SYNOPSIS OF RECOMMENDATIONS FROM PRESENTATIONS, DISCUSSIONS, AND COMMENTS

from
A Public Meeting
of the
Office of Dietary Supplements (ODS), National Institutes of Health
held on
May 20, 2005 in Bethesda, Maryland

The revised ODS Strategic Plan for 2004-2009, *Promoting Quality Science in Dietary Supplement Research, Education, and Communication*, was adopted in January 2004. It included recognition of a possible need for mid-course modifications during the five years. This Public Meeting was one of several activities related to maintaining the currency of the ODS Strategic Plan. It provided an opportunity for representatives of the ODS stakeholder community and other interested parties to comment on the revised Strategic Plan and its five goals (see Appendix). Participants were asked to identify emerging needs and opportunities for possible inclusion in the ODS program portfolio. In addition, comments were solicited from persons and organizations unable to attend the Public Meeting.

The recommendations made by one or more of these participants are listed under four major headings: General, Research, Education, and Communication. "General" recommendations include aspects of each of the five goals of the Strategic Plan, and "Research" recommendations are related to one or more of goals 1-4. The recommendations on "Education" are related to one or more of the five goals, while those for "Communication" primarily address goal 5.

General

- Since its inception, ODS has been a driving force in dietary supplement research, education, and communication. It should increase its efforts to meet this mission within its intellectual and fiscal resources and with the same high scientific quality that has marked its programs in the past.
- The resources available to ODS are not sufficient to meet its broad mission. Therefore, ODS needs to examine its programs and activities continually to maintain both balance and focus in its portfolio. ODS should examine its utilization of resources annually and revise its priorities and efforts within and among the five goals of its Strategic Plan. Initially, this review should focus on projects and activities that have been in place the longest and have received large amounts of support for several years.
- A more proactive stance in initiating and supporting evidence-based reviews (EBRs) of supplements, especially those supplements in widest use should be implemented. The need for EBRs to evaluate available scientific knowledge and gaps in that knowledge will increase as the funding of research requires more prioritization, the public's need for reliable information about dietary supplements grows, and government decision-making processes require a stronger base of scientific support. In addition, these EBRs can assist the ODS in prioritizing its support of programs and activities in succeeding fiscal years. (See related recommendation under “Research” below.)

- Give consistent attention to the major tenet of ODS's mandate to be the preeminent source of sound information on the quality, safety, and efficacy of dietary supplements for many audiences, including the general public, the federal government, and research scientists.
- Explore the potential for the ODS having independent grant-making authority. Such authority would provide ODS with additional capacity, flexibility, and autonomy to carry out its public mandate to foster more research on supplements.
- Establish a "gift fund" for unsolicited financial contributions from various sources. The funds collected should be used to support aspects of the ODS communications program that to date have had lower priority because of budget limitations.

Research

- Expand the emphasis on interdisciplinary research approaches in investigating the biological and cellular effects of dietary supplements. Whenever possible, incorporate the techniques emerging from new research concepts and technologies.
- Conduct EBRs on the 10-20 most commonly used dietary supplements to provide an objective basis for considering future research needs on the safety, efficacy, and biological activity of these substances. Consider conducting abbreviated EBRs to meet this recommendation when the scientific literature on a supplement is known to be fragmented or limited.
- Increase support for the Analytical Methodology and Reference Materials Program. The pending adoption of good manufacturing practices (GMPs) for dietary supplements will require additional validated analytical methods and standardized reference materials for research and labeling of safe and effective products.
- Integrate relevant objectives of the Analytical Methodology and Reference Materials Program with those of the Botanical Research Centers initiative as well as other multiyear projects (including the ODS-sanctioned training laboratories recommended below under "Education").
- Develop and support and develop a comprehensive database of dietary supplements that codes products by brand name, ingredients, and other relevant criteria. Such a database would greatly aid researchers in assessing the extent to which supplements contribute to nutrient intake and how their biological effects may affect health and reduction of disease risks.
- Facilitate collaborations with relevant public and private-sector organizations that support and conduct research on dietary supplements, giving attention to the need to undertake investigations utilizing appropriate analytical, pre-clinical, and clinical study protocols in such studies.
- Consider increasing support for research on these topics:
    - Interactions among dietary supplements, foods, and drugs, including additional emphasis on a wider range of botanical supplements, and substances such as enzymes, probiotics and other biologicals.

