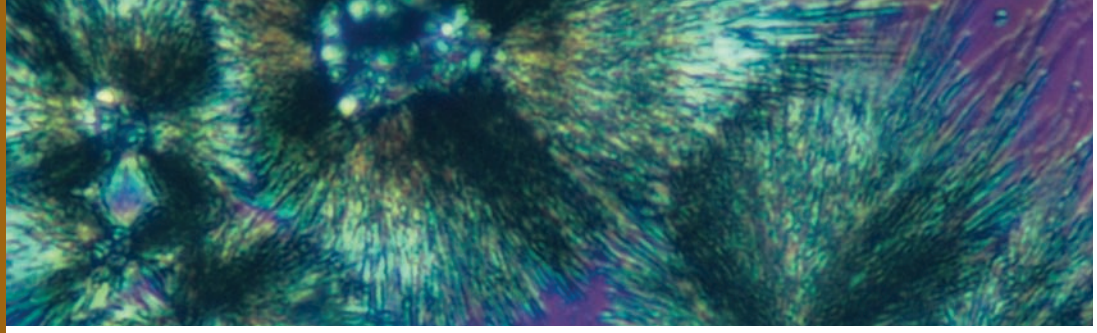


STRATEGIC PLAN
2010-2014

NATIONAL INSTITUTES OF HEALTH

Office of Dietary Supplements Strategic Plan

STRENGTHENING KNOWLEDGE AND UNDERSTANDING OF DIETARY SUPPLEMENTS

Office of Dietary Supplements
Office of the Director
National Institutes of Health
U.S. Department of Health and Human Services

Table of Contents

COVER PHOTOS
Top: Vitamin E crystal
Middle Left: Fish oil capsules
Middle Right: Blueberries
Bottom: Milk thistle

Introduction

The Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) is pleased to present its strategic plan for 2010–2014. This document was developed from a year's worth of reflection on the return on our investments, and what new challenges await. It was also shaped by the thoughtful input, comments, and advice we have received from our stakeholder communities throughout the federal government, academia, the dietary supplement industry, consumer advocacy and education groups, and interested consumers.

Our efforts are centered on dietary supplements, products that the majority of Americans take and on which they spend about $25 billion a year. At least 50,000 products are available that contain vitamins and minerals, herbs and botanicals, and other ingredients such as glucosamine, fish oils, and probiotics. Yet for many of these dietary supplements, there are questions about their effectiveness and safety.

For almost 15 years, ODS has worked to answer such questions. The ODS mission is to strengthen the 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. While our mission has remained constant, our goals and objectives, described in this strategic plan, have evolved as new issues of high priority have emerged.

ODS allocates the majority of its resources to cofund research with other NIH institutes and centers, to investigate the potential roles of dietary supplements in promoting health and reducing the risk of chronic disease. ODS also engages its federal partners in activities to fill essential needs that would not otherwise be addressed. For example, ODS now leads a multi-pronged initiative designed to identify and address research gaps related to vitamin D. Its major elements include sponsorship of a systematic review of the literature on efficacy and safety; conferences, workshops, and roundtable discussions on the topic; development of much-needed analytical tools for vitamin D measurement in foods and dietary supplements; and a standard reference material to help with the measurement of vitamin D levels in blood. As with all ODS projects, the results are shared with our stakeholders through the ODS Web site, fact sheets, conferences, and publications directed to scientists, health professionals, and consumers.

Through the work of ODS's talented staff and scientific partners, more knowledge is available than ever before about the benefits and risks of dietary supplements, supplement quality has improved, and the public has more and better guidance about whether and how to incorporate these products into their health care practices. Our new strategic plan will guide ODS activities in a manner consistent with the priorities of the NIH director, Dr. Francis Collins, for improving the health of the nation.

I encourage you to communicate with us as we progress toward our common goal of increasing high-quality scientific research to provide sound information on dietary supplements.

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

I. Background

The year 2010 marks the 15th year of the Office of Dietary Supplements (ODS), and the ODS Strategic Plan for 2010–2014 presents a fresh evaluation of goals to guide future activities. During its first nine years (1995–2004) ODS defined its mission and established programs and activities at a time of significant budget growth. The years 2004–2009 were marked by a stable budget and a maturation of programs and activities promoting the study of dietary supplements at the National Institutes of Health (NIH).

Origins of the Office of Dietary Supplements

The history of ODS is rooted in legislation and subsequent congressional language that form the basis of the ODS mission and its programs. ODS was created in 1995 and placed in the Office of Disease Prevention, Office of the Director, NIH, to meet the requirements of the Dietary Supplement Health and Education Act (DSHEA) of 1994. The DSHEA defined the purposes and responsibilities of ODS as follows:

Purposes:

- To explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care.
- To promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

Responsibilities:

- To conduct and coordinate scientific research within NIH relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases.
- To collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources.
- To serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of NIH, the Director of the Centers for Disease Control and Prevention (CDC), and the Commissioner of the Food and Drug Administration (FDA) on issues relating to dietary supplements. These issues include dietary intake regulations, the safety of dietary supplements, the claims characterizing the relationship between the use of dietary supplements and the prevention of disease or other health conditions and the maintenance of health, and scientific issues arising in connection with the labeling and composition of dietary supplements.
- To compile a database of scientific research on dietary supplements and individual nutrients.
- To coordinate funding relating to dietary supplements for the NIH.

Subsequent congressional mandates directed ODS to develop a botanical research center initiative (1999), conduct evidence-based reviews of the efficacy and safety of dietary supplements (2001), accelerate the validation of analytic methods and reference materials for dietary supplements (2004), and support the development of a dietary supplement label database (2004).

The DSHEA established a formal definition of "dietary supplement" using several criteria.[1] By law, a dietary supplement is a product taken by mouth that contains a dietary ingredient, including vitamins, minerals, amino acids, herbs or botanicals, or other substances that can be used to supplement the diet.

In defining a dietary supplement, the DSHEA allowed the labels of dietary supplements to

include various types of statements. However, a manufacturer may not make claims about the use of a dietary supplement to diagnose, prevent, mitigate, treat, or cure a specific disease unless it has approval to do so under the new drug provisions of the Federal Food, Drug and Cosmetics Act.

The ODS Strategic Planning Process

ODS has used strategic planning to establish and review the goals that drive its activities since its establishment in 1995. This process involves communicating with multiple constituencies to obtain broad input and reflect the best thinking possible. The first ODS strategic planning process included discussions with NIH institute and center directors and with representatives of the scientific community, industry, other federal agencies, and the public to identify areas of common interest.

ODS developed its mission statement as part of its first strategic planning process in 1998. This statement remains relevant today:

*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.*

A comprehensive approach to the ongoing review and evaluation of ODS activities was an important component of the 2004–2009 strategic plan, and ongoing evaluations continue to be a high priority. ODS held a public meeting in 2005 to engage stakeholders in evaluating its strategic plan. During this meeting, representatives of the ODS stakeholder community and other interested parties identified emerging needs and opportunities that informed future ODS activities.

An ODS senior staff retreat took place in November 2006 to address mission-derived priorities in research, communication, and education, and to adjust priorities as needed. The retreat's outcomes included updated program summaries, priorities for outside evaluation of programs, and two internal staff reports, one on research priorities and one on industry outreach.

ODS established the Federal Working Group on Dietary Supplements and coordinated the group's first meeting in 2005 (see Appendix A). The working group enhances communications between the NIH institutes and centers represented by the group and other federal agencies interested in dietary supplement research. The group also promotes an ongoing review and evaluation of ODS activities. The working group meets twice yearly and serves as a forum for discussing dietary supplement-related programs, initiatives, and topics of common interest. The March 2008 meeting was devoted to a review of the ODS strategic goals for 2004–2009 in preparation for the next strategic plan.

ODS commissioned a paper in 2008 to provide the background material for the next strategic plan. ODS senior staff and an oversight committee established for the strategic plan, with representatives from federal partner agencies (see Appendix B), reviewed this background paper, *A Report to the Public*. The report, which ODS posted on its Web site (http://ods.od.nih.gov) in November 2008, contains detailed information on ODS programs, activities, and accomplishments. ODS subsequently solicited comments on the report from the public through a series of four Webinars with stakeholders in January and February of 2009 (see Appendix C). ODS posted links to the recordings of these Webinars on its Web site.

The 2010–2014 ODS Strategic Plan captures the momentum of ODS's programs and activities and the many evaluative comments received from various sources since ODS issued its previous strategic plan.

[1] According to the DSHEA, a dietary supplement "is (i) a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients; (ii) intended for ingestion in pill, capsule, tablet, or liquid form; (iii) not represented for use as a conventional food or as the sole item of a meal or diet; (iv) labeled as a dietary supplement; and includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision)."

II. Programs and Progress: 2004–2009

FIGURE 1. ODS OVERALL BUDGET TREND

ODS Extramural Investments

The ODS budget grew rapidly from 2000 to 2004; since 2004, the ODS budget has been relatively stable (Figure 1.)

ODS's FY2009 budget was $27.7 million. This budget was largely targeted to extramural investments in research.

In FY2008, ODS awarded $22.3 million to extramural projects. The distribution of these funds by project type—grants, contracts, and interagency agreements—is shown in Figure 2. The largest allocation was for research grants. ODS does not award research grants directly but selectively cofunds meritorious peer-reviewed research relevant to dietary supplements that NIH institutes and centers submit.

The research areas that ODS supported in FY2008 are shown in Figure 3. ODS cofunded grants with nine NIH institutes and centers (see Appendix D) and these partnerships are the key means by which ODS supports dietary supplement research. The second largest allocation, accounting for approximately 30% of the ODS extramural budget, was for the development of research tools for dietary supplements. Key partners in the development of research tools were other federal agencies as well as NIH institutes and centers (see Appendix D).

Meeting the ODS Mission

In meeting its mission to strengthen knowledge and understanding of dietary supplements, ODS invests intellectual leadership and dollars. ODS extramural investments can be categorized into four broad areas: research support (to develop new knowledge), research tools (to develop research resources), communications (to disseminate knowledge), and science–policy interactions (to translate knowledge to public health). Although the funds that ODS invests primarily support research and, to a lesser extent, research tools, the intellectual leadership of the ODS staff is another source of extramural investment. These intellectual investments focus primarily on science–policy interactions, communication, and research tools (see Appendix E for a list of staff publications).

