

Promoting Quality Science in Dietary Supplement Research, Education, and Communication

A STRATEGIC
PLAN FOR THE
OFFICE OF
DIETARY
SUPPLEMENTS:
2004-2009

The Office of
Dietary
Supplements

Office of the
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Promoting Quality
Science in Dietary
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February 3, 2004

Congress enacted the Dietary Supplement Health and Education Act of 1994 to address growing public interest in the potential value of dietary supplements in maintaining optimal health and reducing the risk of disease. This law established the Office of Dietary Supplements (ODS) in 1995 at the National Institutes of Health (NIH) in the Department of Health and Human Services. The goal in creating ODS was to coordinate and conduct basic and clinical research, develop education and communication programs directed to all segments of the public and private sectors with an interest in dietary supplements, and coordinate federal efforts related to issues associated with dietary supplements. The first strategic plan for ODS, published in 1998, was entitled "Merging Quality Science with Supplement Research: A Strategic Plan for the Office of Dietary Supplements." It has guided and challenged ODS during its early years and has provided a solid basis for program development and support of ODS activities. I am heartened by the progress made since then in all of these areas.

However, times have changed and another major leap forward is needed. The store of human knowledge has expanded exponentially. The impact of discoveries about the human genome on health and disease is being realized. Emerging techniques in both the physical and biological sciences have provided new opportunities in the study of dietary supplements for promoting health and reducing the risk of chronic diseases. We anticipate that, by 2009, major changes will have occurred in how research is conducted, what research will be needed or possible, what training and education are needed to meet these changes, and what techniques of public communication ODS must be prepared to meet these changing circumstances.

To accomplish this task, ODS initiated a strategic planning process in 2003 to guide activities and programs for its next 5 years. A background paper that reviewed programs and initiatives of ODS from 1995 to 2003 was prepared and made available on the ODS Web site. A public meeting was held in May 2003; invited speakers and small discussion groups identified both opportunities and needs in research, communication, education, and coordination of efforts with other organizations. In addition, comments on the background paper and topics for inclusion in a revised strategic plan were solicited from the ODS constituency via its Web site.

I sincerely appreciate the thoughtful counsel of my colleagues and of individuals and organizations in the broad community that ODS serves. All of the information and views garnered in the strategic planning process have been used in the synthesis of this revised ODS Strategic Plan, "Promoting Quality Science in Dietary Supplement Research, Education, and Communication: A Strategic Plan for 2004-2009." The goals for ODS in the coming years are consistent with those of the NIH Roadmap Initiative announced by the NIH director, Dr. Elias Zerhouni.

I encourage you to communicate with us as we progress toward our common goal of enhancing quality research to provide scientifically sound information to the public.

Sincerely yours,



Paul M. Coates, Ph.D., Director
Office of Dietary Supplements



Executive Summary

The review of ODS activities and programs developed under the five original goals led to two general conclusions. First, these goals provided a sound framework to guide ODS programs from 1998 to 2003. Second, each goal addressed an essential part of the framework but the goals were interdependent. Thus, the original goals essentially have been retained as the focus of ODS programs in 2004-2009. The goals and initiatives presented in this plan for 2004-2009, just as those developed in the first plan in 1998, emphasize the important role of ODS in research, education, and communication.

Goals:

- 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 activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.

ODS will promote quality science in dietary supplement research, education, and communication by placing greater emphasis on the use of emerging technologies and greater emphasis on cross-disciplinary studies, expanding the infrastructure of human resources, fostering translation of research results, and establishing a process for regular evaluation of ODS programs and activities. The ODS strategic plan for 2004-2009 provides a roadmap for ODS to address both current and future research, education, and communication needs and opportunities related to dietary supplements.



Background

THE INITIAL YEARS: 1994-1998

Interest in and use of dietary supplements has grown exponentially in the past two decades. Public concerns about disease prevention and control now include increased attention to the prevention and management of chronic diseases. Wider appreciation for the role of nutrition and the discovery and widespread use of vitamins and minerals also contributed to improvements in public health during this time. A complementary component of this trend has been heightened public awareness of personal responsibility for maintenance and improvement of health and well-being as costs of health care continued to rise. Thus in the past 20 years, public attention and the use of natural products to improve the quality of life, enhance performance, and prevent chronic debilitating diseases have increased significantly.

In many cases, however, verification of the composition of dietary supplements and scientific evidence validating claims was fragmented or missing. Public need for information about dietary supplements has driven the quest for research on the effectiveness and safety of these products and dissemination of such information.

To preserve the public's access to dietary supplements, Congress passed the Dietary Supplement Health and Education Act (DSHEA; Public Law 103-417) in October 1994.¹ This bill amended the Federal Food, Drug, and Cosmetic Act and addressed aspects of that law relating to the definition, composition, and labeling of, and claims for dietary supplements. DSHEA also acknowledged the interest in improving and expanding the scientific basis for supplement use and in providing the public and health providers with information to guide the making of informed decisions on supplement use. DSHEA established the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) to address these scientific and informational issues.

- The legislation included two overarching mandates for ODS that govern its activities:
- “Explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care...”
 - “Promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions...”

DSHEA also charged the ODS director with several responsibilities and duties that include efforts to:

- Conduct and coordinate research within NIH on dietary supplements and the extent to which their use can limit or reduce the risk of diseases,
- Collect and compile results of research on dietary supplements,
- Provide advice to other Department of Health and Human Services (DHHS) agencies related to dietary supplements, and
- Compile a database of scientific research on dietary supplements and nutrients.

