Draft Strategic Plan
2022–2026

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

2022

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FROM THE ODS DIRECTOR

I. Overview and Introduction

The history of the Office of Dietary Supplements (ODS) is rooted in legislation—the Dietary Supplement Health and Education Act (DSHEA) of 1994 (see Appendix A)—and subsequent congressional language that form the basis of its mission, vision, and programs. The passage of DSHEA followed two related and important legislative changes. In 1976 Congress prohibited the Food and Drug Administration (FDA) from limiting the potency of vitamins and minerals in dietary supplements or regulating them as drugs based on their potency. In 1990, nutrition labels on packaged foods were mandated by the Nutrition Labeling and Education Act (NLEA) and certain health claims that could be made for food and food products were permitted. Related questions about the labeling and regulation of dietary supplements led Congress to pass the DSHEA in 1994 in which dietary supplements were classified as a special category of food, and the Secretary of the Department of Health and Human Services (HHS) was directed to establish an Office of Dietary Supplements within the National Institutes of Health.

Through its programs, funding opportunities, and activities, and consistent with the overall mission of Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), ODS helps strengthen existing programs related to dietary supplement research and research training at NIH Institutes and Centers and Offices (ICOs) and enhances the array of resources available to dietary supplement researchers and other ODS stakeholders.

Mission, Vision, and Goals

As a result of the strategic planning process (see Section IV), ODS has refined and reaffirmed its mission statement and refined its goals with a stated vision for research on dietary supplements and health outcomes, which maintains the focus on the office's core purpose and responsibilities as mandated by DSHEA. In addition to the four goals on which ODS focused in prior strategic planning periods, the Office has added a fifth goal that delineates the need for actively coordinating and supporting collaborative dietary supplement research efforts across NIH. ODS's goals recognize the increasing interest across NIH and other Federal agencies in understanding the knowledge gaps that exist with respect to dietary supplements at a time when dietary supplement usage across the United States continues to grow. The Nutrition Business Journal reports dietary supplement sales of $55.7 billion in 2020.

The **mission** *of ODS is to support, conduct, and coordinate scientific research and provide intellectual leadership for the purpose of strengthening the knowledge and understanding of dietary supplements to foster an enhanced quality of life and health for the U.S. population.*

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

ODS's five ***goals*** *are:*

1. *Expand the scientific knowledge base on dietary supplements by stimulating and supporting a full range of biomedical research and by developing and contributing to collaborative initiatives, workshops, meetings, and conferences.*
2. *Enhance the dietary supplement research workforce through training and career development.*
3. *Foster development and dissemination of research resources and tools to enhance the quality of dietary supplement research.*
4. *Translate dietary supplement research-findings into useful information for consumers, health professionals, researchers, and policymakers.*
5. *Coordinate and support the development of collaborative initiatives to address gaps in dietary supplement research.*

II. Scientific Strategy

As the lead federal entity addressing the scientific exploration of dietary supplements, ODS continues to advance the research agenda and knowledge base for this class of goods. The key to ODS's success is the balance it achieves between its roles as a communicator of existing and new knowledge; facilitator of research; developer of resources; trainer of researchers; and coordinator and collaborator with NIH Institutes, Centers, and Offices (ICOs), academic researchers, federal and state agencies, and non-governmental organizations (NGOs).

The details of ODS's scientific strategy for 2022-2026 are presented by individual goals and strategies below.

GOAL 1: Expand the scientific knowledge base on dietary supplements by stimulating and supporting a full range of biomedical research and by developing and contributing to relevant initiatives, workshops, meetings, and conferences.

Today, more than 80,000 dietary supplement products are available that contain vitamins and minerals, herbs and botanicals, and other ingredients (such as glucosamine, fish oils, and probiotics). Dietary supplements are consumed by about half of adults and one third of children and adolescents in the United States.Yet there are questions about the exact ingredients, efficacy and safety of many dietary supplements. ODS plans to continue working in collaboration with NIH ICs and other research institutions to answer such questions. ODS will continue to choose research priorities based on public health importance, and will use systematic reviews as a primary assessment tool to address efficacy and safety issues. ODS will also use systematic reviews to translate research results for public health policy decision-making.