- The potential value of supplements in reducing risks of debilitating chronic diseases such as inflammatory disease and the metabolic syndrome.
- The influence of composition and various forms of nutritional supplements in meeting the needs of various subsets of the population as well as individuals with special nutritional requirements.
- Consumer use of dietary supplements, including reasons and motivations for use, their understanding of supplement label information (e.g., instructions for use and claims), and their most common sources of supplement-related information.
- Development of more and better biological markers and measurable biological endpoints that characterize the consumption of specific dietary supplements. Such studies should focus on supplements for which standardized reference materials are available.
- Development of clinical-study methodologies that better evaluate the biological consequences of consuming dietary supplements whose chemical composition is incompletely characterized.

Education

- Focus educational programs on the most commonly used dietary supplements and their potential roles in health and the prevention and reduction of risks of major chronic diseases.
- Foster a shared sense of the mission and goals of ODS within institutions of higher learning that will enable investigators in such institutions to acquire the necessary knowledge and skills to conduct high-quality research on dietary supplements.
- Explore opportunities and expand efforts to use recognized approaches for educating various groups about dietary supplements. These approaches include small training grants from both public (such as the National Institutes of Health [NIH] , the United States Department of Agriculture, the Department of Defense, and the Department of Education) and private sources (such as foundations and industry); travel awards for young investigators and graduate students; support of short courses on specific research techniques and tools; publication awards; and sabbatical and intern appointments within ODS and the NIH units that conduct research and training relevant to the goals of the ODS Strategic Plan.
- Explore opportunities and expand efforts to use innovative and new approaches to educate various audiences about dietary supplements. These might include establishing a network of ODS-sanctioned training laboratories that emulate the currently funded Botanical Research Centers, Clinical Nutrition Research Centers, and similar NIH centers.
- Expand the use of the mass media (television, video, etc.) as an educational approach across the communications program by partnering with other public and private sector organizations with mutual interests.

- Educate selected media representatives (such as science, health, and consumer-affairs reporters) about supplement issues to enhance their capabilities to provide scientifically sound and practical information about these products.
- Increase education and outreach efforts for specific programs, particularly the Analytical Methodology and Reference Materials Program and the clinical investigations of the safety and efficacy of specific dietary supplements.
- Expand educational programs to increase the communication between healthcare providers and patients about dietary supplement issues. For example, health care providers should learn what supplements patients take and patients should know that this information is important.
- Take a more active role in improving nutrition globally by exploring opportunities to partner with national and international organizations that have mutual interests.

Communication

The majority of observations, suggestions, and recommendations received addressed one or more aspects of current ODS communication activities and additional opportunities that the ODS should consider. For this reason they are grouped into several categories.

Outreach materials and approaches

- Develop a comprehensive plan to increase the visibility, frequency, availability, and distribution of ODS products, including its Web site, newsletter, listserv, and fact sheets.
- Give greater attention to producing scientifically sound products (e.g., fact sheets) that are updated in a timely fashion to incorporate important new research and information addressing issues and controversies. This activity is fundamental to meeting the ODS mandate to be the preeminent source of credible scientific information on the safety and efficacy of dietary supplements.
- As with the ODS educational programs, give priority across the ODS communications activities that focus on the most commonly used dietary supplements and their potential roles in optimizing health, influencing health care delivery practices, and reducing the risks of major chronic diseases.
- Increase the user-friendliness of ODS materials, including the Web site and Fact Sheets. One way is to present the information in a uniform and consistent format whenever possible.
- Emphasize the importance of publishing the results of research on dietary supplements. Such efforts would provide more useful information not only on the safety and efficacy of these products but also provide users of such information with the scientific data that they may need for other purposes.
- Provide more information on interactions between food, drugs, and dietary supplements in currently available outreach materials. Explore preparation of a separate pocket guide on interaction information.
- Add links on the ODS Web site to other information sources on dietary supplements and indicate the scientific objectivity and completeness of that information.