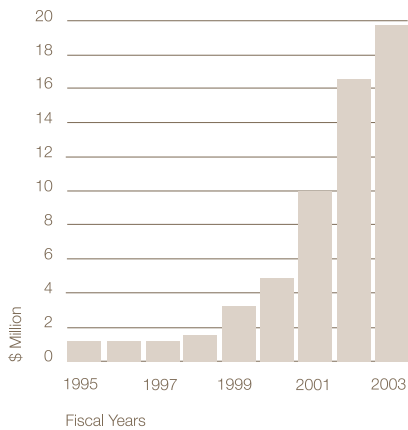
Scientific Goals of the Original Strategic Plan

- 1 Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease.
- 2 Evaluate the role of dietary supplements in physical and mental health and in performance.
- 3 Explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.
- 4 Improve scientific methodology as related to the study of dietary supplements.
- 5 Inform and educate scientists, health care providers, and the public about the benefits and risks of dietary supplements.

ODS was formally established on November 27, 1995, within the Office of Disease Prevention in the Office of the Director at NIH. The NIH associate director for disease prevention met with representatives of professional, scientific, and trade organizations interested in dietary supplements to determine the state of scientific knowledge on substances, ingredients, and preparations considered to be dietary supplements. Discussions were also held on approaches to developing the several databases on these topics that were mandated by DSHEA.

During the following months, the first ODS director, Dr. Bernadette M. Marriott, met with NIH institute and center (IC) directors to present the purposes and possible activities of ODS and identify areas of common interest. She also expanded the dialogue with representatives of the scientific community, industry, other agencies of the federal government, and the public to engage their participation in the future development of ODS. In 1998, after a series of public meetings, a mission statement was formulated and these efforts culminated in publication of the ODS mission and a 5-year strategic plan.²

The strategic plan identified five equally weighted goals and proposed objectives within each goal. Each scientific goal was responsive to the Congressional mandates and was incorporated as a critical component of the ODS mission. The objectives related to specific scientific areas proposed by the participants in the strategic planning process and helped to form the suggested research priorities for the next 3-5 years. ODS has focused its efforts on the five goals and many of the objectives within each.



Since its modest beginnings in 1995 and identification of strategic goals in 1998, ODS has expanded efforts to address these goals as programs have been developed and results of research published. The funding for ODS programs from 1995 to 2003 is shown in Figure 1. In 1998, ODS funded four small research grants; by 2003, the ODS research portfolio included 69 grants for investigator-initiated research, the funding of 6 botanical research centers, and 9 training and career development grants. In addition, 10 interagency agreements were in place, covering such topics as analytical methods validation, database development, and evidence-based reviews. All of these efforts are funded in collaboration with 16 NIH ICs as well as 6 non-NIH federal agencies and private sector organizations.

In 2003, ODS had eight scientific and two full-time support staff as well as 10 contractors engaged in scientific and administrative support activities. In addition to the director, the deputy director and each of the senior scientific staff manage one or more of the ODS programs. Since its inception, ODS has used contractors to augment staff; for example, science writers, copy editors, meeting coordinators, and scientific consultants have been assigned to specific projects. In addition, ODS has benefited from the advice and counsel of over 300 professionals from academia and industry. They have assisted in the drafting of scientific documents, provided peer review of research proposals and manuscripts, and aided in the development and evaluation of ODS programs.

1 Annual Congressional appropriations to ODS: 1995-2003



PROGRAMS AND PROGRESS: 1998-2003

Increasing financial support accelerated implementation of the goals in the original strategic plan. Each program that was initiated is consistent with the mandates of DSHEA and with the five broad goals that formed the basis of the strategic plan.

During the past 5 years, ODS has:

- Organized and sponsored conferences and workshops on topics identified in the strategic plan;
- Supported research using existing NIH mechanisms ranging from individual basic research projects such as grants to more complex research activities with NIH ICS (e.g. the botanical research centers);
- Provided support for research of mutual interest to other federal agencies through cofunding, cooperative agreements, and contracts;
- Identified and supported evidence-based reviews such as the Agency for Healthcare Research and Quality (AHRQ) report on the safety and efficacy of ephedra;
- Initiated a program to enhance analytical methodology and develop standard reference preparations of dietary supplements for basic and preclinical research and clinical studies;
- Participated in support of training and career development both within NIH and in academia;
- Developed an ODS Web site, an ODS listserv, and, recently, an ODS newsletter;
- Created publicly available databases such as International Bibliographic Information on Dietary Supplements (IBIDS) and Computer Access to Research on Dietary Supplements (CARDS);
- Prepared fact sheets on vitamins, minerals, and botanicals; and,
- Supported and strengthened collection and dissemination of data on use and characteristics of dietary supplements.

Additional information about these programmatic efforts is available on the ODS Web site and in the 2003 *Background Paper for Strategic Planning for 2004-2009*.³

NIH has experienced a remarkable growth in support, with an approximate doubling of its budget from 1998 to 2003. This support has been accompanied by recognition of the need for collaboration across scientific disciplines and, within NIH, across ICS and for increased emphasis on translation of scientific knowledge to improvements in health and welfare of the public. Since its inception in 1995, ODS has fostered collaborative endeavors and transfer of results of scientific investigations to practical application to public health improvements as central precepts of the ODS mission.

HOW ODS WORKS

ODS has played a critical and expanding role in fostering collaborative scientific activities within NIH, within DHHS, and across other federal agencies and the private sector. Over the period of the last strategic plan, 1998-2003, the annual ODS budget expanded from \$3.5 million to just under \$20 million. This growth provided exciting new opportunities for research, research resources, workforce training, and information programs that could only be contemplated when the plan was originally written.

ODS leverages its fiscal resources by using existing mechanisms of NIH and the federal government to further scientific knowledge and understanding of dietary supplements. This requires cooperation and collaboration with the NIH ICS, other federal agencies, and private-sector organizations and institutions. Since its inception, ODS has used two complementary approaches to accomplish its mission.