Strategy 1-1: Increase understanding of the health impacts and biological effects of dietary supplements.

ODS will identify supplement-related public health areas and support innovative research to evaluate the health effects of dietary supplements – primarily for promoting health and reducing the risk of disease – and the underlying biological mechanisms by which they do so. In addition to co-funding new research with partner NIH ICs, ODS will continue to increase the exposure to and awareness of research on botanical and non-botanical dietary supplements by co-funding expanded research aims for existing NIH grants, thus stimulating more investigations of dietary supplements' health effects.

In a joint effort with the National Center for Complementary and Integrative Health (NCCIH), ODS will continue to promote collaborative, transdisciplinary research on the safety, effectiveness, and mechanisms of action of inherently complex natural products, especially

botanicals, that have a high potential to affect human health and to support the development of methods and resources that will enhance the progress of this research. The NIH Centers for Advancing Research on Botanical and Other Natural Products (CARBON) program will continue to conduct preclinical research to inform future clinical trials, along with early-phase clinical trials, and accelerate state-of-the-art, high-throughput, and high-content method development.

ODS will continue to guide and coordinate data-collection activities across the federal government for the purpose of tracking dietary exposure to dietary supplements. ODS will support research to identify and measure biomarkers of nutrient exposure and status in relation to chronic disease in populations and individuals.

Recent research—such as that supported by the NIH Human Microbiome Project—has revealed many insights into the influence of human-associated microbes on health and nutrition and has raised many more research questions. ODS will seek to understand the role of the microbiome in mediating the effects of bioactive components in food and dietary supplements. ODS will remain committed to supporting novel research, workshops, symposia, and trans-federal agency efforts aimed at elucidating the functional relevance of the microbiota to nutritional status, energy balance, and risk of disease.

ODS will coordinate and foster collaboration between NIH ICOs with strategic priorities, or funds dedicated to, resilience research programs. ODS will facilitate the collection and harmonization of data on commonalities related to resilience outcomes, phenotype patterns, and measurements of resilience.

Strategy 1-2: Conduct research on patterns of dietary supplement use in the U.S. population.

ODS staff will assess the prevalence, frequency, duration, levels, and types of dietary supplements used in the United States. For example, ODS will continue to use National Health and Nutrition Examination Survey (NHANES) data to investigate dietary supplement usage patterns in diverse population subgroups (such as seniors, pregnant women, infants, children, and adolescents) and consumer use of dietary supplements in combination with widely used over-the-counter and prescription medications. ODS also plans to evaluate the cognitive, behavioral and motivational factors underlying dietary supplement use.

ODS will address and work to identify, evaluate and overcome methodological issues related to assessment of supplement usage in epidemiologic and other study designs. It will also evaluate current and novel laboratory methods to measure supplement usage and nutritional status for individual ingredients in supplements.

Strategy 1-3: Identify knowledge gaps and research needs.

ODS will support and co-sponsor systematic reviews of dietary supplements and their ingredients. Topics will include the efficacy and safety of supplement use and their potential role in reducing disease risk. ODS will also sponsor systematic reviews to assess the strength and quality of the science on the health effects of dietary supplements and their ingredients.

ODS will continue to conduct internal and NIH-wide portfolio analyses with NIH ICs and other federal partners, leading to priority setting for funding decisions and identification of emerging research opportunities.

ODS will lead and sponsor workshops and conferences with NIH ICs and offices to discuss and evaluate the current state of the science. Attendees will include dietary supplement researchers, clinicians, government officials, industry representatives, and other stakeholders.

GOAL 2: Enhance the dietary supplement research workforce through training and career development.