FIGURE 2. ODS TOTAL EXTRAMURAL INVESTMENT IN FY2008
Portfolio Total Value: $22.3M

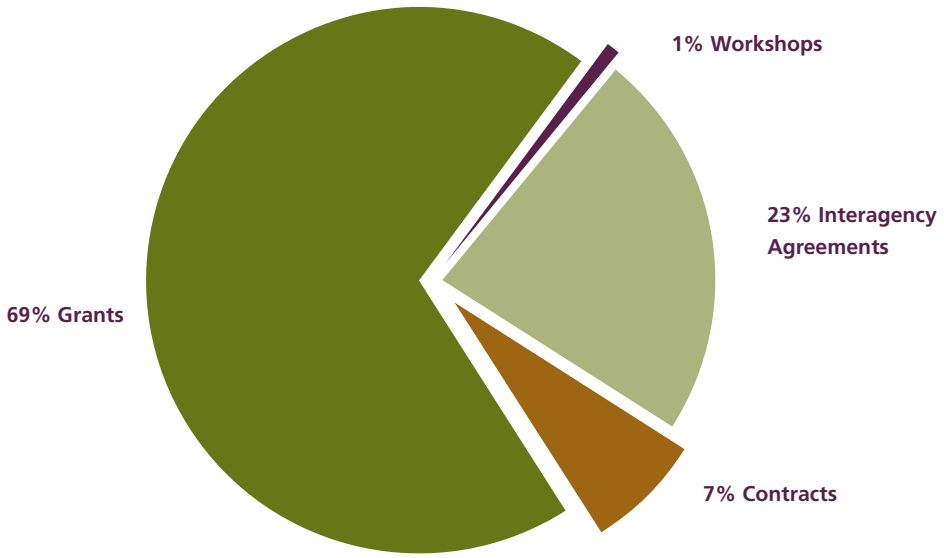
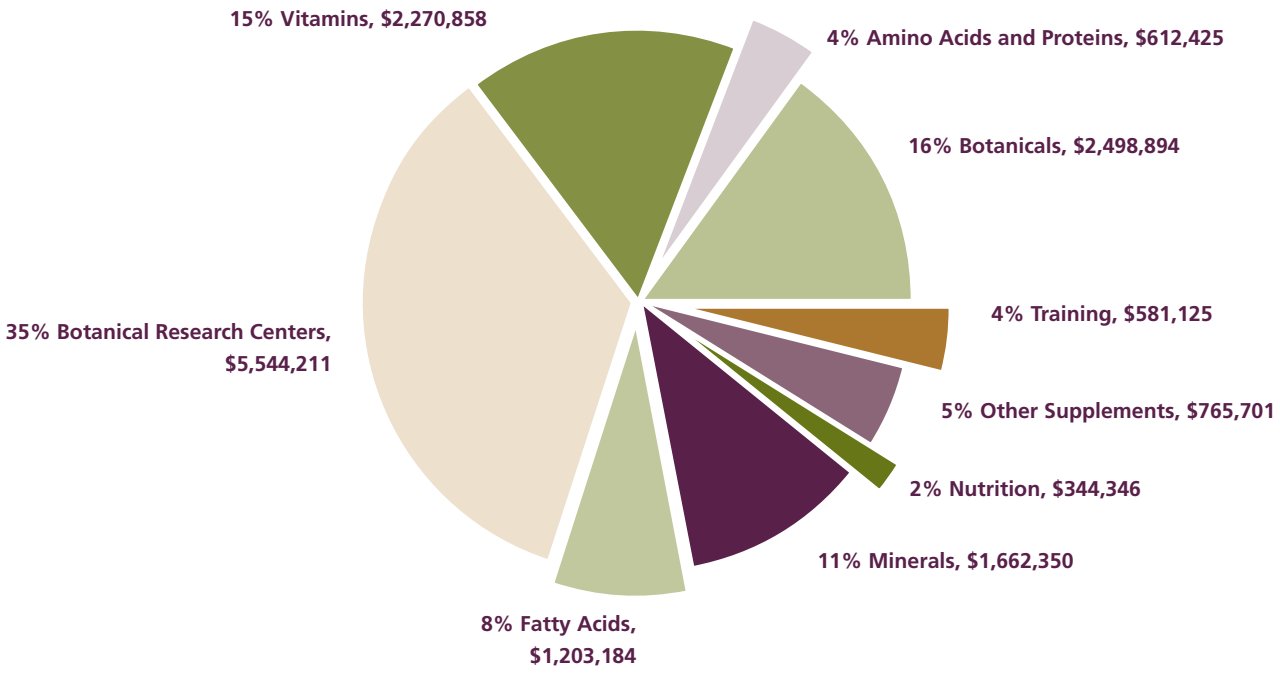


FIGURE 3. SUPPLEMENT CATEGORY BREAKOUT OF ODS COFUNDED GRANTS
In Number of Grants: 104; and Value of Grants: $15.5M



ODS's key activities are grouped into 15 programs under the four categories. An ODS staff member is responsible for overseeing each program and most ODS staff members are active in more than one program. Each program interacts with one or more stakeholder communities, including: research investigators; educators and teachers; health practitioners; research and educational institutions; federal agencies; dietary supplement, food, and related industries; media; consumer and public interest groups; and members of the public. Detailed information on the activities of these programs is included in the background paper, *A Report to the Public*, published on the ODS Web site (http://ods.od.nih.gov).

Area 1: Research support to develop new knowledge

1. **Research Grant Portfolio.** This portfolio consists of grants administered by NIH institutes and centers that receive funding from ODS. This investment supports the discovery of new knowledge on the health effects of dietary supplements.
2. **Botanical Research Centers (BRCs).** ODS established six centers in response to a congressional mandate. ODS administers the centers in partnership with the National Center for Complementary and Alternative Medicine (NCCAM). These centers expand the scientific base for botanicals used as dietary supplements and nutrition.
3. **Training and Career Development.** These extramural investments include cofunding for selected NIH research training and career grants. These grants enable junior scientists to develop a research program related to dietary supplements.
4. **Conferences and Workshops.** Since 2003, ODS has cofunded 100 research conferences and workshops primarily through NIH grant mechanisms, although it also supports conferences and workshops initiated by NIH. These conferences and workshops bring together key scientists to discuss and define the research needs for various dietary supplements.

Area 2: Research tools: resources to support research

5. **Analytical Methods and Reference Materials (AMRM).** ODS established this program in response to a congressional mandate and administers it primarily through contracts that it originates. Supporting the development of analytical methods and reference materials for dietary supplements has been key to making informative studies of dietary supplements possible.
6. **Surveys of Dietary Supplement Use.** ODS provides intellectual and financial support to federal agencies conducting national nutritional surveys that include questions on the use of dietary supplements.
7. **Dietary Supplement Databases.** ODS provides intellectual and financial support and leadership to federal agencies that are establishing databases to enable the interpretation of survey data on public nutrition habits and dietary supplement use. ODS and its federal partners at the U.S. Department of Agriculture (USDA), CDC, National Library of Medicine (NLM), and FDA have created a database of dietary supplement ingredients and are supporting the development of a comprehensive database of dietary supplement labels.
8. **Evidence-based Reviews**. In response to encouragement from Congress, ODS provides intellectual and financial support, primarily to the Evidence-based Practice Centers of the Agency for Healthcare Research and Quality (AHRQ), to conduct reviews that are critical for determining the research needs for selected dietary supplements. AHRQ publishes summaries of these reviews on its Web site and in peer-reviewed journals. Evidence-based reviews are key to identifying the status of scientifically validated knowledge about dietary supplements and important gaps in research. ODS has cosponsored 17 reviews published since 2003 on the health effects of selected dietary supplements.

Area 3: Communications to disseminate knowledge

9. **Communications**. ODS's communication activities include a broad spectrum of outreach activities, such as the ODS Web site, responses to media and public inquiries, exhibits at national meetings, and public and professional information material related to dietary supplements. ODS produces fact sheets on dietary supplements that are publicly available on the ODS Web site. About 90 different information pieces are currently available. In 2009, there were more than 600,000 visits monthly to the ODS Web site. The ODS newsletter has a wide readership and is disseminated electronically to more than 3,500 addresses. ODS staff scientists frequently give lectures and presentations at conferences, seminars, other public-sector venues, and on university campuses.
10. **Computer Access to Research on Dietary Supplements (CARDS).** ODS developed this consumer-friendly, Internet-based database in response to the DSHEA mandate to compile a database of scientific research on dietary supplements. CARDS contains information on more than 8,800 federally funded research projects pertaining to dietary supplements.
11. **International Bibliographic Information of Dietary Supplements (IBIDS).** ODS developed this Internet-based database in response to the DSHEA mandate to collect and compile the results of scientific research related to dietary supplements. IBIDS provides access to more than 760,000 bibliographic citations and abstracts from the published scientific literature on dietary supplements.
12. **Federal Working Group on Dietary Supplements.** ODS established the Federal Working Group on Dietary Supplements in 2005 to share information and discuss issues related to dietary supplements among federal agencies. The working group meets twice a year.

Area 4: Science-policy interactions to translate knowledge to public health

These programs reflect the philosophy that good policy is founded on good science. ODS furnishes expertise in nutritional sciences to address public health issues related to dietary supplements.

13. **Vitamin D Initiative.** This initiative is an evolving partnership with NIH institutes and centers and other federal agencies through the Vitamin D Federal Working Group to address the research gaps related to vitamin D.
14. **Dietary Supplement Use in the Military.** This partnership with the Department of Defense (DoD) is evaluating the impact of dietary supplement use by military personnel.
15. **Dietary Reference Intakes.** ODS supports federal programs to evaluate the reference standards for intakes of vitamins, minerals, and other food components.