2 Flowchart of outcomes of an ODS initiative on dietary supplement bioavailability.

Abbreviations:

AOACI = AOAC International;

DS = Dietary Supplement;

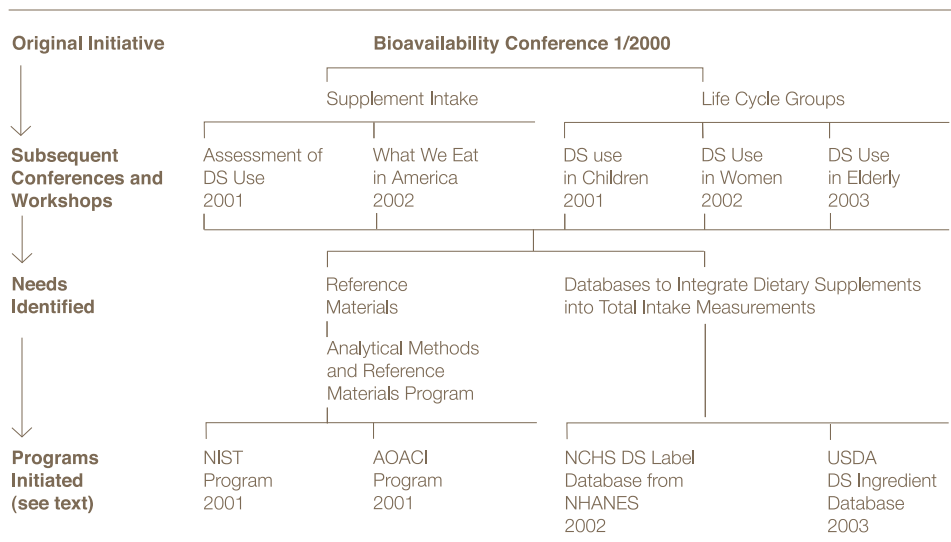
NCHS = National Center for Health Statistics;

NHANES = National Health and Nutrition

Examination Survey;

NIST = National Institute for Standards and Technology;

USDA = U.S. Department of Agriculture



In the first approach, ODS identifies issues and topics that are central to its mission and goals. Workshops and conferences on topics of interest bring together interested parties and serve to elaborate research needs and opportunities for investigation and concomitantly strengthen communication among interested parties. These issues and topics are discussed with relevant NIH ICs, DHHS agencies, other federal agencies, and private-sector organizations and institutions whose mandates and interests include these issues. For example, ODS has used conferences and workshops to determine interests in and opportunities for emphasizing research.

Similar approaches have been used by ODS in the quest for improved methodologies for the study of dietary supplements where shared interests have been identified beyond those of NIH. ODS has collaborated with other federal agencies and private sector organizations and institutions to address such diverse topics as epidemiological survey methodology, analytical chemical techniques for isolation and identification of bioactive ingredients, and electronic database development.

Figure 2 illustrates these approaches to stimulating cooperative and collaborative research efforts among NIH and other federal agencies with common interests in identification and use of dietary supplements. An open ODS conference in early 2000 on the bioavailability of dietary supplements identified several major needs and opportunities for the development of research resources and initiation of research programs. The need to incorporate supplement intake into total dietary intake measures led to further discussions with the U.S. Department of Agriculture (USDA) and the National Center for Health Statistics.

ODS has supported the collection of data on dietary supplement use in the National Health and Nutrition Examination Survey and the NIH-funded USDA National Food and Nutrient Analysis Program. Data from these efforts have identified the need for more data on quantitative and qualitative aspects of dietary supplement intake. This has led ODS to develop the concept of a dietary supplement ingredient database (DSID). A second ODS research program focuses on development of analytical methodology to characterize active ingredients and prepare standard reference materials. Output from this effort will provide standardized methods and materials that can be used in collecting data for DSID. These will, in turn, undergird efforts by making dietary supplement preparations of known content and analyzed by standardized methods available to investigator-initiated research and clinical studies. Ultimately, DSID will provide data on composition of dietary supplements useful in evidence-based reviews and dissemination of appropriate accurate, substantiated scientific information to the public.

In addition to the needs identified and programs initiated noted in Figure 2, the conference on bioavailability and the three conferences on the life cycle noted in Figure 2 also led to the initiation of specific research programs within ODS and cooperatively with NIH ICs. These programs included Diet, Methylation Processes and Health (RFA CA-03-016) and Role of S-Adenosyl-Methionine in the Treatment of Alcoholic Liver Disease (RFA AA-02-011). These four conferences also resulted in organization of NIH workshops to clarify the specific need to establish research programs focusing on nutritional genomics and proteomics in cancer prevention, the role of iron in alcoholic liver disease, and vitamin D and health in the 21st century. Information about these initiatives is available on the ODS Web site (<http://ods.od.nih.gov>).

ODS also recognized the need for evidence-based reviews of dietary supplement efficacy and safety. The 2003 review *Ephedra and Ephedrine for Weight Loss and Athletic Performance* by the Evidence-Based Practice Centers Program of AHRQ was initiated and supported by ODS and the National Center for Complementary and Alternative Medicine⁴ (<http://www.ahrq.gov>).

In the second approach, ODS identifies ongoing and emerging programs within the ICs where a potential role for research, education, and communication about dietary supplements can be explored. This activity identifies issues requiring specific knowledge about dietary supplements. As a result, ODS input can improve aspects of planned or ongoing studies such as study methodology and outcome measurement. ODS can also support the addition of a research objective concerning dietary supplements to a request for applications or a program announcement where common investigative purposes are optimally served. To obtain ODS support, the NIH institute or center sponsoring an investigator-initiated grant may be asked to add an objective related to dietary supplements—for example, the addition of data collection on the use of dietary supplements to the design of the International Population Study of Macronutrients and Blood Pressure. Similarly, ODS has participated in initiatives of the Fogarty International Center such as research on micronutrient supplementation in developing countries.

Thus, working in collaboration with and using existing mechanisms of organizations within and outside NIH, ODS has been able to stimulate research and educational programs and, at the same time, put greater emphasis on communication about the role of dietary supplements in health and disease. In pursuing and funding these activities, ODS adheres to the evaluation criteria set forth in the original strategic plan. ODS will continue to use these criteria in supporting future programs.