Despite the widespread use and availability of dietary supplements, the scientific underpinnings of the potential health effects of the vast majority of ingredients and combinations remains relatively underrepresented in the published peer-reviewed literature. Therefore, funding is needed to develop and support a cadre of researchers who productively study dietary supplements and to recognize their work as an important area of investigation.

Strategy 2-1: Support scientific training programs and continuing education activities.

The co-funding that ODS provides to extramural researchers will also give them access to ODS staff expertise. ODS will continue to co-fund training grants and career development grants with partner ICs to train junior scientists in methodologies that will enhance dietary supplement research. All components of the CARBON centers, for example, will train young investigators (students, postdoctoral fellows, and new faculty) and encourage recruitment of junior researchers through the support of innovative pilot projects.

ODS will continue an administrative supplement grant program that co-funds expanded aims for grants for up to a year. This will allow investigators, including junior scientists, to expand the scientific scope of their NIH-funded projects to include work related to dietary supplements.

The ODS Research Scholars Program will provide one-year competitive scholarship opportunities for NIH intramural scientists to study the role of dietary supplements and/or their ingredients in health promotion and disease prevention.

The ODS will continue to provide a thorough overview about issues, concepts, unknowns, and controversies about dietary supplements and supplement ingredients through its annual Mary Frances Picciano Dietary Supplement Research Practicum. ODS will continue to broaden the practicum's reach by making a video archive of the presentations available on the ODS website. ODS will sponsor ODS Seminar series on a monthly basis featuring presentations by experts who conduct research on dietary supplements, nutrition, and related issues.

ODS will help sponsor workshops conducted by scientific organizations (such as the Federation of American Societies for Experimental Biology (FASEB), the American Society for Nutrition (ASN), and others) that include a focus on dietary supplements or a topic relevant to ODS.

Strategy 2-2: Provide continuing education activities and career development for professionals through opportunities to work with ODS.

ODS will continue to offer postdoctoral and career training in its offices. ODS plans to maintain its sponsorship of fellows through the John A. Milner Fellowship with the U.S. Department of Agriculture (USDA) and the American Association for the Advancement of Science's (AAAS) Science & Technology Policy Fellowship. ODS will explore other mechanisms to support postdoctoral research training in collaboration with other NIH ICs and federal agencies.

ODS will continue to offer opportunities for academic faculty members to work at ODS during their sabbaticals. Mid- and senior-level faculty members will work with ODS for up to one year to develop experience in investigating dietary supplements and to work with ODS scientists on new initiatives. For example, ODS developed a new initiative related to iron with the help of a visiting professor from Cornell University. ODS also provides an opportunity for retired nutitionists to work with the office (part-time) in order to broaden ODS's staff scope and bring needed expertise to workshops and to facilitate mechanisms working with other federal partners.

Strategy 2-3: Provide funding to stimulate research training in federal laboratories.

ODS will continue to train young intramural investigators in the stimulating environments of research laboratories across the federal government. ODS will maintain its support for the ODS Intramural Research Scholars Program, a one-year competitive scholarship opportunity for NIH intramural junior scientists who have at least one year of postdoctoral research experience. This program will enable them to develop expertise in the scientific exploration of dietary supplements for health promotion and disease prevention.

ODS will maintain its support for interagency agreements to sponsor junior and senior investigators at collaborating federal agencies, such as the National Institute of Standards and Technology (NIST) and the USDA, on projects of mutual interest. An interagency agreement

with NIST, for example, supports a postdoctoral fellow in metrology (the science of measurement).

GOAL 3: Foster development and dissemination of research resources and tools to enhance the quality of dietary supplement research.

There is an ongoing need to develop new research methodologies, resources, and tools to support the study of dietary supplements. ODS will continue to coordinate the creation and dissemination of analytical tools for the characterization of dietary supplement ingredients through its Analytical Methods and Reference Materials (AMRM) program. It will also continue to work to improve survey instruments for observational studies, resources and methodologies for pre-clinical and clinical trials, and will continue to work with NCCIH and The National Center for Advancing Translational Sciences (NCATS) to develop product integrity guidance documents. This effort will continue to expand beyond dietary supplements to include the measurement of biomarkers of nutrient status in blood and other biological specimens.