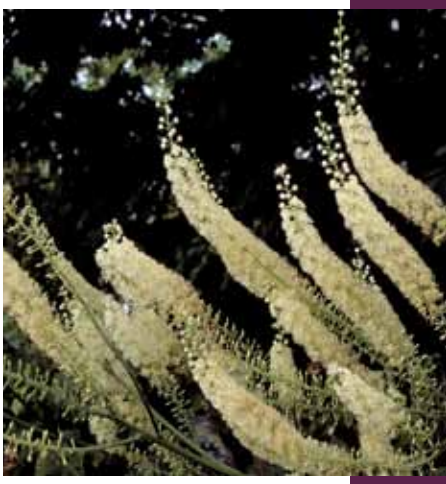
Impact of ODS: Examples of ODS Collaborative Projects and Programs

ODS's program staff members interact frequently with the staffs of other NIH institutes, centers, and federal agencies as well as with the research and dietary supplement communities. The following examples illustrate how ODS activities develop through these interactions.

Analytical Methods and Reference Materials (AMRM) for Dietary Supplements

ODS created the AMRM program in 2002 to build an infrastructure and provide funding to support the development of validated analytical methods and standardized reference materials for assessing product quality and to make these methods and reference materials readily available to the user community (Saldanha LG, Betz JM, Coates PM, 2004; see Appendix E). ODS established these goals as the result of two stakeholder meetings that it organized in 2002. Stakeholders recognized that the use of the wrong or poorly standardized and inconsistent products would harm research and that both the dietary supplement industry and the research community need reference materials and validated analytical methods.

In 2006 ODS convened an expert panel to review the AMRM program's progress and make recommendations for the future. The development



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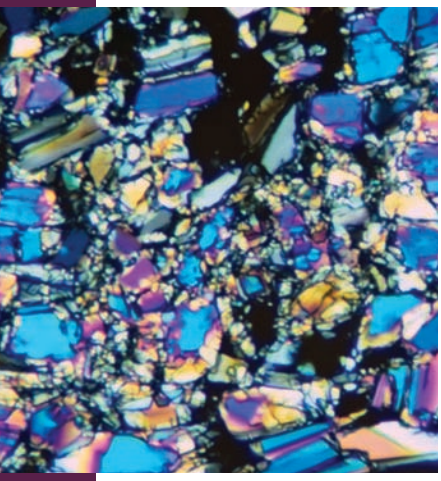

Vitamin D Crystal

of analytical methods had initially focused on botanicals and the concomitant need for standard reference materials to serve the needs of private analytical laboratories and the dietary supplement industry. The expert panel recommended that the AMRM program address vitamins and minerals, a major segment of the dietary supplement market. With ODS support, the National Institute of Standards and Technology (NIST) has now developed 18 certified reference materials for botanicals, vitamins, and minerals. Various laboratories have developed 35 analytical methods for a variety of specific supplements. The need for analytical methods and reference materials remains great and the expert panel recommended that the AMRM program accelerate its pace. ODS held two methodology workshops, one on vitamins and one on trace elements, in 2009 with academic and industry participation to prioritize materials and methods needed.

As the body of information on analytical methods and reference materials has expanded, it has become evident that additional effort is needed to publicize the availability of these resources. ODS has accomplished this through a dedicated section on the ODS Web site and presentations at national meetings that stakeholders in the dietary supplement industry attend.

Multivitamin/Mineral (MVM) Supplements

ODS's partnership with the National Health and Nutrition Examination Survey (NHANES) has enabled the collection of data on the use of dietary supplements by a nationally representative sample of the American public. Through this partnership, NHANES has documented the prevalence of MVM supplement use by Americans. Approximately one third of U.S. adults who participated in NHANES reported taking MVM supplements.

This finding led to the challenge of determining the benefits and risks associated with MVM use. ODS and the NIH Office of Medical Applications of Research (OMAR) sponsored a review of MVM use and its impact on disease prevention by an Evidence-based Practice Center supported by AHRQ. The review concluded that few examples could be documented of disease prevention through MVM supplement use[2] and that the "current level of public assurance of the safety and quality of MVMs is inadequate."

This review formed the basis for the *NIH State-of-the-Science Conference on Multivitamin/Mineral Supplements and Chronic Disease Prevention*, in 2006, featuring an independent panel. The independent panel found that:

In general, MVMs are used by individuals who practice healthier lifestyles, thus making observational studies of the overall relationship between MVM use and general health outcomes difficult to interpret. Despite the widespread use of MVMs, we still have insufficient knowledge about the actual amount of total nutrients that Americans consume from diet and supplements. This is at least in part due to the fortification of foods with these nutrients, which adds to the effects of MVMs or single-vitamin or single-mineral supplements. Historically, fortification of foods has led to the remediation of vitamin and mineral deficits, but the cumulative effects of supplementation and fortification have also raised safety concerns about exceeding upper levels. Thus, there is a national need to improve the methods of obtaining accurate and current data on the public's total intake of these nutrients in foods and dietary supplements.

The conference proceedings are available at http://consensus.nih.gov/2006/2006MultivitaminMineralSOS028main.htm.

ODS is actively working with federal partners to address this national need on multiple fronts. Specifically, ODS is providing tools and resources for determining the upper safe limits for individual vitamin and mineral intakes by assembling a public database of dietary supplement label information in partnership with NLM, supporting the USDA in developing an analytically

[2] a) Folic acid use by women of childbearing age to prevent neural tube defects in their offspring and b) the combination of calcium and vitamin D (but neither nutrient alone) have a beneficial effect on bone mineral density and fracture risk in postmenopausal women.

validated database of active ingredients in MVM supplements, improving analytical methods and reference materials for analyzing dietary supplements, refining survey questions to obtain better information on supplement use, and expanding research on the basic biological mechanisms by which supplements might modify disease risks. With support from ODS, NIST has developed a new certified reference material that can be an important quality assurance tool for measuring the amounts of vitamins, carotenoids, and trace elements in MVM dietary supplements.

Vitamin D

Vitamin D is a unique nutrient because people can meet their vitamin D needs in two distinct ways: by endogenous production from sun exposure, and by eating foods and taking dietary supplements containing this nutrient. In addition to enhancing calcium metabolism, accumulating evidence indicates that vitamin D may play other roles in human health, including supporting immune function; reducing inflammation; and supporting cell proliferation, differentiation, and programmed cell death. Because vitamin D may have these important functions, vitamin D deficiency may contribute to various chronic diseases.

At a time when the importance of vitamin D to health has stimulated new research, concerns about the sufficiency of vitamin D levels in the U.S. population are growing. Reports of rickets (the classic vitamin D deficiency disease) and low blood levels of the biomarker of vitamin D status—25-hydroxyvitamin D—among various subgroups of the U.S. population raise questions about the effectiveness of current public health approaches to ensuring vitamin D adequacy.

ODS is uniquely situated within NIH to focus attention on these issues and to coordinate research that includes several NIH institutes and centers on the many facets of vitamin D. These efforts will take time to produce results. Ultimately, ODS expects that its vitamin D-related activities will inform the reappraisal of the standards for Dietary Reference Intakes (DRIs) of vitamin D across an expanded set of conditions for maintaining human health.

ODS's vitamin D activities began formally with a conference in 2003, *Vitamin D and Health in the 21st Century: Bone and Beyond*, cosponsored by ODS and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

ODS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Cancer Institute (NCI), and the American Society for Nutrition cosponsored a second conference, *Vitamin D and Health in the 21st Century: An Update*, in 2007. The highlights of this conference were presented in a symposium at the 2008 Experimental Biology Annual Meeting and published in a supplement to the *American Journal of Clinical Nutrition* (August 2008). Also in 2007, AHRQ completed and released an evidence-based review, *Effectiveness and Safety of Vitamin D on Bone Health*, sponsored by ODS.

Notable results of these efforts include the formation of the Federal Working Group on Vitamin D, which is translating the research needs in this area into actions by appropriate federal research groups. In addition, NIST has now developed standard reference materials for vitamin D to facilitate analyses of this nutrient in foods and human fluids. Furthermore, researchers are analyzing NHANES data on vitamin D for trends in the public's nutritional status. Most recently, in 2009, AHRQ updated an evidence-based review of the health effects of vitamin D and calcium. Currently, the Food and Nutrition Board of the Institute of Medicine (IOM) is reconsidering the dietary recommendations for vitamin D and calcium. The NIH institutes and centers are assisting in this effort by funding opportunities to support research that will address the gaps in knowledge.

Lemon Balm

III. Strategic Plan for 2010–2014

The foundation for the 2010–2014 strategic plan remains three-fold: the congressional mandates set forth by the DSHEA, the DSHEA definition of a dietary supplement, and the ODS mission statement. ODS programs will be evaluated for their potential impact on public health.

Echinacea

Mission

The mission of ODS remains the same: 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.

ODS's priorities will reflect input from Congress, federal partners, the scientific community, industry, and the public.

Vision

The vision of ODS is that consumers, health professionals, government officials, and other policy makers will have ready access to scientific information of the highest quality on the health effects of dietary supplements.

Strategic Goals for 2010–2014

The ultimate goal of ODS-sponsored activities and programs is to provide science-based information about dietary supplements that relates to health promotion and disease prevention. ODS will accomplish this by continually evaluating current science, identifying gaps in the knowledge base, seeking relevant research strategies and tools to fill those gaps, and translating research into useful information. ODS will measure the results by the number of grants funded, research tools developed, information pieces written, initiatives and workshops developed by staff, and manuscripts published by staff. ODS will assess the impact of these results over time as they inform policy on dietary supplements and influence health practices.

Based on the input from ODS's federal partners and other stakeholders, ODS has consolidated its strategic goals to guide the activities of the office over the next five years.

Goal 1: Provide intellectual leadership by fostering research to analyze and evaluate the role of dietary supplements in promoting health and reducing the risk of disease.
Goal 2: Expand the general scientific knowledge base on dietary supplements by funding new research and training.
Goal 3: Support the development of research tools for the study of dietary supplements.
Goal 4: Make the most up-to-date scientific knowledge about dietary supplements publicly available.

IV. Translating ODS Strategic Goals to Actions

Goal 1: Provide intellectual leadership by fostering research to analyze and evaluate the role of dietary supplements in promoting health and reducing the risk of disease.

ODS is increasingly addressing issues in public health nutrition, particularly issues related to vitamins and minerals. A balanced diet is the primary source of these important nutrients and manufacturers are fortifying many foods with them. Americans use vitamins and minerals, especially MVM products, widely to supplement their diets. How are these trends affecting the health of the population? What are the upper safe limits for various vitamins and minerals? Do these levels need to be adjusted for special populations, such as pregnant women, children, and people who are elderly or frail? ODS will develop a population studies program addressing public health nutrition issues related to dietary supplements, in collaboration with federal partners.