ODS CONSTITUENCY

The ODS constituency includes, in its broadest sense, researchers and other scientists with expertise in a wide range of disciplines, all health care providers and the associated industries, and the public at large. In essence, ODS interacts at multiple levels and in various ways with the wide spectrum of individuals, organizations, and institutions in both the private and public sectors that have interests or concerns about dietary supplements. ODS recognizes that although its constituency is primarily domestic, its efforts and activities influence other countries worldwide.

This is a broad constituency with considerable variation and overlap in perspectives, interests, and needs. During the initiation of information programs in 1998-2003, the needs of the scientific community received greater attention from ODS and the other segments of the ODS constituency received lesser attention.

Evaluation Criteria in the Original Strategic Plan

- *Ensure relevance of projects and programs to the ODS mission.*
- *Expand experimental possibilities and develop emerging or innovative research strategies and methods where appropriate.*
- *Fund research of the highest quality, consistent with the values of NIH.*
- *Support research that addresses important public health needs.*
- *Partner and collaborate with other institutions and organizations.*

The ODS Constituency

- *Research investigators*
- *Educators and teachers*
- *Health practitioners*
- *Research and educational institutions*
- *Scientific, medical, and professional organizations and institutions*
- *Executive and legislative branches of the federal governments*
- *State and local government*
- *Dietary supplement, food, drug, and related industries*
- *The media*
- *Consumer and public interest groups*
- *Individuals and the public at large*



Vision of the Future

ODS MISSION

The original strategic plan included a mission statement that incorporates the mandates expressed in DSHEA: “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.” This mission statement has guided the initiation and evolution of programs since ODS was established.

Most comments and suggestions received by ODS in the process of reviewing and revising its strategic plan recommended that ODS expand rather than redirect its programmatic efforts within the original mission statement. Thus, ODS will keep the mission statement as its guiding principle for the foreseeable future.

ODS is committed to developing, supporting, and providing scientifically valid data and information on dietary supplements. It will continue to serve as the focal point for scientific inquiry on this issue by the 27 NIH ICs, other public agencies, and the private sector. The special expertise of the ODS staff and consultants will enhance the development of scientific knowledge. Support for research will ensure that the unique contribution of dietary supplements to human health will receive appropriate consideration and attention in the future. Furthermore, this bridging across disciplines and organizations in the public and private sectors will provide timely, accurate, and reliable information to public health providers, investigators, and the entire ODS constituency.

UNIFYING PRINCIPLES

As the complexity and costs of conducting and managing basic, applied, and clinical research have escalated in recent years, those responsible for funding and management of the federal research system have sought ways to make the enterprise more efficient.

For example, in the Congressional report accompanying the FY 2001 appropriations bill for DHHS, Congress requested that NIH have the Institute of Medicine of the National Academy of Sciences (IOM/NAS) undertake a study as to “whether the current structure and organization of the NIH are optimally configured for the scientific needs of the 21st century”.⁵ The resultant report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* was published recently.⁶ The NAS committee made 14 general recommendations that identified ways to enhance the health of the clinical research enterprise and strengthen cross-NIH strategic planning and funding.

Similarly, both DHHS and NIH revised their strategic plans and initiatives.^{7,8} ODS is responsive to the perspectives and guiding principles of these agency efforts to develop appropriate strategies to meet the research and health needs of the 21st century.

In the course of revising its strategic plan, ODS has taken into account the continuing efforts of DHHS to regularly update the departmental strategic plan. DHHS has established eight goals for FY 2004-2009 to address the DHHS mission to “protect and improve the health and well-being of the American public”.⁷ In addition, the DHHS strategic plan identified certain core values that define its approach to accomplishing its mission. ODS will continue to embrace these principles.



The DHHS plan states and the ODS expects the following:

- “To deliver results that are useful both to the people and communities that are directly served by the Department’s programs and to the taxpayers who pay for these programs,
- To create useful, effective forms of collaboration with partners in regulation, research, service delivery, and management,
- To provide accurate, reliable, understandable, and timely information to our partners and customers.”

In 2002, the NIH director, Dr. Elias Zerhouni, recognized the need to determine how NIH could best meet its mandates in the coming century.^{8,9} He charged senior NIH staff and biomedical leaders from academia, industry, government, and the public to develop a list of compelling initiatives that NIH should pursue to make a major impact on biomedical research and health care delivery. The outcome of this effort, the NIH Roadmap, focuses on three major themes: new pathways to discovery, research teams of the future, and reengineering the clinical research enterprise.⁸

The purpose of the roadmap is to more efficiently translate evolving scientific knowledge into improved health of the public. In developing its revised strategic plan, ODS will expand its existing emphasis on these three themes by:

- Enlarging its efforts to incorporate knowledge and techniques from various disciplines into its strategies,
- Strengthening efforts to build and support interdisciplinary investigative teams that include expertise appropriate to the complex questions about dietary supplement effects and safety, and
- Developing guidelines for more efficient clinical study of dietary supplements that are consistent with accepted scientific principles and that build new partnerships within and outside the ODS constituency.

The ODS strategic plan for 2004-2009 incorporates the vision and thrust of the DHHS strategic plan for 2004-2009 and the NIH Roadmap. ODS is committed to furthering the guiding principles and goals developed by its parent organizations.

SUSTAINING THE ODS UNIQUENESS

ODS has established a tradition of working across the spectrum from basic science to the clinical sciences as well as using innovative approaches and techniques to achieve its goals. To attain the ultimate vision of strengthening knowledge and understanding of dietary supplements, ODS strives to bridge across disciplines and cooperate and collaborate across the public and private sectors where mutual interests lead to a common goal.

The processes of cooperative and collaborative research support used by ODS and the other offices within the Office of the Director at NIH are consonant with the emphasis on integration of scientific activities as identified in the evolving NIH Roadmap. ODS has built a bridge between the disciplinary and disease-oriented approaches of the NIH ICs. The number of research investigations and overall financial efficiency are increased and a broader and more relevant knowledge base is created when dietary supplement investigations are incorporated into IC programs. To sustain and expand this synergistic approach requires an informed, committed, and skilled scientific staff at ODS and interested and engaged scientists and communicators in the academic, commercial, and public sectors. ODS is committed to enhancing these scientific partnerships.