Strategy 3-1: Enhance the development of appropriate study methods for dietary supplement research.

ODS will stimulate the development, evaluation, and use of appropriate and rigorous research paradigms for investigating the efficacy and safety of dietary supplements. For example, ODS will continue to support and plan workshops on the latest knowledge and emerging approaches in the study of dietary supplements (similar to the workshop on the unique challenges of translating natural products research to clinically useful trial outcomes organized and co-sponsored by ODS, and the workshop on assessing the safety of botanical dietary supplements co-sponsored by ODS).

ODS will support the development of cutting-edge approaches to elucidate the mechanisms of action of chemically complex natural product dietary supplements. The Natural Product Technology, Methodology, and Productivity Optimization (NP-TEMPO) Center component of the CARBON program develops methods to accelerate research on complex natural products such as botanicals for human health and establishes collaborations to refine applications of these methods. Another component of the CARBON program, the Natural Product Magnetic Resonance Database (NP-MRD) has established a resource that will serve as a repository specifically for natural product nuclear magnetic resonance spectra, which provides a growing suite of powerful tools for assigning, refining, and comparing molecular structure asignments and metadata. This repository with its associated tools provides an important new resource to support the rigor and progress of natural products research.

ODS will also encourage the development and use of appropriately validated biomarkers of nutrient status in studies of the health effects of dietary supplement ingredients. In addition, through its Population Studies Program, ODS will help to develop tools to evaluate dietary supplement usage more precisely in national health surveys and other large cohorts.

The ability to compare, reproduce, and replicate published research results is essential for building scientific knowledge. ODS will ensure that its co-funded grants adhere to rigorous standards for dietary supplement identification to ensure product integrity using a paradigm established by the NCCIH. ODS will also continue to promote the highest quality research in dietary supplements by requiring investigators to thoroughly characterize and report the composition of the products they use in mechanistic and clinical investigations.

ODS will continue to collaborate with NIST to administer the HealthAssessment Measurements Quality Assurance Program (HAMQAP) to enable laboratories to improve the accuracy of their analytical measurements of foods, dietary supplements, and biological samples.

ODS will coordinate with NIH ICOs to facilitate the development of research tools to enhance the advancement of resilience research.

Strategy 3-2: Foster the highest-quality laboratory analyses for dietary supplement constituents to enhance the quality of dietary supplement products by developing and promoting validated analytical methods and certified reference materials.

NIST is a main U.S. producer of reference materials that industry and academia can use to ensure precision and accuracy in measurements. Through its collaborative interagency activities, ODS will continue to advance the development of reference materials for dietary ingredients and natural products and to produce and make available certified reference materials.

Furthermore, ODS will foster the development, optimization, validation, and use of reliable and accurate analytical techniques for identifying and quantifying specific dietary supplement ingredients and potential contaminants. ODS will support these efforts through funding for research grants, interagency agreements, and contracts with NGOs.

Strategy 3-3: Develop and provide publicly accessible databases for use in clinical, epidemiological, and other population research on dietary supplements.

ODS will continue to compile dietary supplement product label information in a publicly accessible database. As it has done since launching the Dietary Supplement Label Database (DSLD) in 2013, ODS will continue to add dietary supplement product label information to the DSLD and ensure its reliability. ODS will also continue to call on external experts and request public comments to further enhance the DSLD by increasing its utility for researchers and consumers.

ODS will continue to prioritize its efforts to work with the USDA to analyze ingredients for the Dietary Supplement Ingredient Database (DSID) based on their public health relevance. ODS will also support analyses of ingredients in both foods and dietary supplements to estimate total intakes, especially of key nutrients.