- Continue publication of the *Annual Bibliography of Significant Advances in Dietary Supplement Research*, but include more consumer-oriented reports from peer-reviewed publications.
- Provide more information on dietary survey methodology, dietary supplement use, and the content of publicly available databases.

Communicating with the public

- Communicate dietary-supplement-related science in ways that serve both public understanding and the goals of the ODS Strategic Plan. Communication of health messages to the public requires use of approaches and techniques known to be effective. ODS should seek and can benefit from advice, experience, and proven approaches developed by public and private sector organizations on communicating the science of nutrition and dietary supplements (see related recommendation in next section).
- Ensure that ODS databases are not only easily accessible and publicly available but also understandable and searchable with contents that are designed for the broad interests of the ODS stakeholder community.
- Expand efforts to reach vulnerable populations, minorities, and individuals with low literacy skills and/or without computer access.
- Explore ways to provide materials in languages other than English as an approach to reaching wider audiences.

Communicating with other professional stakeholders

- Expand collaborations with relevant public and private-sector organizations to communicate scientific information to the public about supplements. In this regard, various scientific societies, professional organizations, trade associations, consumer-advocacy groups, and other entities together with the public information offices of the Department of Health and Human Services, NIH, FDA, and other federal departments have mutual interests with ODS. Explore and implement collaborative and cooperative partnerships where appropriate.
- Re-examine the relative emphasis within the ODS communications program that ODS places on reaching various segments of its user community in terms of approach, format, message content, and specific information needs. Ensure that the media (print, radio, television, etc.), educators at various levels, and healthcare providers are recognized as important components of the user community.
- Exhibit at selected national scientific, professional, and industry meetings and use these as opportunities to educate and communicate with important ODS stakeholder groups.

Communicating with the federal government

- Develop and implement more formal and efficient mechanisms to communicate with federal partners. The enabling legislation that established ODS states that its director will "serve as the principle advisor to the Secretary and to the Assistant Secretary of 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 the Food and Drug

Administration on issues related to dietary supplements....." While ODS has addressed this role informally in the past, it requires greater attention in the future. In addition to those areas specified in the ODS enabling legislation, consider expanding proactive efforts to include the following:

- Stimulating consensus building on issues such as trans-agency or trans-NIH research initiatives.
- Providing EBRs and other synopses of scientific information that might have an impact on regulatory decision-making and policy determinations.
- Identifying federally sponsored web sites that provide publicly available information on dietary supplements, taking the lead in efforts to both address the consistency of the scientific bases of the content, and linking these sites more efficiently.

New initiatives

- Make ODS scientific staff more available to the media. For example, convene workshops at professional meetings of writers, publishers, and other media representatives that would focus on dietary-supplement issues and approaches to reporting the state of science that supports responsible use of dietary supplements.
- Sponsor an annual national conference focused on scientific studies that support the understanding of dietary supplement safety and efficacy.
- Prepare an annual report addressing progress on meeting the goals of the ODS Strategic Plan and significant outcomes from each program.

APPENDIX

ODS MISSION STATEMENT

The mission of ODS has been and continues to be 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.

GOALS of the STRATEGIC PLAN for 2004-2009

1. Expand the evaluation of the role of dietary supplements in disease prevention and in reduction of risk factors associated with disease.

2. Foster research that evaluates the role of dietary supplements in maintaining and improving optimal physical and mental health and performance.

3. Stimulate and support research to further understanding of the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.

4. Promote and support the development and improvement of methodologies appropriate to the scientific study of dietary supplement ingredients.

5. Expand and conduct outreach efforts that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.