THE NEXT 5 YEARS: CONTINUING THE QUEST

The strategic plan for ODS 2004-2009 maintains the five goals established previously. It also identifies a number of specific initiatives that are component topics and interrelated issues within the goals.

The ultimate purpose of the revised ODS strategic plan is to improve the health of the public and to meet the Congressional mandates in DSHEA by increasing support for quality scientific research and by communicating information to the public on the role of dietary supplements in health promotion and disease prevention.



ODS will continue its approach to leveraging the science of dietary supplements through cooperation and collaboration with its public- and private-sector partners. The advances in knowledge across the chemical, biological, and health science disciplines seen in the past several years can be expected to expand at an ever-increasing rate in the future. ODS anticipates that its research approaches and operational activities will contribute to the emphasis on translational research and clinical investigation as proposed in the DHHS report and in the NIH director's roadmap.^{6,8}

As it moves forward, ODS will focus on the five concepts derived from in the DHHS strategic plan and the NIH Roadmap.

- ***Promote and foster the use and expanded application of research results.*** Within ODS these include several recently initiated programs such as the analytical methods and reference materials program, dietary supplement ingredient database, and program for evidence-based review of dietary supplement efficacy and safety. All are resources at an early stage of development but underpin future high-quality research in this field. By 2009 these resources should be sufficiently developed to be available throughout the research community. They may serve as the basis for a product-development program in industry that is far more comprehensive than at present, and regulatory agencies will have a robust, science-based dataset on which to base decisions. Public health policy will be shaped by research findings based on these critical resources.
- ***Support investigation of bioactivity of dietary supplements by using emerging technologies such as genomics, proteomics, metabolomics, high-throughput molecular screening assays (and the attendant high-end needs for computation), and nanotechnology in order to understand the effect of dietary supplements on gene expression and mechanisms of action.*** Recent advances in using these innovative technologies in many facets of contemporary biological and medical research suggest they can provide new and as yet unexplored ways to address basic questions about the mechanisms by which dietary supplement ingredients exert their effects.
- ***Expand the infrastructure of human resources.*** In every discipline the progress of research depends primarily on the creation and availability of well-trained and well-educated investigators. The same holds true for the communication of new scientific information to individuals and organizations that need and use such information. Further advances in knowledge of the benefits and risks of dietary supplements require greater investment in training and career development programs. Understanding the role of dietary supplements in health and disease requires training, maintaining a critical mass of qualified investigators, and attracting researchers from related disciplines. ODS plans to expand its involvement with existing NIH intramural and extramural systems and programs for both domestic and international training and career development of investigative and clinical researchers with expertise in dietary supplements and appropriate related disciplines. Special attention will be directed to including minorities and women in training and career development opportunities.
- ***Develop scientifically rigorous population-based studies that can test supplement interventions to reduce the risk of common diseases.*** The evaluation of hypotheses suggesting dietary supplement efficacy and safety requires basic, preclinical, and clinical investigations. Before costly large clinical trials are undertaken, limited human studies that test hypotheses and provide evidence supporting the concept of efficacy and safety are critical components of establishing benefits and risks. Such studies cut across anticipated end-points such as disease prevention or health improvement. Both proof-of-concept and large clinical trials require highly coordinated interdisciplinary research teams. New experimental designs and interventional approaches with dietary supplements need to be developed and will involve partnerships within and outside the ODS constituency.
- ***Establish a mechanism for regular evaluation of the ODS research portfolio and with each iteration refocus the portfolio to meet emerging needs and challenges. This process will provide a benchmark of progress and has been effective since the inception of ODS.*** Future planning will require continued involvement by all stakeholder communities. ODS will initiate actions to enhance this necessary activity in the future while also maintaining the flexibility in support of research that is demanded by the rapid expansion of scientific knowledge and opportunities.

Goals and Initiatives for 2004-2009

INTRODUCTION

Comments received during the revision of the strategic plan uniformly endorsed the five goals and recommended that they continue to guide ODS in the next 5 years. However, concerns were expressed that both research needs and opportunities required that a greater emphasis on integrated approaches that recognize the interrelationships and interdependence of specific programs and activities. In addition, the need to explore the use of emerging technologies and increase the emphasis on cross-disciplinary studies in addressing dietary supplement research issues were expressed. These observations suggest that identification of overarching strategies would be useful in recognizing the cohesiveness of future initiatives aimed at expanding knowledge on each goal.

The revised ODS strategic plan for 2004-2009 identifies specific initiatives within the five generic goals. This wording reflects the intention of maintaining flexibility in its programmatic efforts to address both current and future issues.

In reviewing the ODS activities and programs developed under the five original goals during its initial years, the ODS staff reached two general conclusions. First, the five goals provided a sound, comprehensive framework to guide ODS programs. Second and perhaps more important, each goal addressed an essential part of the framework but the goals were interdependent. For example, studies of disease risk reduction and improvement of health and performance have different endpoints but often use the same experimental interventions or investigative approaches. Similarly, confirmation of dietary supplement source and identity, standardization of composition of ingredients in clinical trials, and appropriate analytical methodology for objectively assessing experimental outcomes are important aspects of both preclinical and clinical investigations regardless of whether disease prevention, health improvement, or performance improvement is the purpose of the study. Finally, dissemination of accurate and complete research results is difficult when data are absent or incomplete. Communication of research results in regard to disease prevention or risk reduction, health and performance maintenance or improvement, or methodological aspects of research requires that the database contain information that is as complete and objective as possible.

The 37 original objectives identified research, educational, and communication interests of the NIH ICs, offices within the NIH director's office, other federal agencies, and private sector organizations and institutions that participated in the strategic planning process. Considerable progress has been made in the past 5 years in addressing many of the original objectives. However, as science and technology have progressed and expanded, so have the potential opportunities for undertaking heretofore difficult research studies. As a result, the specific objectives identified in 1998 were only a partial list of the range of topics and issues that can be addressed now and in the future.