ODS will continue to maintain and enhance the Computer Access to Research on Dietary Supplements (CARDS) database of federally funded research projects to include more years of data. ODS will also develop a more user-friendly interface and create a more precise and informative research-categorization system for CARDS.

GOAL 4: Translate dietary supplement research findings into useful information for consumers, health professionals, researchers, and policymakers.

ODS provides an array of information on dietary supplements and their ingredients that the public views as reliable and up to date. Dietary supplement users will continue to benefit from free access to this objective information. Along with the general public, the website-user community includes health professionals, researchers, and policymakers. ODS will continue to collaborate with others in translating research findings into actionable information for public policy and guideline development.

Strategy 4-1: Develop and maintain informational resources on dietary supplements for diverse audiences.

ODS will publish new dietary supplement fact sheets (the most frequently viewed materials on the ODS website) and revise existing fact sheets as necessary to keep them current. It will also prepare fact sheets on other ingredients in dietary supplement products and on dietary supplements for specific purposes. ODS will continue to create several forms of each fact sheet: a detailed, referenced version directed to health professionals and easy-to-read versions in both English and Spanish directed to consumers.

ODS will periodically review and update the ODS website to ensure that it meets the needs and interests of users. ODS will further increase access to ODS informational resources through various outreach efforts, such as expanding and promoting its service that provides personal responses from ODS nutrition staff to questions about dietary supplements from ODS website users.

ODS will continue to explore ways to increase our reach using govDelivery and other communication services such as Meltwater. The use of an email subscription and marketing service called govDelivery by Granicus has helped ODS gain access to a large network of federal, state, and local government clients and subscribers.

Strategy 4-2: Provide leadership on dietary supplement research and educational activities within the federal government.

By congressional mandate, ODS advises the DHHS and its agencies on matters related to dietary supplements, and it will continue to do so. For example, ODS scientists and the staff of the U.S. Food and Drug Administration's (FDA) Office of Dietary Supplement Programs will continue to meet by conference call on a regular basis.

To further collaborative efforts on dietary supplement research, education, and communications beyond the Department of Health and Human Services, ODS will continue to lead the Federal Working Group on Dietary Supplements (FWGoDS) that includes representatives of most NIH ICs and other federal agencies. Through these efforts, ODS will continue to build strategic partnerships and engage leaders and stakeholders in exchanging information and ideas on nutrition and dietary supplement research, education, and policy.

Strategy 4-3: Collaborate with stakeholders to inform public health policy and clinical practice related to nutrients and other ingredients in dietary supplements.

Data on food and nutrient intake has been collected for decades. Collecting data on dietary supplement use is more recent and has grown in importance with increased use of dietary supplements by the U.S. population. Dietary supplements can contribute substantially to intakes of several essential nutrients. Food and supplement intakes must be used together for assessing and planning total dietary intakes for individuals and groups and for developing dietary recommendations at the federal and local levels.

In addition to supporting the development of an NHANES Dietary Supplement Database to be used with data from the NHANES to address population dietary supplement intakes, ODS has developed two databases that are used to assess the intake of ingredients in dietary supplements -- the DSLD and the DSID. They were developed in collaboration with federal experts from NIH, USDA, U.S. Department of Commerce (USDOC), FDA and U.S. Department of Defense (DoD).

The development of these databases, in addition to ODS's support for the collection and analysis of dietary supplement use in NHANES, now permit population-based estimates of total dietary intake. ODS staff in collaboration with other federal agencies, have produced prevalence estimates and reviewed existing and developed new data collection and analysis methods and resources. This work allows for the assessment of dietary supplement quality (through studies of disintegration of supplements) with particular focus on nutrients and supplements of current public health concern (iron, iodine, folic acid and folate, prenatal and infant and child multivitamins, and herbal supplements). It also facilitates the accurate collection of prevalence data from high-risk target populations (infants, toddlers, pregnant and lactating women and older adults). The work on the databases and on methods for data collection and analysis has been

accomplished by staff from various ODS program areas and through collaborations with FDA, National Library of Medicine (NLM), National Cancer Institute (NCI), the Uniformed Services University of the Health Sciences, the Centers for Disease Control and Prevention (CDC) and the USDA, USDOC, and DoD.

