviews in the nutrition arena is now receiving extensive scrutiny, and ODS needs to be an active participant in evaluating whether this is the best approach to understanding the complex role of nutrients in health and disease. CRN

[4] Heaney, *J. Nutr*. 2008;138: 1591–1595; Pérez-Escamilla, *J Nutr*. 2007;137(2):478-9; Ames et al. *Am J Clin Nutr* 2007;86:522–5; Heaney *Am J Clin Nutr* 2006;84:471–2

[5] Kuehn, *JAMA*. 2006;296(16):1955-1957

welcomes the opportunity to work together with ODS to address this and other research questions on dietary supplements going forward.

ODS was the moving force behind the 2006 NIH State of the Science Conference on Multivitamins.[6] While a conference such as this can be beneficial when undertaken at the appropriate time, it can be damaging if it focuses on the wrong questions or if it is undertaken at a time when the evidence is known to be inadequate. The multivitamin conference was a prime example of a predictably disastrous outcome. While the most common use of multivitamins is for supporting general health, the conference focused on questions relating to disease prevention and treatment. At the time there was a paucity of RCT evidence on multivitamins and yet the conference demanded a focus on RCTs, completely ignoring observational studies. Furthermore, while the conference name (and resulting conclusions) utilized the term "multivitamin", none of the reviewed research actually involved the traditional multivitamin (i.e. a term commonly defined as a tablet containing at or close to 100% of the daily value for most essential nutrients). In contrast, all of the reviewed research involved single or combinations of several nutrients, but nothing resembling what is commonly referred to as the multivitamin. The outcome was as expected – an influential report that received national press coverage for its conclusion that the evidence for disease prevention with multivitamins was inadequate, and that there was little basis for taking a multivitamin in the first place. This was a conference that should not have occurred when it did, has been misconstrued by both the scientific community[7] and the consumer media to have addressed "multivitamins" as we know them. In the future, CRN urges ODS to include a delegate from CRN and other industry groups in evaluating which topics are appropriate

[6] NIH State-of-the-Science Conference on Multivitamin/Mineral Supplements and Chronic Disease Prevention May 15-17, 2006, Bethesda, MD http://consensus.nih.gov/2006/2006MultivitaminMineralSOS028html.htm
[7] Neuhouser ML, et al. *Arch Intern Med*. 2009 Feb 9;169(3):294-304.

candidates for major conferences and also which speakers are considered to be objective by both ODS and the dietary supplement industry.

Analytical methods and standard reference materials. Until recently, methods of analysis for dietary supplements were woefully lacking, but today through partnerships with AOAC, the National Institutes of Standards and Technology (NIST) and USDA, ODS has made great progress in developing appropriate methods and reference standards.[8] Much remains to be done in the area of methods development and validation, however, and this is one activity where expansion is urgently needed, since scientifically valid and fit-for-purpose methods are a prerequisite for meaningful and reproducible scientific research on any product or functional component and are essential for quality control and compliance with Good Manufacturing Practices (GMPs). CRN has recently become more engaged in ODS' Analytical Methods and Standard Reference Materials program. When the need arises to communicate to the dietary supplement industry specific requests and/or the status of the program and in particular the applicability and acceptability of specific methods, we encourage ODS to take better advantage of CRN and the other trade associations. In addition to utilizing us as a resource to reflect the industry's view on various topics and issues, ODS could utilize CRN to communicate to and solicit specific feedback from our member companies. We believe that to date, this is a resource that has been underutilized by ODS.