GOALS AND INITIATIVES

The five original statements of goals have been retained as the charge for ODS programs in 2004-2009. They emphasize research (the first four) and information communication and education (the fifth). They maintain continuity in the ODS mission and purpose over a 10-year span. Some changes in wording have been incorporated to reflect progress toward these goals; identification of emerging needs; and development of new techniques, approaches, and opportunities.

The initiatives associated with goals 1 and 2 identify research needs and opportunities that may involve similar or related experimental or clinical approaches. However, the two goals and their respective initiatives are listed separately because the purpose of each initiative and the experimental and clinical endpoints are specific to each goal. In addition, initiatives within the other goals that are related to goals 1 and 2 are identified by an asterisk.



Goals

- 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 activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.*

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

- Expand research that advances assessment of the potential roles of dietary supplements in disease prevention and risk reduction as identified in DSHEA and in the original ODS strategic plan.
- Stimulate and support evidence-based evaluations of the role of dietary supplements, including evaluation of the safety and efficacy of supplement use in the prevention and reduction of risks for chronic diseases.
- Place greater emphasis on identifying opportunities for NIH interdisciplinary research on dietary supplements where interests and opportunities exist in the programmatic goals of several NIH ICs. For example, collaborate with ICs in clinical trials designed to evaluate the role of dietary supplements in disease prevention and risk reduction, with due regard for safety and efficacy as appropriate.
- Encourage investigators submitting research applications to NIH in response to initiatives to include studies that can add to the knowledge base concerning the roles of dietary supplements in various disease states.
- Expand the cadre of research scientists qualified by training and career development to undertake investigations on dietary supplements with particular emphasis on young investigators, minorities, and women, including those with expertise and interests in dietary supplements and those in related disciplines.
- Explore and foster new approaches to the study of dietary supplements in various activities and conditions resulting from disabilities and disease conditions.
- Foster research that focuses on beneficial and adverse interactions of dietary supplements with foods, drugs, and other dietary supplements in healthy persons and those with selected conditions where these interactions may affect disease prevention and risk reduction.

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

- Stimulate and support evidence-based evaluations of the role of dietary supplements in maintenance of optimal health, well-being, and physical and mental performance with appropriate attention to both safety and efficacy.
- Place greater emphasis on identifying opportunities for NIH interdisciplinary research on dietary supplements where interests and opportunities exist in the programmatic goals of several NIH ICs. For example, collaborate with ICs in clinical trials designed to test the role of dietary supplements in maintaining optimal health and performance including both beneficial and adverse effects where appropriate.
- Encourage investigators submitting research applications to NIH in response to initiatives to include studies that can add to the knowledge base concerning the beneficial and other effects of dietary supplements on optimal health and performance.
- Explore and foster new approaches to the study of dietary supplements in various activities and conditions consistent with optimal health, well-being, and physical and mental performance.
- Foster research that focuses on beneficial and adverse interactions of dietary supplements with foods, drugs, and other dietary supplements in healthy persons and those with selected diseases where these interactions may affect disease prevention and risk reduction.



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.

- Stimulate additional research on how dietary supplements moderate, alter, or enhance metabolic, physiological, and psychological processes associated with maintenance or lack of optimal health and performance during the life cycle.*
- Encourage greater collaboration on research within NIH on identifying and exploring the possible roles of dietary supplements and their bioactive ingredients on cellular, tissue, and organ metabolic changes that characterize various diseases and disorders and optimal health throughout the life cycle.*
- Expand emphasis on the application of new and emerging technologies such as genomics and proteomics to identify specific actions of selected dietary supplements on subcellular and cellular systems as well as on tissues and organ systems in order to enhance knowledge of how these substances produce or influence harmful biochemical, physiological, and psychological effects.*
- Explore approaches to the study of bioactive substances, particularly complex mixtures, that may help us to understand the mechanisms by which dietary supplements derived from plants and animals exert biological activities.

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

- Support partnerships between dietary supplement research centers and interested ICs that will increase emphasis on chemical and biological characterization as well as biological effects of selected dietary supplement ingredients.
- Expand the development of valid, reliable analytical techniques for identifying specific dietary supplements and their bioactive ingredients to meet the needs of investigators studying the role of dietary supplements in health disease. Produce and make available standardized reference materials appropriate for basic, preclinical, and clinical studies on the biological effects of dietary supplements in health and disease.*
- Facilitate research on validation of the accuracy, sensitivity, and specificity of unique biomarkers of dietary supplement effects on known endpoints and their surrogates associated with specific chronic diseases, optimal health, and improved performance.*
- Explore and develop guidelines on appropriate methods for determining the biological effects of dietary supplements in preclinical studies, including animal model systems, and clinical studies focused on efficacy or safety, including studies that address interactions with other ingested substances and lifestyle factors affecting health and disease development.*
- Stimulate further development and promote the use of paradigms for investigating the efficacy and safety of dietary supplements, including evidence-based evaluation of available information, standardized and known product composition, and appropriate preclinical studies as the basis for initiation of clinical trials.*
- Expand emphasis on and continue to promote development of new and improved data collection techniques and epidemiological and survey methodologies that provide a valid, reliable scientific basis for identifying needs for analytical methods, determining the composition of dietary supplements, and determining patterns of dietary supplement use in various population groups identified by demographic factors.
- Collaborate with appropriate groups on surveys that assess dietary supplement use in order to estimate prevalence, frequency, duration, and type of use with the underlying goal of determining the relationships of usage patterns to health and disease risks. Improve measurement of dietary supplement and nutrient intakes and incorporate these improved measures into clinical studies to enhance the measurement of effects.