The ODS iodine initiative provides a specific example of this work. ODS is working with multiple federal agencies to follow up on a series of workshops held to identify research needs in this area. Major projects in this initiative seek to improve assessment of iodine status in the U.S. population; encourage the submission of investigator-initiated grant applications to study various aspects of iodine nutrition particularly in humans; and measure the iodine content of foods and dietary supplements and release the information in publicly-accessible databases.

GOAL 5: Coordinate and facilitate the development of collaborative initiatives to address gaps in dietary supplement research.

Since its inception, ODS has supported and facilitated the development of dietary supplement research. As dietary supplements are marketed and used to address concerns across the health spectrum, research is vital to understanding the usage of these supplements and their impact on health and physiological systems. In this new strategic planning period ODS will create a new initiative to systematically identify ongoing dietary supplement research and foster and facilitate collaborations among NIH ICOs. This coordination role will allow ODS to more easily identify dietary supplement research gaps and provide the leadership needed for them to be addressed.

Strategy 5-1: Identify ongoing and upcoming dietary supplement research programs within NIH and the federal government.

As the field of dietary supplement research continues to expand, ODS will identify and catalog NIH-funded and other federally-funded research relevanat to dietary supplements for the purpose of fostering and coordinating dietary supplement research collaborations across NIH and between NIH and other federal agencies. Initially, ODS will rely on its existing programs and initiatives to identify dietary research programs and will supplement this knowledge with a thorough NIH dietary supplement portfolio analysis using available NIH research program databases.

Strategy 5-2: Increase collaborations among dietary supplement research programs within NIH and the federal government.

Through its existing program workshops and meetings, ODS seminars, and working groups (the Trans-NIH Resilience Working Group and the Federal Working Group on Dietary Supplements), as well as through staff participation in Working Groups across the NIH (e.g., the Coordinating Committee for Research on Women's Health) ODS leverages opportunities to encourage dietary

supplement research collaborations across NIH and with other federal agencies. The ODS will create and sponsor a new NIH Dietary Supplement Research Coordinating Committee. This committee will formalize ODS' coordinating role with the objective of increasing collaboration among NIH ICOs whose programs include work on dietary supplements and the intersection of dietary supplements and nutrition research. Members will include representatives from NIH ICOs who have been appointed by their directors.

The purpose of the NIH Dietary Supplement Coordinating Committee will be to identify emerging and cross-cutting research areas and to develop platforms for encouraging collaborative initiatives across NIH and within the federal government. Research coordination may be achieved by the Coordinating Committee through the identification of co-funding and administrative supplement grant opportunities to further encourage the integration of dietary supplement research into existing research programs.