Other types of dietary supplements also need additional study. For example, how safe and effective are the many botanicals found in dietary supplements? How safe and effective are probiotics?

Strategy 1-1

- Continue to stimulate and support evidence-based reviews of dietary supplements, including evaluations of the safety, efficacy (results under ideal conditions), and effectiveness (results under real-world conditions) of supplement use and their role in reducing disease risk.

Action Items:

ODS will continue to stimulate and support evidence-based reviews of dietary supplements. These reviews will provide independent, comprehensive, and objective assessments of available information on specific questions. With the National Institute of Mental Health (NIMH), AHRQ, and OMAR, ODS is already cosponsoring an evidence-based review and state-of-the-science conference on nutrition and cognitive decline. ODS will also cosponsor, with NCCAM and the FDA, an evidence-based review of probiotic safety through AHRQ. ODS will address additional topics as research issues arise.

Strategy 1-2

- Stimulate the development and use of research designs for investigating the safety, efficacy, and effectiveness of vitamins, minerals, and other bioactives as dietary supplements.

Action Items:

ODS will work with federal partners to determine how to use new data to update evidence-based reviews and when those data should trigger a reconsideration of the DRI values set by the Food and Nutrition Board of the IOM. This process is already underway for calcium and vitamin D. ODS will also work with federal partners to explore the nutritional status of other important nutrients of public health concern, such as folate and omega-3 fatty acids, that are used in supplements.

ODS will continue to sponsor workshops that bring experts together to address outstanding issues and suggest research designs to resolve these issues.

For example, NIH has been supporting research on the many forms of soy for a range of outcomes. Questions concerning which forms of soy might be better for studies of specific health outcomes and the appropriate doses led

ODS and NCCAM to commission an AHRQ evidence-based review of the literature on soy. The resulting report (http://www.ahrq.gov/clinic/tp/soytp.htm) found a large, but weak, body of literature with equivocal findings. Key issues include the wide variety of soy products and formulations used to investigate a large number of conditions and poor reporting or study design limitations. In addition, human studies may be compromised because soy is used in producing processed foods for humans, such as water-packed tuna, so that human subjects participating in clinical studies are likely to have unknown exposure to soy ingredients, such as isoflavones. ODS and other NIH institutes and centers convened a workshop in 2009 to provide guidance for the next generation of human research using soy protein and isoflavones. NIH will disseminate this guidance widely through publications, Web sites, and symposia.

ODS will also sponsor a workshop on approaches to economic analyses of dietary supplement and other nutritional interventions for chronic disease prevention.

Strategy 1-3

- Support and expand continued collaboration with appropriate federal groups to estimate the prevalence, frequency, duration, levels, and type of dietary supplements used by Americans, with the underlying goal of determining the relationships of usage patterns to health and disease risks.

Action Items:

ODS will continue to actively collaborate with its partners to include questions about the use of dietary supplements in nutrition and health surveys and to assist in analyzing and publishing data related to dietary supplements. An important ODS partner is CDC's National Center for Health Statistics (NCHS). NCHS leads two important surveys, NHANES, a survey of the health and nutritional status of adults and children in the United States, and the National Health Interview Survey (NHIS), which collects information on a broad range of health topics through personal household interviews. ODS meets quarterly with NHANES staff to review issues of common interest.

Staff from ODS, NHANES, and NCI formed a team in 2008 to monitor dietary supplement use in the United States using NHANES data. This team will track the prevalence of dietary supplement use over time and the amount of nutrients that dietary supplements contribute to the diet. The goal is to monitor total nutrient intakes from both diet and dietary supplement sources; previous methodological challenges have precluded the calculation of total nutrient intakes from NHANES data. The team is exploring strategies to combine data on nutrient intakes from the diet and from dietary supplements to provide the most accurate estimates of nutrient exposure at the population level.

The team will focus on folate—a vitamin and a common dietary supplement. Since 1998, foods in the United States have been fortified with folic acid (a synthetic form of folate) to decrease the incidence of neural tube defects in the developing fetus. As a result, the U.S. population generally has adequate folate intake levels through diet alone. However, the effect of folic acid fortification on other segments of the population is not clear. A small working group will discuss folate and vitamin B12 assays for population studies. These discussions will identify the analytical methods that need to be validated and the Standard Reference Materials (SRM™) needed.

ODS will continue working with the DoD Dietary Supplements Committee and the Military Nutrition Division of the U.S. Army Research Institute of Environmental Medicine on issues relating to the use of dietary supplements by military personnel. The DoD committee is currently addressing the issues and recommendations outlined in the 2008 IOM report, *Use of Dietary Supplements by Military Personnel.*

Strategy 1-4

- Develop an ODS program for the evaluation of dietary supplement use, including the assessment of biological measures of supplement exposure and associated health effects in populations.

Action Items:

ODS will address the recognized need to evaluate biological measures of nutritional status and their association with health outcomes in large, nationally representative populations, such as the NHANES sample. Dietary supplements can contribute to the total nutrient intake and thus can influence overall nutrient status. The new ODS Population Studies program will build the capacity to analyze population data, such as those from NHANES and other survey research programs, using several mechanisms to select high-priority projects that ODS could conduct on its own or in collaboration with others.

The program's goals in its first five years are to:

1. Design, conduct, and publish research on the benefits and risks of dietary supplements using representative population data, such as NHANES data.
2. Provide epidemiological and statistical expertise and support to the Director of ODS in collaboration with other ODS projects.
3. Recruit and mentor postdoctoral candidates in nutritional epidemiology.

Initially, work will focus primarily on vitamin D, especially its biological marker of status, through a series of collaborative research projects with several universities and other federal agencies.

Strategy 1-5

- Facilitate research on the validation and utility of biomarkers for the effects of dietary supplements on surrogate and clinical endpoints.

Action Items:

Biomarkers are chemical or physical entities that can be measured and the measurements then used to assess disease progression, disease risk, and exposure to predefined substances, such as nutrients. ODS will hold workshops to assess the use of biomarkers related to dietary supplement intake and determine research needs, including the need to validate analytical methods and develop reference materials for selected biomarkers.

The first workshop will focus on biomarkers of exposure and participants will discuss inconsistencies between results obtained from quantitative determination of selected nutrient levels in biological materials, such as serum. The focus will be not only on procedures to improve the accuracy and precision of these analytical methods, but also on how and why results using different methods may not agree. A second workshop will address biomarkers of effect, or measurements associated with clinical effects. The focus will be on developing general principles to identify biomarkers of effect using both case studies and theoretical considerations.

Goal 2: Expand the scientific knowledge base on dietary supplements by funding new research and training.

ODS places a high priority on working with NIH institutes and centers and identifying opportunities to cofund outstanding research grants related to dietary supplements. ODS cofunding of research has had substantial impact. For every dollar that ODS invested in research related to dietary supplements in 2007, NIH institutes and centers invested $17. In addition, ODS often provides intellectual assistance on issues related to dietary supplements to NIH program managers overseeing research grants that include dietary supplements.

Strategy 2-1

- Support research on the mechanisms underlying the effects of dietary supplement use on health and disease. ODS will continue to identify and cofund grants with NIH institutes and centers whose research-specific aims address:
  - Genetic, molecular, biochemical, cellular, metabolic, or physiological mechanisms underlying the actions of dietary supplements.
  - Cognitive and behavioral factors underlying the use of dietary supplements.
  - Safety, efficacy, and effectiveness of dietary

supplements, including bioavailability and drug interactions.

Action Items:

ODS will continue to request peer-reviewed applications to cofund from NIH institutes and centers four times a year. ODS reviews these applications and prioritizes them for cofunding. ODS is especially interested in supporting clinical research on dietary supplements that addresses mechanisms of action and safety to reduce disease risk.

Strategy 2-2

- Identify opportunities for NIH-sponsored interdisciplinary research on dietary supplements where interests and opportunities exist in NIH institute and center programmatic goals.

Action Items:

ODS will continue to work proactively with NIH institutes and centers in cosponsoring funding opportunity announcements (FOAs). With the Federal Working Group on Vitamin D, ODS is currently drafting FOAs with other NIH institutes and centers to address research questions for vitamin D.

ODS will also cosponsor workshops and conferences to identify research opportunities for dietary supplements.

ODS will maintain the BRCs program and continue to reevaluate and refine the program's objectives. During the past 10 years, these centers have conducted collaborative integrated interdisciplinary studies of botanicals, particularly those used as ingredients in dietary supplements. The centers have developed approaches to study the complex chemistry of botanicals and their bioactive constituents using cutting-edge proteomics tools and state-of-the-art mass spectrometry applications. The centers also emphasize preclinical studies to explore mechanisms of disease prevention or risk reduction.

ODS will collaborate with NIH institutes and centers in supporting clinical trials designed to evaluate the role of dietary supplements in health promotion, disease prevention, and risk reduction, with due regard for safety, efficacy, and effectiveness.

ODS will seek to promote use of the NIH Human Microbiome Project, which is comprehensively characterizing the microbial communities that are indigenous to humans and their roles in human health and disease. Microflora are key to the biologic basis of intestinal and nonintestinal conditions. ODS is particularly interested in probiotics and prebiotics added to food and dietary supplements that influence the intestinal microbiome.

ODS will continue to collaborate with NIH institutes and centers, especially NCI, in supporting the NIH epigenetics initiative, which nurtures the study of factors that modify gene expression. "Epigenetics" refers to post-translational changes in the gene that may be inheritable. Environmental influences, including diet, may bring about epigenetic changes. Epigenetics research may be key in exploring the basis of some effects of dietary supplements. Currently, several studies are assessing the possible effects of folate and other methyl donors as sources of epigenetic changes.

Strategy 2-3

- Expand the cadre of research scientists qualified to investigate dietary supplements, with an emphasis on investigators in the early stages of their research careers.

Action Items:

ODS will continue to identify and support investigators with an interest in developing a research program that includes dietary supplements. ODS will also continue to sponsor the attendance of early-career investigators at ODS-sponsored workshops and conferences. In addition, ODS will continue to support visiting academic scientists on sabbatical to work at ODS. Finally, ODS will continue to offer a yearly practicum on dietary supplements to trainees and faculty interested in incorporating the study of dietary supplements into academic curricula.