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

- Serve as a key informational resource to DHHS and other federal agencies on issues related to dietary supplements as stated in DSHEA.*
- Promote the transfer and translation of information about dietary supplements from ODS to NIH and other federal agencies and encourage the use of this information by academia, industry, and other segments of the ODS constituency.
- Sponsor evidence-based reviews of the effectiveness and safety of dietary supplements and provide guidance to the scientific community, the media, and the public.
- Ensure that evidence-based scientific information is integrated into ODS health communications and education programs directed to the public at large.
- Encourage similar efforts with public- and private-sector partners (with particular attention to media representatives) to increase the availability of scientifically valid information critical to helping the public make decisions about the use of dietary supplements in health care.
- Increase the information available to health care providers and investigators in other disciplines to improve their understanding of and research on the roles of dietary supplements in health care delivery.
- Facilitate ease of access to ODS information and databases by all interested persons and organizations, with due regard for scientific peer review of validity and accuracy; educational, language, and cultural differences; and protection of privacy where appropriate. ODS anticipates that its efforts in this and related initiatives can be a model for the international ODS constituency.
- Assess public- and private-sector use of current ODS databases in order to enhance accessibility and utility of the information obtained.
- Improve ODS communication approaches to identify optimally effective tools and techniques for reaching the various segments of the ODS constituency and disseminating research findings to ODS public- and private-sector partners.

EVALUATING ODS PROGRESS

A consistent theme within ODS that was reinforced by comments of participants in the strategic planning process is the need for ODS to continue evaluating programmatic progress and responding to evolving opportunities and challenges. That is, the revised strategic plan for 2004-2009 should include ongoing evaluation of the progress of existing ODS programs, needs for new programs, and prioritization of resource allocation among existing and emerging demands generated by the ODS constituency. Participants in the strategic planning process also stressed that open communication with all public and private sectors of the ODS constituency is a critical component of this process.

ODS has used a number of approaches to obtaining guidance and counsel on program needs, development, and evaluation: open sessions such as conferences and workshops, ad hoc groups to review the progress of specific programs, individual and collective consultations, and ad hoc steering groups of federal employees. Figure 2 is an example that depicts the evolution of programs based on the outcomes of one conference. These efforts have had several common attributes:

- Each typically focused on one specific scientific issue related to exploring research needs and opportunities; that is, it existed for a limited purpose and was essentially an ad hoc activity.
- The concept of a research need or opportunity was presented and discussed at an open meeting of a scientific organization and additional views of interested parties were obtained.
- Intramural and extramural recommendations and input from NIH ICs, interested federal agencies, and other sources were solicited and analyzed by ODS staff.
- Summaries of these efforts were made available publicly on the ODS or other Web sites or published. The summaries were authored by presenters and did not imply a formal consensus.
- Depending on the resources, interest, and approaches available, programs were established and funded by various means (e.g., NIH program announcements, requests for proposals, grants, contracts, cooperative agreements).

As the several programs have been established and have grown, their purposes and contributions to scientific knowledge about dietary supplements have become increasingly interrelated and interdependent. Continued growth of ODS programs in number, size, and complexity can be expected, although the rate of growth is uncertain.

For these reasons a mechanism or approach is needed to guide implementation of the revised strategic plan for 2004-2009. On the basis of approaches that have served ODS well in the past, the proposed approach should be essentially ad hoc, provide for public input, include guidance from knowledgeable individuals (as opposed to consensus of a group of experts), and be publicly available. However, implementation or actions should be the responsibility of the ODS director or the director's designees. To meet this need, ODS will establish a two-part comprehensive approach to ongoing review and evaluation of ODS programs.

This approach will be initiated in 2004 and will include annual consultations with representatives of the broad ODS constituency. It is anticipated that a different mix of representatives will attend each year depending on the topics receiving emphasis. ODS will provide background material on ODS programs for the open meetings. Invited speakers will be asked to provide their opinions about progress on ODS program initiatives and to suggest additional needs and promising opportunities. Each ad hoc external consultative group meeting will provide an opportunity for public comment. By attending such meetings or commenting on the ODS Web site, interested persons and organizations will be able to provide their input to the ODS review and evaluation process. The records of these meetings will be available publicly and will serve as a resource to the ODS steering group (see below). The purpose of these efforts is to provide an opportunity for a wide range of input on ODS initiatives.

The second part of this approach will be the organization of an ODS steering group on programs and priorities. Members will be federal employees representing the ICs and agencies with which ODS collaborates regularly. Background materials on ODS programs and synopses of ad hoc external consultative group meetings prepared by ODS staff will provide a basis for discussion of programmatic priorities and identification of additional needs. A report of the steering group meeting will be publicly available on the ODS Web site.

The establishment of an ODS steering group on programs and priorities has many advantages. The group's purpose will be to regularly advise the ODS director about the state of ODS programs, progress towards stated goals, and emerging needs that may influence priorities for the programs and goals; the group will have the information provided by the ad hoc external consultative groups as well as the collective knowledge of its members as resources. An ODS steering group will provide a measure of continuity of review and evaluation over the 5 years of the strategic plan. The addition of members as needed or the rotation of IC representatives will allow integration of emerging areas of interest. Implementation of this evaluation effort over the next 5 years will provide a sound basis for developing a continually evolving sequence of programmatic efforts consistent with the roadmap being developed by NIH as an overall guideline on marshaling its resources to meet public health needs. Such a steering group will help ODS to meet the Congressional mandates of DSHEA.

This process will provide a way for ODS to maintain a focus on coordination and cooperation as stated in DSHEA:

- Conduct and coordinate research within NIH relating dietary supplements and the extent to which their use can limit or reduce the risk of diseases.
- Coordinate funding related to dietary supplements for NIH, extending the efforts of the Human Nutrition Research and Information Management (HNRIM) system and CARDS to collate and make available data on dietary supplement research funding.
- Provide information and advice to other DHHS and other federal departments and agencies related to dietary supplements.





Concluding Statement



ODS has made significant progress in advancing recognition of the need for and the conduct of quality scientific research on dietary supplements. These efforts have markedly increased the availability of objective evidence-based information useful to the public in making decisions about the efficacy and safety of dietary supplements. Much has been accomplished since 1995 but considerably more needs to be done. Thus, the ODS strategic plan for 2004-2009 provides a roadmap intended to catalyze research that will expand the scientific knowledge base to improve the health of the public.