Dietary supplement product database. ODS is also making important strides toward creating two comprehensive dietary supplement product databases, one in conjunction with the National Library of Medicine based on product label information and one in cooperation with USDA

[8] http://ods.od.nih.gov/Research/Analytical_Methods_and_Reference_Materials_Program.aspx

based on actual analysis of product content. We are in support of these initiatives, as it is important to understand the amount and extent of dietary supplement use by Americans and the contributions this use makes to overall nutrient intake and nutritional status. This topic was also addressed in a report issued by the Government Accountability Office (GAO), which at the request of Congress, reviewed FDA's ability to regulate the dietary supplement industry.[9] The report stated that FDA should have the authority to require dietary supplement companies to "provide a list of all dietary supplement products they sell and a copy of the labels and update this information annually". This recommendation is based on the expectation that FDA should be aware of the products that are being sold in the marketplace. While we agree with this premise, this appears to be duplicative of ODS' ongoing efforts in this area. CRN encourages ODS to continue with these initiatives and, to avoid needless duplication, provide FDA ready and open access to the databases.

Biomarkers. CRN is also pleased to see in the Strategic Plan the emphasis on development and validation of biomarkers for exposure, efficacy and toxicity. The promise of dietary supplements is in their ability to help maintain health and wellness and avoid chronic disease. From a research standpoint these are extremely difficult and costly endpoints to assess. The dearth of validated biomarkers for surrogate endpoints of chronic disease is a major obstacle for dietary supplement research. Validating additional biomarkers as surrogate endpoints is absolutely essential for the future of nutrition research and the prosperity of the dietary supplement industry. We welcome any and all opportunities to work with ODS on this most important research initiative.

[9] United States Government Accountability Office. Report to Congressional Requesters. DIETARY SUPPLEMENTS: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding. GAO-09-250, January 2009

Outreach efforts

ODS also recognizes the need to engage in outreach efforts, in order to disseminate research results and help the public interpret the results of scientific studies relating to dietary supplements. This is captured in one of the five goals of ODS: "Expand and conduct outreach efforts that inform and educate the public, healthcare providers, and scientists about the benefits and risks of dietary supplements." However, despite this being one of five goals, less than 2% of the ODS FY2008 extramural budget was dedicated to Communications efforts (compared to 73% of FY2008 extramural budget dedicated to research support).[10] CRN recommends that the amount dedicated to outreach and communication be increased substantially to better reflect the importance of this fifth goal.

Within the past several years, ODS has begun efforts to educate the research community on dietary supplements through the establishment of the annual week-long Dietary Supplement Practicum.[11] While we applaud ODS' efforts for both devising the concept and investing the time and resources to organize and execute the Practicum, we would like to offer the help of CRN and other supplement industry associations in the development of and participation in the program. While many of the chosen speakers the past several years possess expertise in scientific and regulatory affairs and consumer and scientific research, few, if any have actually spent time working in the industry; fewer still have actually set foot in a manufacturing facility. These are unique perspectives that could be represented in the Practicum and would provide important first-hand knowledge of how the industry works.

[10] A Report to the Public Office of Dietary Supplements, National Institutes of Health, Fall 2008
[11] http://odspracticum.od.nih.gov/

CRN believes the ODS approach to outreach still needs some further modification, in light of the office's Congressional mandate. The ODS is comprised of scientists with a professional commitment to objectivity, and discussions with the staff make it clear that they believe their ability to thrive within the NIH environment and more generally within the scientific community depends in part on objective assessment of dietary supplements. It is CRN's observation that there are times when the ODS staff's comments appear to be unnecessarily and inappropriately negative, given the organization's mandated mission. Following are a few examples.

At a November 2008 scientific meeting relating to cancer research,[12] an ODS staffer spoke on the subject of dietary supplements and cancer claims, pointing out some egregious examples of unfounded claims. CRN agrees that there are some egregious claims in the marketplace, and CRN fully supports the need to enforce the law and crack down on such claims, but we also believe such claims represent the fringes of the marketplace and are not characteristic of the mainstream of the industry. The ODS speaker made no such distinction but spoke about outrageous claims as though they were typical of dietary supplement marketing, holding the entire category up to ridicule for the entertainment of the audience. This behavior failed to meet the goal of providing scientists and the public with objective information about the overall category of dietary supplements.