Goal 3: Support the development of research tools for the study of dietary supplements.

ODS has led the federal effort to identify and develop research tools needed to study dietary supplements. These tools include validated analytical methods and reference materials for dietary supplements, surveys of dietary supplement use, and databases of dietary supplement ingredients and labels.

In 2008 and 2009, ODS convened expert review panels to identify gaps in analytical methods for vitamins and minerals and to prioritize needs. In the next five years, ODS will incorporate these recommendations into a research development program. Validated analytical methods and standard reference materials are needed to measure specific ingredients in dietary supplement products, as well as in body fluids and tissues after ingestion (e.g., to assess nutrient status markers in population-based studies addressing public health issues).

Data on dietary supplement intake are needed for population studies and individual assessments. The tools and resources needed include questionnaires to identify the supplements that people take, a database of dietary supplement ingredients, a comprehensive label database, and software to assess usual intakes. This makes it possible to analyze health trends. This information gleaned from population studies can also inform people's efforts to improve their own health status.

Strategy 3-1

- Continue a program for the development and validation of analytical methods and reference materials for the study of dietary supplements.
  - – Identify needs for analytical methods and reference materials.
  - – Foster development, optimization, and validation of reliable and accurate analytical techniques for identifying and quantifying specific dietary supplement ingredients, as well as potential contaminants.
  - – Produce and make available standard reference materials.

Action Items:

ODS will continue to support the development of reference materials with its federal partners, especially NIST. The development of reference materials based on saw palmetto, bitter orange, green tea, black cohosh, berries of the genus Vaccinium, soy, kudzu, and red clover is currently in progress. NIST is also preparing oils extracted from a number of plants (perilla, flaxseed, evening primrose, and borage), and a mixture of vegetable oils with values assigned for forms of vitamin E as SRMs™. NIST has developed serum-based SRMs™ for vitamin D, and is doing the same for vitamins B6, and B12.

ODS will expand its efforts to promote development of validated methods of analysis for dietary supplement ingredients. These efforts will draw on the outcomes of ODS's 2008 and 2009 workshops on methodologies for measuring vitamins and minerals in dietary supplements.

ODS will continue to work with the FDA on developing validated methods for identifying potential contaminants in dietary supplements and with the USDA on the development of validated methods for determining potentially toxic components of botanical dietary supplements.

Strategy 3-2

- Encourage the development of state-of-the-art technologies for botanical identification and for the study of complex herbal dietary supplements.

Action Items:

ODS will continue supporting the USDA's assessment of the reliability of chromatographic profiles and spectral fingerprints for identifying botanical materials and their extracts. ODS will also continue supporting the development of

other analytical methods for botanical ingredients by independent laboratories.

Strategy 3-3

- Support the development of databases of dietary supplement labels and ingredients for use in clinical, epidemiological, and other studies to allow more accurate determination of supplement intake.

Action Items:

ODS will continue its intellectual and financial support of databases of dietary supplements.

The Dietary Supplement Ingredient Database (DSID) provides statistical estimates—based on chemical analysis—of the nutrient content of selected ingredients in dietary supplements, compared with label-reported ingredient levels. The Agricultural Research Service Nutrient Data Laboratory of the USDA planned and developed the DSID in 2004, with support from ODS and other government collaborators. The 2009 release of the DSID provides estimated levels of 18 vitamin and mineral ingredients derived from analytical data for 115 representative unspecified adult MVM supplements. This information is important when using NHANES data on dietary supplement intake to estimate true MVM intake. Additional dietary supplement ingredients, including MVMs for children and expectant mothers, calcium-containing dietary supplements, omega-3 fatty acids, and botanicals, will be included in future releases of the database as funds permit.

On a parallel course to DSID, with funding from ODS and NLM, a pilot study to determine the feasibility of developing a Web-based database of the labels of all dietary supplements sold in the United States was recently completed. At the conclusion of the project, this Dietary Supplement Label Database will include the ingredients listed on the labels as well as an image of the labels.

ODS will continue to support NCI's effort to develop an automated database for data on 24-hour recall of food and dietary supplement intake.

Cranberries

Goal 4: Make the most up-to-date scientific knowledge about dietary supplements publicly available.

Information about dietary supplements is available from a wide variety of sources, including government and commercial providers, articles published in scientific journals, books and magazines, and sellers of these products. Even savvy individuals find it difficult to navigate these resources, critically evaluate their contents, and extract the information needed to assess supplement efficacy, safety, and quality.

A need exists for one authoritative source to collect, evaluate, and summarize science-based, reliable information on dietary supplements and to present this information in various forms to diverse audiences in a range of venues. ODS, as that authoritative source, plans to accelerate its efforts to synthesize this information and bring it to the attention of federal agencies, health care providers, investigators, and consumers.

Strategy 4-1

- Serve as a key information resource to the Department of Health and Human Services (HHS) and other federal agencies on issues related to dietary supplements, as stated in the DSHEA.

Action Items:

ODS will continue to identify and respond to emerging issues related to dietary supplements that affect the health of the public through a network of government contacts and working groups.

ODS will continue to promote the exchange and translation of information about dietary supplements between ODS, NIH, and other federal agencies through workshops, seminars, and federal working groups. In particular, ODS will continue working with the Federal Working Group on Dietary Supplements to coordinate and disseminate information on dietary supplements among federal partners. Most recently, the Federal Trade Commission, which oversees claims in advertising for dietary supplements, joined the working group. ODS will invite additional federal partners to join the working group as collaborative opportunities emerge.

ODS will continue to participate actively in a wide range of trans-NIH and federal working groups and committees that pertain to dietary supplements, in addition to the Federal Working Group on Dietary Supplements.

Strategy 4-2

- Provide reliable, science-based information on dietary supplements and further expand the availability of information on dietary supplements and their use in promoting wellness.

Action Items:

ODS will continue to develop and expand its Web site because the Internet has become a key resource for making information widely available.

ODS is developing new fact sheets on dietary supplement ingredients to add to its collection. The Health Professional fact sheets currently on the ODS Web site are primarily directed to health care providers who desire a comprehensive overview of a nutrient. These documents provide detailed scientific summaries and are thoroughly referenced. ODS also plans to prepare two versions of fact sheets designed for health-conscious laypersons without a background in nutrition or medicine; 1) the Consumer version will serve the educated lay reader as well as health care providers who want a brief review and update of knowledge on a particular nutrient; and 2) the QuickFacts version will provide brief and basic overviews of nutrients. It will be two pages long and easy to read. Both the Consumer and QuickFacts versions will include links to definitions of technical terms. ODS will update all versions of its fact sheets regularly and will develop new ones on additional topics.

ODS will improve access to the databases of dietary supplement ingredients and labels that are accessible through the ODS Web site.

ODS has developed an expanded Web site with dietary supplement analytical methods and reference materials for academic and industrial laboratories. This Web site (http://ods.od.nih.gov/FactSheets/AMRMProgramWebsite.asp) provides access to detailed information on the methods and materials developed with ODS support.

Strategy 4-3

- Facilitate access to databases of research projects and research results.

Action Items:

ODS provides IBIDS, a bibliographic database on dietary supplements, and CARDS, a database of federally funded research projects on dietary supplements. Although these databases are primarily for researchers and health care practitioners, they are also available to the public. ODS is working with NLM to explore alternative ways to configure IBIDS. ODS will continue to support CARDS as part of the NIH's Human Nutrition Research and Information Management system, which tracks nutrition funding.

Strategy 4-4

- Alert public- and private-sector partners of news and research on dietary supplements.

Action Items:

ODS has developed an extensive listserv of more than 3,500 addresses for the electronic distribution of materials. ODS distributes its formerly paper-based newsletter, the *ODS Update*, electronically. ODS can transmit its electronic newsletter more frequently than the paper version and the newsletter can include a wider range of timely information. The success of the *ODS Update* presents an opportunity to

Fish Oil Capsules

develop a second electronic newsletter that is targeted specifically to consumers.

ODS has published nine *Annual Bibliographies of Significant Advances in Dietary Supplement Research*. ODS is reevaluating this effort to develop an alternative approach for calling attention to research advances.

ODS staff regularly give presentations at scientific meetings and conferences and to consumer groups on the latest dietary supplements science. ODS plans to maintain a list of upcoming presentations and a list of past staff presentations on the ODS Web site. In addition, ODS will provide summaries of ODS-sponsored workshops and conferences on its Web site.

The national media are increasingly asking ODS to provide information, perspective, and quotations on dietary supplement-related issues and controversies. The ODS staff respond rapidly and effectively to consumer and media inquiries, regularly comment on new and emerging research, and coordinate lines of communication with the media. In addition, ODS communications tools (Web site, fact sheets, exhibits at conferences, pamphlets) are valuable and current.

Butterfly Weed

Strategy 4-5

- 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 promotion and disease prevention.

Action Items:

ODS will continue to exhibit and participate in professional, industry, and consumer-based conferences and meetings to better reach its stakeholders.

ODS will build on the annual Dietary Supplement Research Practicum, a one-week educational opportunity at NIH designed for faculty and doctoral-level students in all health-related disciplines. This intensive practicum provides a thorough overview of and grounding in issues, concepts, research gaps, and controversies related to dietary supplements and supplement ingredients. The program emphasizes the importance of scientific investigations to evaluate the efficacy, safety, and value of dietary supplements for health promotion and disease prevention. ODS will explore the potential for developing a practicum targeted specifically to dietitians and other health care practitioners.

V. Conclusion

This strategic plan outlines the goals and strategies that will guide ODS activities in 2010 to 2014. ODS developed these goals and strategies by consulting with ODS's many collaborative partners, reflecting on strategies that have proven successful, and embracing both ongoing and future opportunities. Indeed, ODS looks to its network of federal partners with an interest in dietary supplements to explore emerging public health issues and examine how best to address these issues through research.

ODS remains committed to its ongoing mission of strengthening the knowledge and understanding of dietary supplements through research, dissemination of research results, and public education. ODS will strive to realize its vision that consumers, health professionals, government officials, and other policy makers will have ready access to high quality scientific information on the health effects of dietary supplements. ODS will continue to coordinate and assess research on dietary supplements so that the public can make informed decisions on incorporating dietary supplements into their diets as part of their personal health planning.