The development of the revised strategic plan has been an open process that benefited from the input of a broad range of persons and organizations interested in dietary supplements. The revised strategic plan includes strategies to address goals, identifies initiatives within each goal, and outlines a process to evaluate progress toward those goals. It is an ambitious blueprint for the future. ODS recognizes that improvements in knowledge and understanding about dietary supplements will require greater attention to strengthening the linkages among basic, translational, and clinical research as well as the use of new and emerging technologies. ODS is uniquely positioned to initiate, promote, and facilitate the meeting of these challenges because of its tradition of emphasizing cooperation and collaboration with a wide spectrum of public agencies and private organizations that have shared interests and resources.



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Appendix A: The ODS Web Site

Readers are encouraged to visit the ODS Web site (<http://ods.od.nih.gov>) for additional information on dietary supplements in general and on the various activities and programs of the Office of Dietary Supplements. The What's New section of the home page is updated regularly and contains announcements of recent publications, future meetings, and opportunities for funding of research initiatives supported by ODS.

The ODS Web site includes six main areas of general information of wide interest to the broad ODS constituency as well as more specific topics and links to additional information and databases.

- *Welcome to ODS* includes frequently asked questions, a Web site map, signup for the ODS Listserv, and the capability to search the entire Web site.
- *What's New* highlights news, events, and related information of current interest.
- *Health Information* contains ODS fact sheets on vitamins, minerals, and botanicals; a list of available publications; the International Bibliographic Information on Dietary Supplements (IBIDS database); and more resources on the role of dietary supplements in health and disease.
- *Research Programs & Information* describes the major ODS research programs and access to the Computer Access to Research on Dietary Supplements (CARDS database).
- *Grant & Funding Opportunities* covers current and forthcoming announcements of funding for research studies and education programs, partnering opportunities, and a list of grants and other awards cofunded by ODS.
- *Strategic Planning* includes the original 1998 ODS strategic plan and the background paper for the recently completed strategic plan for 2004-2009: "Promoting Quality Science in Supplement Research, Education, and Communication."

Both the format and the content of the ODS Web site are undergoing revision to improve ease of use and to include additional information useful to the ODS user constituency. Users are encouraged to provide feedback on additional topics and information they think would improve and expand the utility of the ODS Web site.

Appendix B: ODS Strategic Planning Process

The original strategic plan in 1998 was developed with considerable input from National Institutes of Health (NIH) institutes and centers, federal agencies, and other interested persons and organizations. It guided ODS activities and programs during the initial years. However, large increases in the ODS budget and programmatic efforts have occurred. On the basis of considerable progress toward the original goals and expanded programs beyond those contemplated in 1998, the ODS director determined that an updated strategic plan for 2004-2009 was important.

The process of developing a revised strategic plan was initiated in early 2002. Information and data on the several ODS research, education, and communication activities and programs were assembled. These were summarized in a background paper that reviewed the programs that ODS established from 1998 to 2002 and noted progress in key areas of the 1998 strategic plan.

The Strategic Planning Steering Group was organized in 2003. Members included senior scientists representing NIH institutes, centers, and offices along with senior scientists from the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, National Center for Health Statistics at the Centers for Disease Control and Prevention, and U.S. Department of Agriculture—institutes and agencies that share common interests with ODS in regard to dietary supplement research and communication (See Appendix C). The steering group has provided oversight and review during the genesis of the strategic plan for 2004-2009.

The background paper and the goals and objectives of the original strategic plan were posted on the ODS Web site. The background paper solicited comments and suggestions on future ODS activities from the broad community of ODS collaborators, constituents, and other interested parties (e.g., government, academia, industry, consumers). Individuals and organizations were encouraged to review the Web site information and participate in the strategic planning process. Comments and suggestions were requested by e-mail, mail, or facsimile for a 4-month period from March to July 2003.

A public meeting was held in Bethesda, Maryland, on May 8-9, 2003. Speakers at the plenary session introduced topics and issues that identified possible needs and opportunities in research, education, and communication. The background paper and plenary talks were the basis for discussions at subsequent small group discussion sessions. Meeting attendees explored and suggested ODS activities and programs consistent with its mission for possible incorporation into the 2004-2009 ODS strategic plan.

The transcript of the public meeting together with comments received from individuals and organizations via the ODS Web site and additional input from members of the steering group provided the basis for the draft of the 2004-2009 ODS strategic plan. The draft plan was reviewed sequentially by the ODS senior staff, the steering group, participants at the open meeting, and other participants. A further-revised draft was placed on the ODS Web site and comments and suggestions were solicited from the public. Finally, the revised ODS strategic plan was reviewed and approved by the ODS director.

Copies of the *ODS* strategic plan for 2004-2009, "Promoting Quality Science in Supplement Research, Education, and Communication," are available on the *ODS* Web site and from *ODS*: Office of Dietary Supplements
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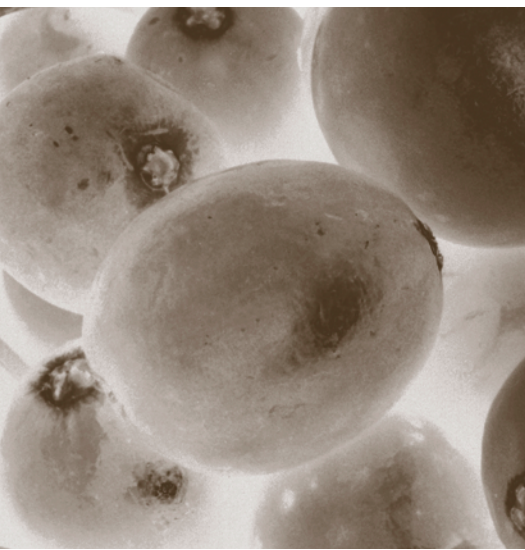
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