ODS staff members frequently make presentations regarding trends in consumer usage of dietary supplements. The typical presentation tracks the size and growth of the industry, beginning from 1994, the date of enactment of DSHEA.[13] This gives or reinforces the impression that industry growth was uniquely fueled by DSHEA, which is not the case. In fact,

[12] Presentation by Mary Frances-Picciano, Ph.D. at the American Institute for Cancer Research Annual Research Conference on Food, Nutrition, Physical Activity and Cancer, November 2008, Washington, DC
[13] Picciano MF, "Who's Taking What?", presentation at ODS Practicum, May 2007, Bethesda, MD

the industry's growth in the two or three decades before DSHEA was also dynamic, and providing a longer view would more fairly describe the phenomenon of the longstanding consumer interest in dietary supplements. Similarly, there is a need to re-examine the data regarding the number of dietary supplement products on the market in 1994 compared to current times. The Strategic Plan asserts that there were only about 4000 products on the market in 1994, compared to an estimated 50,000 in 2008. The 1994 figure is a gross underestimate which needs to be corrected. The figure "4,000" is taken from the "findings" of DSHEA, but it is incorrect and should not continue to be cited as fact. In FDA's 1993 and 1994 initial proposed and final rules for nutrition labeling for dietary supplements, the agency estimated that there were perhaps 25,000 dietary supplement products on the market, of which perhaps 5,000 were vitamin and mineral products.[14] CRN believes the DSHEA figure and the FDA estimate of the number of vitamin and mineral products may have been based on a research report regarding vitamin and mineral supplements used by consumers included in the 1986 National Health Interview Survey, which captured only a fraction of the products in the marketplace.[15] FDA's revised rules for nutrition labeling for dietary supplements in 1997 estimated the number of dietary supplement products to be approximately 29,000.[16] Thus, it would appear that a reasonable estimate of the number of products on the market in 1994 would be in the neighborhood of 25,000 – not 4,000. CRN urges ODS to ensure the accuracy of its statements about the size and growth of the industry, to the same degree that it attempts to ensure the accuracy of its evaluation of consumer usage data. It would also be valuable for ODS to more fully characterize the thousands of products on the market, recognizing that this figure may

[14] Federal Register 58:33715-33731 (June 18, 1993) and Federal Register 59:350-378 (January 4, 1994)
[15] Park YK, Kim I, Yetley EA. Characteristics of vitamin and mineral supplement products in the United States. AJCN 1991; 54:750-759
[16] Federal Register 62:49826-49858 (September 23, 1997)

include hundreds of brands of identical or similar products – hundreds of brands of three to five different levels of vitamin C or vitamin E, for example, or hundreds of different store brands of essentially identical formulations of multivitamins mimicking a handful of leading national brands. To be sure, the figure includes a vast array of distinct product types – but nowhere near 25,000 or 50,000 unique products.

In March 2005, ODS held a public workshop[17] to address some of the controversies and questions raised by a scientific report that misrepresented the safety of vitamin E.[18] One of the objectives of the workshop was to examine the safety of vitamin E for the purpose of determining whether in-process or soon-to-be initiated clinical trials involving vitamin E should continue or be terminated (such as the SELECT trial). The conclusion from the workshop was that there was no safety issue with vitamin E and the trials could continue as planned. An additional objective should have been to inform the public on the status of vitamin E safety, about which the public was tremendously confused at the time. In fact, ODS had indicated that a workshop report would be issued to the public. To this date, the office has not followed through on that commitment. Furthermore, when it subsequently reviewed the safety of supplemental vitamin E, the Agency for Healthcare Research and Quality (AHRQ) concluded "…we find no convincing evidence to suggest vitamin E supplement use increases risk of death per se"[19], this too was poorly disseminated by ODS.