Appendix A. Federal Working Group on Dietary Supplements (as of December 2009)

NATIONAL INSTITUTES OF HEALTH (NIH) INSTITUTES AND CENTERS

CC: Clinical Center – Ann Berger, M.D., M.S.N.

CSR: Center for Scientific Review – Lynn E. Luethke, Ph.D.

FIC: John E. Fogarty International Center for Advanced Study in the Health Sciences – Josh P. Rosenthal, Ph.D.

NCCAM: National Center for Complementary and Alternative Medicine – Linda C. Duffy, Ph.D.

NCI: National Cancer Institute – Cindy Davis, Ph.D.

NEI: National Eye Institute - Natalie Kurinij, Ph.D.

NHLBI: National Heart, Lung, and Blood Institute - Darla Danford, D.Sc., M.P.H.

NIA: National Institute on Aging – Judy Hannah, Ph.D.

NIAAA: National Institute on Alcohol Abuse and Alcoholism - Rosalind Breslow, Ph.D., M.P.H., R.D.

NIAID: National Institute of Allergy and Infectious Diseases – Christopher Taylor, Sc.D.

NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases – Gayle Lester, Ph.D. and Joan McGowan, Ph.D.

NIBIB: National Institute of Biomedical Imaging and Bioengineering – Christine A. Kelley, Ph.D.

NICHD: Eunice Kennedy Shriver National Institute of Child Health and Human Development – Daniel J. Raiten, Ph.D.

NIDA: National Institute on Drug Abuse – Jag H. Khalsa, Ph.D. and Vishnudutt Purohit, D.V.M., Ph.D.

NIDCD: National Institute on Deafness and Other Communication Disorders – Amy Donahue, Ph.D. and Gordon B. Hughes, M.D.

NIDCR: National Institute of Dental and Craniofacial Research – Ruth Nowjack-Raymer, M.P.H., Ph.D.

NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases – Mary E. Evans, Ph.D.; Pamela Starke-Reed, Ph.D. (Representative of the NIDDK Division of Nutrition Research Coordination)

NIEHS: National Institute of Environmental Health Sciences – Scott Masten, Ph.D. and Elizabeth A. Maull, Ph.D.

NIGMS: National Institute of General Medical Sciences – Scott Somers, Ph.D. and Donna M. Krasnewich, M.D., Ph.D.

NIMH: National Institute of Mental Health – Mi Hillefors, M.D., Ph.D.

NINDS: National Institute of Neurological Disorders and Stroke – Robin Conwit, M.D.

NINR: National Institute of Nursing Research – Paul A. Cotton, Ph.D., R.D.

NLM: National Library of Medicine – Naomi Miller, M.L.S.

Office of the Director:

OBSSR: Office of Behavioral and Social Sciences Research – Elisa L. Klein, Ph.D.

ODP: Office of Disease Prevention – Barry Portnoy, Ph.D.

ODS: Office of Dietary Supplements – Paul M. Coates, Ph.D.

ORDR: Office of Rare Diseases Research – Stephen C. Groft, Pharm.D. and Rashmi Gopal-Srivastava, Ph.D.

ORWH: Office of Research on Women's Health – Vivian W. Pinn, M.D. and Lisa Begg, Dr.P.H., R.N.

OTHER FEDERAL AGENCIES

AHRQ: Agency for Healthcare Research and Quality – Iris R. Mabry-Hernandez, M.D., M.P.H.

CDC: Centers for Disease Control And Prevention – Joel E. Kimmons, Ph.D. (National Center for Chronic Disease Prevention and Health Promotion); Vicki L. Burt, Sc.M., R.N.; David A. Lacher, M.D., M.Ed. (National Center for Health Statistics)

FDA: U.S. Food and Drug Administration – Shaw Chen, M.D., Ph.D. (Center for Drug Evaluation and Research); Vasilios H. Frankos, Ph.D. and Kathleen C. Ellwood, Ph.D. (Center for Food Safety and Applied Nutrition)

FTC: Federal Trade Commission – Michelle K. Rusk, J.D. and Christine Lee, J.D.

NIST: National Institute of Standards and Technology – Stephen A. Wise, Ph.D.

ODPHP: Office of Disease Prevention and Health Promotion – Kathryn Y. McMurry, M.S.

USARIEM: U.S. Army Research Institute of Environmental Medicine – Andrew J. Young, Ph.D.

USDA: U.S. Department of Agriculture – John W. Finley, Ph.D.

Appendix B. NIH/Agency Federal Strategic Planning Steering Committee for the Office of Dietary Supplements

Vicki L. Burt, Sc.M., R.N., Chief, Planning Branch, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)

Richard R. Cavanagh, Ph.D., Deputy Director, Chemical Science and Technology Laboratory, National Institute of Standards and Technology

Cindy Davis, Ph.D., Program Director, Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute, NIH, HHS

Vasilios H. Frankos, Ph.D., Director, Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, HHS

John Y. Killen, M.D., Deputy Director, National Center for Complementary and Alternative Medicine, NIH, HHS

Molly Kretsch, Ph.D., National Program Leader, Human Nutrition, Agricultural Research Service, U.S. Department of Agriculture

Scott Masten, Ph.D., Director, Office of Nomination and Selection, National Toxicology Program, National Institute of Environmental Health Sciences, NIH, HHS

Martina V. Taylor, M.T. (ASCP), Senior Advisor for Disease Prevention, Office of Disease Prevention, Office of the Director, NIH, HHS

EX OFFICIO

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

Julia B. Freeman, Ph.D., Senior Scientific Consultant, Office of Dietary Supplements, Office of the Director, NIH, HHS

William R. Harlan, M.D., Consultant

Appendix C. Webinar Presentations

The National Institutes of Health (NIH) Office of Dietary Supplements (ODS) held four Webinars for public comment on ODS programs and activities during its 2010–2014 strategic planning process. Each Webinar had a different focus. Recordings of the Webinars are available at: http://ods.od.nih.gov/Strategic_Planning_2010-2014/Webinar_Schedule.aspx

RESEARCH SUPPORT
Thursday, January 29, 2009, 1–2 pm EST

Presenters and commentators:

- **Public Partner Presenter:** Connie Weaver, Ph.D., Director, Botanical Research Center, Purdue University
- **Federal Partner Presenter:** John Killen, M.D., Deputy Director, National Center for Complementary and Alternative Medicine, NIH, Department of Health and Human Services (HHS)
- **Public Partner Commentators:** Michael McIntosh, Ph.D. R.D., Lucy S. Keker Excellence Professor, Department of Nutrition, University of North Carolina, Greensboro
- **Federal Partner Commentator:** John Milner, Ph.D., Chief, Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute, NIH, HHS

RESEARCH TOOLS
Tuesday, February 3, 2009, 2–3 pm EST

Presenters and commentators:

- **Public Partner Presenter**: Neal Craft, Ph.D., President, Craft Technologies, Inc.
- **Federal Partner Presenter:** Joanne Holden, M.S., Supervisory Nutritionist, Agriculture Research Service, U.S. Department of Agriculture
- **Public Partner Commentator:** Joseph Lau, M.D., Professor of Medicine, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center
- **Public Partner Commentator:** Lisa Harnack, Dr.P.H., M.P.H., R.D., Associate Professor and Director, Nutrition Coordinating Center, University of Minnesota School of Public Health

SCIENCE POLICY
Wednesday, February 11, 2009, 1–2 pm EST

Presenters and commentators:

- **Public Partner Presenter:** Christine L. Taylor, Ph.D., R.D., Scholar, Food and Nutrition Board, Institute of Medicine, National Academies of Sciences
- **Federal Partner Presenter:** Joan McGowan, Ph.D., Director, Division of Musculoskeletal Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH, HHS
- **Public Partner Commentator:** Barry Shane, Ph.D., Professor and Nutritionist, Agricultural Experiment Station, University of California, Berkeley
- **Federal Partner Commentator:** Vasilios (Bill) Frankos, Ph.D., Director, Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS

COMMUNICATIONS
Thursday, February 19, 2009, 2–3 pm EST

Presenters and commentators:

- **Public Partner Presenter:** Patsy Brannon, Ph.D., R.D., Professor, Department of Nutritional Sciences, College of Human Ecology, Cornell University
- **Public Partner Presenter:** Susan Borra, R.D., Executive Vice President and Managing Director, Nutrition, Food & Wellness, Edelman
- **Federal Partner Presenter:** Janet Austin, Ph.D., Director, Office of Communication and Public Liaison, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH, HHS

Appendix D. Federal Cofunding Partners, 2004–2009

1. National Institutes of Health (NIH) institutes and centers that cofunded research projects with the Office of Dietary Supplements (ODS) in 2004–2009, in order of ODS cofunding amount in 2008:

NCCAM National Center for Complementary and Alternative Medicine

NCI National Cancer Institute

NHLBI National Heart, Lung, and Blood Institute

NIA National Institute on Aging

NIAAA National Institute on Alcohol Abuse and Alcoholism

NIAMS National Institute of Arthritis and Musculoskeletal and Skin Diseases

NICHD Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIDDK National Institute of Diabetes and Digestive and Kidney Diseases

FIC John E. Fogarty International Center for Advanced Study in the Health Sciences

Additional Institutes that cofunded projects with ODS in 2004–2007

NIAID National Institute of Allergy and Infectious Diseases

NIDCD National Institute on Deafness and Other Communication Disorders

NIGMS National Institute of General Medical Sciences

NIMH National Institute of Mental Health

NINDS National Institute of Neurological Disorders and Stroke

2. NIH institutes and centers and other federal agencies that cofunded the development of research tools with ODS in 2004–2009, in order of ODS cofunding amount in 2008:

A. NIH Institutes and Centers

NCI National Cancer Institute

NEI National Eye Institute

NICHD Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIDDK National Institute of Diabetes and Digestive and Kidney Diseases

NLM National Library of Medicine

B. Other federal agencies

AHRQ Agency for Healthcare Research and Quality

CDC Centers for Disease Control and Prevention

FDA Food and Drug Administration

NIST National Institute of Standards and Technology

USDA Department of Agriculture

Appendix E. Office of Dietary Supplements Staff Publications, 2004–2009

2004

Coates PM, Chausmer A. Introduction to Conference on Psychoactive Botanical Products. Pharmacol Therap 2004;102:97-8.