ODS is in the unique position to objectively and credibly comment on issues of such controversy and confusion. The organization possesses the expertise, knowledge base, proper perspective and objectivity the public desperately needs in these instances. This is not to suggest

[17] *Vitamin E Workshop*, March 7-8, 2005, Bethesda, MD
[18] Miller ER 3rd, et al. *Ann Intern Med*. 2005 Jan 4;142(1):37-46
[19] *Multivitamin/Mineral Supplements and Prevention of Chronic Disease,* Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, Rockville, MD. The Johns Hopkins University Evidence-based Practice Center, Baltimore, MD, AHRQ Publication No. 06-E012, May 2006

that ODS should issue conclusive statements when the data do not warrant it, nor should this be viewed as a request for ODS to issue public endorsements for dietary supplements. ODS should not assume that every communication to the public is perceived as a public health statement. On the contrary, what the public simply needs is a bias-free balancing voice.

Dietary supplement fact sheets. Another aspect of the ODS outreach program includes providing dietary supplement fact sheets on the website. Many of the fact sheets on nutritional components of dietary supplements are heavily oriented toward conventional foods and do not appear to have been developed with dietary supplements in mind. In the ODS webinar on communications, speakers emphasized the need for concise and informative web-based materials providing actionable information to consumers. CRN would like to be included in the team that reviews and redesigns the current fact sheets with a view of conveying useful information about the availability, uses, and safety of dietary supplements, in addition to conventional food information from the DRI reports and the *Dietary Guidelines for Americans.*

Bibliography of significant advances in dietary supplement research. ODS is also be commended for the establishment of its Annual *Bibliography of Significant Advances in Dietary Supplement Research.*[20] For the past nine years, this publication has provided a comprehensive collection of some of the excellent research conducted and published on dietary supplements on an annual basis. CRN believes the *Bibliography* has served as a valuable resource for industry stakeholders and that it should continued to be published annually. However, we also believe that to date the *Bibliography* has not been leveraged or utilized to its full potential. Future iterations should be translated into forms of communication that can be recognized and

[20] http://ods.od.nih.gov/Research/Annual_Bibliographies.aspx

understood by the various stakeholders, including healthcare professionals, members of Congress and consumers. This recommendation comes, not as a means to provide stakeholders with a comprehensive review of the evidence supporting the use of dietary supplements, but instead to demonstrate that high quality research is being conducted on these products.

ODS mandate from DSHEA to advocate for dietary supplements

There is support for the proposition that Congress intended for ODS to serve as an "advocate" for dietary supplements. CRN staffers and many CRN members were actively involved in the development of DSHEA, and were involved in extensive discussions regarding the placement and role of ODS. DSHEA was enacted largely for the purpose of ensuring the continued availability of a wide range of dietary supplements, at a time when FDA appeared to be planning to restrict such availability (as discussed in an Advance Notice of Proposed Rulemaking published in the Federal Register of June 18, 1993).[21] In addition to addressing the immediate problem, however, the legislators involved in enacting DSHEA also sought to address the underlying issue, which appeared to be a bias against dietary supplements within FDA and within some segments of the scientific community. They sought to redress that bias by creating an Office of Dietary Supplements within the government, prominently placed in order to wield meaningful influence, but grounded in science. After much discussion of alternatives, the legislators decided that placement of ODS within NIH would provide the best outlook both for enhancing the science base and for creating an authoritative voice for dietary supplements.

A Senate report on DSHEA provides insight into the thinking behind the creation of ODS.[22] The report, submitted by Senator Hatch from the Senate Committee on Labor and Public

[21] Federal Register 58:33690-33700 (June 18, 1993)
[22] Senate Report on DSHEA, Senate Report 103-410, October 8, 1994

Welfare, indicates that the purpose of ODS "is to coordinate research on dietary supplements, serve as an advocate within NIH and HHS for dietary supplements, and advise the Secretary and senior officials on dietary supplement issues." (See Attachment B for the text of the section of the Senate Report dealing with the role of ODS.) While the ODS staff may not be comfortable with the role of being "advocates" for dietary supplements, CRN believes they should seek to be more balanced in their public statements and should also strive to provide more balance based on the totality of the evidence when asked to comment on negative scientific findings or reports.

ODS as advisor to NIH, CDC and FDA

In enacting DSHEA, Congress assigned an additional duty to. DSHEA directed ODS to serve as "the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements," including regulatory issues, the safety of dietary supplements, claims about disease prevention and health maintenance, and scientific issues relating to labeling or product composition. CRN suggests that this public policy advisory role for ODS could be just as important as the groundbreaking work ODS has done in the scientific arena. Undoubtedly ODS has performed this function from time to time behind the scenes, but there may be an opportunity to expand this aspect of the ODS activities. In fact, in one of the ODS webinars in February 2009, FDA's Dr. Vasilios (Bill) Frankos specifically urged ODS to amend its Strategic Plan to incorporate the goal of serving as an advisor to FDA on dietary supplements, including testing of products as needed and evaluating safety. This was later reiterated in the GAO report which recommended that the Agency conduct more consumer outreach and education on dietary

supplements.[23] CRN generally agrees with the recommendation that more consumer education is needed on dietary supplements, but we believe that ODS is better positioned to carry out this task than the regulators who are charged with policing the industry. As such, CRN recommends that ODS include in its Strategic Plan an emphasis on consumer education in a manner that at a minimum supplements FDA activities.

Finally, speaking on behalf of CRN's staff and its member companies, we would urge ODS to more actively engage the trade associations representing the responsible dietary supplement industry as partners and collaborators in planning and implementing its activities. CRN is pleased to have this opportunity to join other members of the public in commenting on the ODS Strategic Plan, but would welcome a more substantive relationship, perhaps as a member of a stakeholder advisory committee, analogous to the existing Federal Dietary Supplement Working Group. At present, the Working Group consists of solely NIH scientists with a few FDA staff. In addition to its existing members, the Working Group might be composed of an additional six to eight stakeholders, selected upon through application, and include up to two consumer groups, two to three trade association representatives, and a specialist in administrative law. We believe that balancing the group in this manner would provide ODS a source of regular and more efficient feedback regarding its efforts and also help ODS to better understand the dietary supplement marketplace.

CRN congratulates ODS on almost 15 years of growth and development, and we look forward to working with the ODS staff on initiatives that will further expand the scientific base underlying the public's intense interest in dietary supplements.

[23] United States Government Accountability Office. Report to Congressional Requesters. DIETARY SUPPLEMENTS: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding. GAO-09-250, January 2009

Respectfully submitted,

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Attachment A: Language of DSHEA regarding establishment and role of ODS

ESTABLISHMENT: The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

PURPOSE: The purposes of the Office are—

(1) To explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve healthcare; and

(2) To promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

DUTIES: The Director of the Office of Dietary Supplements shall –

(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

(2) Collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including –

(A) Dietary intake regulations;

(B) The safety of dietary supplements;

(C) Claims characterizing the relationship between –

(i) Dietary supplements; and

(ii) (I) prevention of disease or other health-related conditions; and

(II) Maintenance of health; and

(D) Scientific issues arising in connection with the labeling and composition of dietary supplements;

(4) Compile a database of scientific research on dietary supplements and individual nutrients; and

(5) Coordinate funding relating to dietary supplements for the National Institutes of Health.

Attachment B: Language of Senate Report on DSHEA, Senate Report 103-410, October 8, 1994, Section pertaining to ODS (p. 20 of report)

Section 13 authorizes $5 million to establish at the National Institutes of Health a new Office of Dietary Supplements. The purpose of this office is to coordinate research on dietary supplements, serve as an advocate within NIH and HHS for dietary supplements, and advise the Secretary and senior officials on dietary supplement issues.

It is not the intent of the Committee that in establishing this new office the NIH have any regulatory authority over dietary supplements. Rather, the committee envisions that the new office will serve an advocacy role within the Department of Health and Human Services, providing scientific information about these products which can be used in both the regulatory and policy-making processes.

The Committee is hopeful that the National Institute of Health will devote increased attention both to research in dietary supplements and dissemination of research findings to the public in terms that the lay public can understand.

The Committee commends the NIH Office of Alternative Medicine for its recent conference on the "Role of Botanicals in American Healthcare."

(emphasis added)