Dwyer JT, Picciano MF, Betz JM, Coates PM. Mission and activities of the NIH Office of Dietary Supplements. J Food Compost Anal 2004;17:493-500.

Huang SM, Hall, SD, Watkins P, Love LA, Serabjit-Singh C, **Betz JM**, Hoffman FA, Honig P, **Coates PM**, Bull J, Chen ST, Kearns GL, Murray MD; Center for Drug Evaluation and Research and Office of Regulatory Affairs, Food and Drug Administration, Rockville, MD, USA. Drug interactions with herbal products and grapefruit juice: a conference report. Clin Pharmacol Ther 2004;75:1-12.

Purohit V, Russo D, **Coates PM**. Role of fatty liver, dietary fatty acid supplements, and obesity in the progression of alcoholic liver disease: introduction and summary of the symposium. Alcohol 2004;34:3-8.

Radimer K, Bindewald B, Hughes B, **Picciano MF**. Dietary supplement use in adults in the US, 1999-2000. Am J Epidemiol 2004;160:339-49.

Raiten DJ, **Picciano MF**. Vitamin D and health in the 21st century: bone and beyond. Executive summary. Am J Clin Nutr 2004;80(Suppl):1673S-7S.

Saldanha LG, Betz JM, Coates PM. Development of the analytical methods and reference materials program for dietary supplements at the National Institutes of Health. J AOAC Int 2004;87:162-5.

Seifried HE, Anderson DE, Sorkin BC, **Costello RB**. Free radicals: the pros and cons of antioxidants. Executive summary report. J Nutr 2004;134:3143S-63S.

Yetley EA, Rader JI. Modeling the level of fortification and post-fortification assessments: U.S. experience. Nutr Rev 2004;62:S50-9.

2005

Costello RB, Chrousos GP. Other bioactive food components and dietary supplements. In: Committee on Military Nutrition Research, Food and Nutrition Board, Institute of Medicine, ed. Nutrient Composition of Rations for Short-term, High-intensity Combat Operations. Washington, DC: National Academies Press, 2005.

Davis CD, **Swanson CA**, Ziegler RG, Clevidence B, **Dwyer JT**, Milner JA. Executive summary report Promises and perils of lycopene/tomato supplementation and cancer prevention. J Nutr 2005;135:2014S-29S.

Davis CD, Clevidence B, **Swanson CA**, Ziegler RG, **Dwyer JT**, Milner JA. A research agenda for lycopene/tomato supplementation and cancer prevention. J Nutr 2005;135:2074S.

Dwyer JT, Allison DB, **Coates PM**. Dietary supplements in weight reduction. J Am Dietet Assoc 2005;105(Suppl):S80-6.

Haggans CJ, Regan KS, Brown LM, Wang C, Krebs-Smith J, **Coates PM**, **Swanson CA**. Computer access to research on dietary supplements: a database of federally funded dietary supplement research. J Nutr 2005;135:1796-9.

Reaves L, Steffen LM, **Dwyer JT**, Webber LS, Lytle LA, Feldman HA, Hoelscher DM, Zive MM, Osganian SK. Vitamin supplement intake is related to dietary intake and physical activity: The Child and Adolescent Trial for Cardiovascular Health (CATCH). J Am Diet Assoc 2006;106:2018-23.

Vogel JH, Bolling SF, **Costello RB**, Guarneri EM, Krucoff MW, Longhurst JC, Olshansky B, Pelletier KR, Tracy CM, Vogel RA, Vogel RA, Abrams J, Anderson JL, Bates ER, Brodie BR, Grines CL, Danias PG, Gregoratos G, Hlatky MA, Hochman JS, Kaul S, Lichtenberg RC, Lindner JR, O'Rourke RA, Pohost GM, Schofield RS, Shubrooks SJ, Tracy CM, Winters WL Jr; American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents (Writing Committee to Develop an Expert Consensus Document on Complementary and Integrative Medicine). Integrating complementary medicine into cardiovascular medicine. A report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents (Writing Committee to Develop an Expert Consensus Document on Complementary and Integrative Medicine). J Am Coll Cardiol 2005;46:184-221.

2006

Dwyer JT, Picciano MF, Betz JM, Fisher KD, Saldanha LG, Yetley EA, Coates PM, Radimer K, Bindewald B, Sharpless KE, Holden J, Andrews K, Zhao C, Harnly J, Wolf WR, Perry CR. Progress in development of an integrated dietary supplement ingredient database at the NIH Office of Dietary Supplements. J Food Compost Anal 2006;19:S108-14.

Ershow AG, **Costello RB**. Dietary guidance in heart failure: a perspective on needs for prevention and management. Heart Fail Rev 2006;11:7-12.

Gilani GS, **Betz JM**. Role of accurate methodology in demonstrating the safety and efficacy of phytoestrogens. J AOAC Int 2006;89:1120.

Potischman N, Cohen BE, **Picciano MF**. Dietary recommendations and identified research needs for The National Children's Study. J Nutr 2006;136:686-9.

Rapaka RS, **Coates PM**. Dietary supplements and related products: a brief summary. Life Sci 2006;78:2026-32.

Roman MC, **Betz JM,** Hildreth J. Determination of synephrine in bitter orange raw materials, extracts, and dietary supplements by liquid chromatography with ultraviolet detection: single-laboratory validation. J AOAC Int 2007;90:68-81.

Sharpless KE, Anderson DL, **Betz JM**, Butler TA, Capar SG, Cheng J, Fraser CA, Gardner G, Gay ML, Howell DW, Ihara T, Khan MA, Lam JW, Long SE, McCooeye M, Mackey EA, Mindak WR, Mitvalsky S, Murphy KE, NguyenPho A, Phinney KW, Porter BJ, Roman M, Sander LC, Satterfield MB, Scriver C, Sturgeon R, Thomas JB, Vocke RD Jr, Wise SA, Wood LJ, Yang L, Yen JH, Ziobro GC. Preparation and characterization of a suite of ephedra-containing standard reference materials. J AOAC Int 2006;89: 1483-95.

Tamura T, **Picciano MF.** Folate and human reproduction. Am J Clin Nutr 2006;83:993-1006.

Tamura T, **Picciano MF.** Folate determination in human milk. J Nutr Sci Vitaminol (Tokyo) 2006;52:161.

2007

Andrews KW, Schweitzer A, Zhao C, Holden JM, Roseland JM, Brandt M, **Dwyer JT, Picciano MF, Saldanha LG, Fisher KD, Yetley E, Betz JM**, Douglass L. The caffeine contents of dietary supplements commonly purchased in the US: analysis of 53 products with caffeine-containing ingredients. Anal Bioanal Chem 2007;389:231-9.

Balk EM, Horsley TA, Newberry SJ, Lichtenstein AH, **Yetley EA**, Schachter HM, Moher D, MacLean CH, Lau J. A collaborative effort to apply the evidence-based review process to the field of nutrition: challenges, benefits, and lessons learned. Am J Clin Nutr 2007;85:1448-56.

Betz JM, Fisher KD, Saldanha LG, Coates PM. The NIH analytical methods and reference materials program for dietary supplements. Anal Bioanal Chem 2007;389:19-25.

Coates PM. Dietary supplements and health: the research agenda. Novartis Found Symp 2007;282:202-7.

Coates PM. Evidence-based reviews in support of health policy decisions. J Natl Cancer Inst 2007;99:1059.

Coates PM, **Thurn A, Dwyer JT.** Introduction to State-of-the-Science Conference: Multivitamin/mineral supplements and chronic disease prevention. Am J Clin Nutr 2007;85 (Suppl):255S-6S.

Davis CD, **Dwyer JT**. The "sunshine vitamin": benefits beyond bone? J Natl Cancer Inst 2007;99:1563-5.

Davis CD, Hartmuller V, Freedman DM, Hartge P, **Picciano MF, Swanson CA**, Milner JA. Vitamin D and cancer: current dilemmas and future needs. Nutr Rev 2007;65 (Pt 2):S71-4.

Dwyer JT. Do functional components in foods have a role in helping to solve current health issues? J Nutr 2007;137(11 Suppl):2489S-92S.

Dwyer JT, Holden J, Andrews K, Roseland J, Zhao C, Schweitzer A, Perry CR, Harnly J, Wolf WR, **Picciano MF, Fisher KD, Saldanha LG, Yetley EA, Betz JM, Coates PM**, Milner JA, Whitted J, Burt V, Radimer K, Wilger J, Sharpless KE, Hardy CJ. Measuring vitamins and minerals in dietary supplements for nutrition studies in the USA. Anal Bioanal Chem. 2007;389:37-46.

London B, Albert C, Anderson ME, Giles WR, Van Wagoner DR, Balk E, Billman GE, Chung M, Lands W, Leaf A, McAnulty J, Martens JR, **Costello RB**, Lathrop DA. Omega-3 fatty acids and cardiac arrhythmias: prior studies and recommendations for future research: a report from the National Heart, Lung, and Blood Institute and Office of Dietary Supplements Omega-3 Fatty Acids and their Role in Cardiac Arrhythmogenesis Workshop. Circulation 2007;116:e320-35.

Pfeiffer CM, Johnson CL, Jain R, **Yetley EA, Picciano MF**, Rader J, **Fisher KD**, Mulinare J, Osterloh JD. Trends in biochemical indices of folate and vitamin B12 status in the United States, 1988-2004. Am J Clin Nutr 2007;86:718-27.

Picciano MF, Dwyer JT, Radimer KL, Wilson DH, **Fisher KD**, **Thomas PR**, **Yetley EA**, Moshfegh AJ, Levy PS, Nielsen SJ, Marriott BM. Dietary supplement use among infants, children, and adolescents in the United States, 1999-2002. Arch Pediatr Adolesc Med 2007;161:978-85.

Picciano MF, Yetley EA, Coates PM. Folate and health. Perspectives in agriculture, veterinary science, nutrition and natural resources. CAB Review 2007;2(0018).

Rimmer CA, Howerton SB, Sharpless KE, Sander LC, Long SE, Murphy KE, Porter BJ, Putzbach K, Rearick MS, Wise SA, Wood LJ, Zeisler R, Hancock DK, Yen JH, **Betz JM**, Nguyenpho A, Yang L, Scriver C, Willie S, Sturgeon R, Schaneberg B, Nelson C, Skamarack J, Pan M, Levanseler K, Gray D, Waysek EH, Blatter A, Reich E. Characterization of a suite of ginkgo-containing standard reference materials. Anal Bioanal Chem 2007;389: 179-96.

Trucksess MW, Weaver CM, Oles CJ, Rump LV, White KD, **Betz JM**, Rader JI. Use of multitoxin immunoaffinity columns for determination of aflatoxins and ochratoxin A in ginseng and ginger. J AOAC Int 2007; 90:1042-9.

Yetley EA. Science in the regulatory setting: a challenging but incompatible mix? Novartis Found Symp 2007;282:59-68.

Yetley EA. Multivitamin and multimineral dietary supplements: definitions, characterization, bioavailability, and drug interactions. Am J Clin Nutr 2007; 85:269S-76S.

2008

Brannon PM, Yetley EA, Bailey RL, Picciano MF. Overview of the conference "Vitamin D and Health in the 21st Century: an Update." Am J Clin Nutr 2008;88: 483S-90S.

Brannon PM, Yetley EA, Bailey RL, Picciano MF. Summary of roundtable discussion on vitamin D research needs. Am J Clin Nutr 2008;88:587S-592S.

Davis RE, Resnicow K, Atienza AA, Peterson KE, Domas A, Hunt A, Hurley TG, Yaroch AL, Greene GW, Goldman Sher T, Williams GC, Hebert JR, Nebeling L, Thompson FE, Toobert DJ, Elliot DL, DeFrancesco C, **Costello RB**. Use of signal detection methodology to identify subgroups of dietary supplement use in diverse populations. J Nutr 2008;138:205S-11S.

Dwyer J, Costello RB. Assessment of dietary supplement use. In: Coulston AM, Boushey CJ, es. Nutrition in the Prevention and Treatment of Disease. 2nd edition. Burlington, MA: Academic Press, 2008:41-56.

Dwyer JT, Picciano MF, Betz JM, Fisher KD, Saldanha LG, Yetley EA, Coates PM, Milner JA, Whitted J, Burt V, Radimer K, Wilger J, Sharpless KE, Holden JM, Andrews K, Roseland J, Zhao C, Schweitzer A, Harnly J, Wolf WR, Perry CR. Progress in developing analytical and label-based dietary supplement databases at the NIH Office of Dietary Supplements. J Food Comp Anal 2008;21:S83-93.

Harnack L, Stevens M, Van Heel N, Schakel S, **Dwyer JT**, Himes J. A computer-based approach for assessing dietary supplement use in conjunction with dietary recalls. J Food Compost Anal 2008;21(Suppl 1):S78-82.

Lichtenstein AH, **Yetley EA**, Lau J. Application of systematic review methodology to the field of nutrition. J Nutr 2008;138(12):2297-306.

Looker AC, Pfeiffer CM, Lacher DA, Schleicher RL, **Picciano MF, Yetley EA**. Serum 25-hydroxyvitamin D status of the US population: 1988-1994 compared with 2000-2004. Am J Clin Nutr 2008;88: 1519-27.

McDowell MA, Lacher DA, Pfeiffer CM**,** Mulinare J, **Picciano MF**, Rader JI, **Yetley EA**, Kennedy-Stephenson J, Johnson CL. Blood folate levels of the U.S. population: what the latest NHANES data show. NCHS Data Brief, No.2. Hyattsville, MD: National Center for Health Statistics, 2008. Available at: **http://www.cdc.gov/nchs/data/databriefs/db06.htm**.

Morris MS, **Picciano MF**, Jacques PF, Selhub J. Plasma pyridoxal 5'-phosphate (PLP) in the United States population: the National Health and Nutrition Examination Survey, 2003-2004. Am J Clin Nutr 2008;87: 1446-54.

Pfeiffer CM, Osterloh JD, Kennedy-Stephenson J, **Picciano MF, Yetley EA**, Rader JI, Johnson CL. Trends in circulating concentrations of total homocysteine among US adolescents and adults: findings from the 1991-1994 and 1999-2004 National Health and Nutrition Examination Surveys. Clin Chem 2008;54:801-13.

Saldanha LG. US Food and Drug Administration regulations governing label claims for food products, including probiotics. Clin Infect Diseases 2008;6(Suppl 2):S119-21.

Sander LC, Putzbach K, Nelson BC, Rimmer CA, Bedner M, Thomas JB, Porter BJ, Wood LJ, Schantz MM, Murphy KE, Sharpless KE, Wise SA, Yen JH, Siitonen PH, Evans RL, Nguyen Pho A, Roman MC, **Betz JM**. Certification of standard reference materials containing bitter orange. Anal Bioanal Chem 2008;391:2023-34.

Schantz MM, Bedner M, Long SE, Molloy JL, Murphy KE, Porter BJ, Putzbach K, Rimmer CA, Sander LC, Sharpless KE, Thomas JB, Wise SA, Wood LJ, Yen JH, Yarita T, NguyenPho A, Sorenson WR, **Betz JM**. Development of saw palmetto (Serenoa repens) fruit and extract standard reference materials. Anal Bioanal Chem 2008; 392:427-38.

Swanson CA, Liu Q-Y. Introduction to the National Institutes of Health Botanical Research Centers Program. Am J Clin Nutr 2008;87:471S.

Taylor CL, **Yetley EA**. Nutrient risk assessment as a tool for providing scientific assessments to regulators. J Nutr 2008;138: 1987S-91S.

Trucksess MW, Weaver CM, Oles CJ, Fry FS Jr, Noonan GO, **Betz JM**, Rader JI. Determination of aflatoxins B1, B2, G1, and G2 and ochratoxin A in ginseng and ginger by multitoxin immunoaffinity column cleanup and liquid chromatographic quantitation: collaborative study. J AOAC Int 2008;91: 511-23.

Whittaker P, Clarke JJ, San RH, **Betz JM**, Seifried HE, de Jager LS, Dunkel VC. Evaluation of commercial kava extracts and kavalactone standards for mutagenicity and toxicity using the mammalian cell gene mutation assay in L5178Y mouse lymphoma cells. Food Chem Toxicol 2008;46:168-74.

Yaroch AL, Nebeling L, Thompson FE, Hurley TG, Hebert JR, Toobert DJ, Resnicow K, Greene GW, Williams GC, Elliot DL, Goldman Sher T, Stacewicz-Sapuntzakis M, Salkeld J, Rossi S, Domas A, Mcgregor H, Defrancesco C, Mccarty F, **Costello RB**, Peterson KE. Baseline design elements and sample characteristics for seven sites participating in the Nutrition Working Group of the Behavior Change Consortium. J Nutr 2008;138:185S-92S.

Yetley EA. Assessing the vitamin D status of the US population. Am J Clin Nutr 2008;88:558S-64S.

2009

Bailey RL, Miller PE, Mitchell DC, Hartman TJ, Lawrence FR, Sempos CT, Smiciklas-Wright H. Dietary screening tool identifies nutritional risk in older adults. Am J Clin Nutr 2009; 90:177-183.

Betz JM, Anderson L, Avigan MI, Barnes J, Farnsworth NR, Gerdén B, Henderson L, Kennelly EJ, Koetter U, Lessard S, Dog TL, McLaughlin M, Naser, B, Osmers RGW, Pellicore LS, Senior JR, van Breemen RB, Wuttke W, Cardellina II JH. Black cohosh: Considerations of safety and benefit. Nutr Today 2009;44:155-62.

Betz JM, Wise SA. More on iodine content of prenatal vitamins. N Engl J Med 2009;360:2582.

Chung M, Balk EM, Ip S, Raman G, Yu WW, Trikalinos TA, Lichtenstein AH, **Yetley EA**, Lau J. Reporting of systematic reviews of micronutrients and health: a critical appraisal. Am J Clin Nutr 2009;89:1099-113.

Looker AC, Lacher DA, Pfeiffer CM, Schleicher RL, **Picciano MF, Yetley EA**. Data advisory with regard to NHANES serum 25-hydroxyvitamin D data. Am J Clin Nutr 2009;90:695-703.

Picciano MF, McGuire MK. Use of dietary supplements by pregnant and lactating women in North America. Am J Clin Nutr 2009;89:663S-7S.

Picciano MF, Yetley EA, Coates PM, McGuire MK. Update on folate and human health. Nutr Today 2009;44:142-52.

Sempos CT, Picciano MF. The intention to treat principle, and the potential impact of excluding data from the analysis of clinical trial data. J Nutr 2009;139:1204.

Yetley EA, Brulé D, Cheney MC, Davis CD, Esslinger KA, Fischer PW, Friedl KE, Greene-Finestone LS, Guenther PM, Klurfeld DM, L'Abbe MR, McMurry KY, Starke-Reed PE, Trumbo PR. Dietary reference intakes for vitamin D: justification for a review of the 1997 values. Am J Clin Nutr 2009;89: 719-27.

Appendix F. Glossary

AHRQ Agency for Healthcare Research and Quality

AMRM Analytical Methods and Reference Materials Program

BRCs Botanical Research Centers

CARDS Computer Access to Research on Dietary Supplements

CDC Centers for Disease Control and Prevention

DoD Department of Defense

DRIs Dietary Reference Intakes

DSHEA Dietary Supplement Health and Education Act of 1994

DSID Dietary Supplement Ingredient Database

FDA U.S. Food and Drug Administration

FOA Funding Opportunity Announcement

IBIDS International Bibliographic Information on Dietary Supplements

IOM Institute of Medicine

MVM Multivitamin/mineral supplements

NCCAM National Center for Complementary and Alternative Medicine

NCHS National Center for Health Statistics

NCI National Cancer Institute

NHANES National Health and Nutrition Examination Survey

NHIS National Health Interview Survey

NICHD Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIH National Institutes of Health

NIMH National Institute on Mental Health

NIST National Institute of Standards and Technology

NLM National Library of Medicine

ODS Office of Dietary Supplements

SRM™ Standard Reference Material

USDA U.S. Department of Agriculture

Office of Dietary Supplements
National Institutes of Health

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