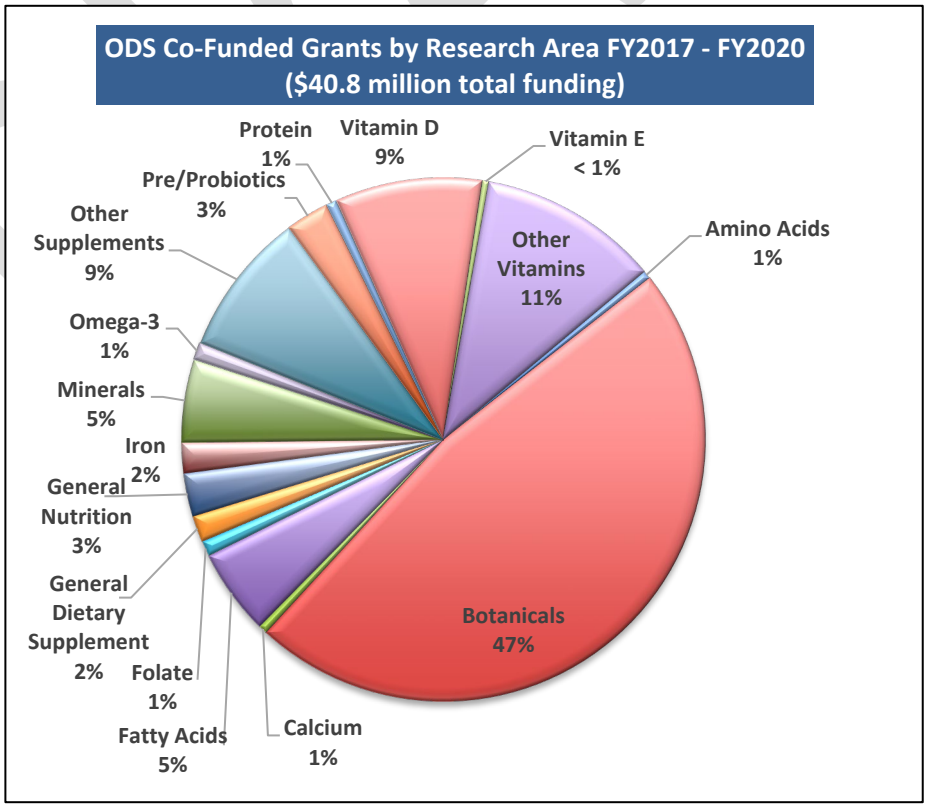
B. ODS Program Activities and Strategic Innovation

Grant Funding Program

The ODS Grants Program supports research on dietary supplements in collaboration with many NIH ICOs with the goal of supporting innovative research to evaluate the health effects of dietary supplements – primarily for promoting health and reducing the risk of disease – and the underlying biological mechanisms by which they do so.

Three main funding approaches are used to build the program's research investment portfolio:

- ODS Co-Funded Research Project and Training Grants supplement existing research project budgets allowing researchers to include dietary supplement related aims that expand the scientific impact of their work.
- Administrative supplements for grants leading to expanded aims of research awarded to principal investigators for research on dietary supplements for direct costs up to $100,000. The grants are designed to support research (within scope of the parent grant) in which the primary emphasis is on dietary supplements and/or supplement ingredients in health maintenance and disease prevention.
- The ODS Scholars Program collaborates with the NIH Office of Intramural Research, targeting early career NIH intramural scientists. Funded projects are generally limited to one year of funding and cannot exceed $100,000. All funded scholars present their results at the annual ODS Scholars Symposium.



Over half of the ODS research budget goes to co- funding grants with NIH IC partners. Of particular note is the CARBON Program, managed in collaboration with NCCIH, which studies the safety and mechanisms of action of botanicals in women's health, metabolic syndrome, cancer, immune function, cardio-vascular disease, and other areas.

ODS Co-Funded Investments with NIH-ICs (FY 2017 through FY 2020)	
	$ Thousands
National Center for Complementary and Integrative Health	19,189
National Institute of Diabetese and Digestive and Kidney Diseases	6,088
National Heart, Lung, and Blood Institute	3,719
National Cancer Institute	3,345
National Institute of Child Health and Human Development	1,948
National Institute on Aging	1,674
National Institute of Allergy and Infectious Diseases	1,187
National Institute of Environmental Health Sciences	1,080
National Institute on Alcohol Abuse and Alcoholism	490
National Institute of Neurological Disorders and Stroke	450
National Institutes of Health Office of the Director	412
National Eye Institute	338
Fogarty International Center	329
National Institute of Arthritis and Musculoskeletal and Skin Diseases	322
National Institute of Biomedical Imaging and Bioengineering	149
National Institute of Mental Health	100

Analytical Methods and Reference Materials (AMRM) Program

The ODS AMRM Program works to enhance the foundation for biomedical research on the health effects of nutrients, botanical constituents, and their metabolites by advancing their analytical characterization in dietary supplements and clinical/biological samples. In addition to providing resources for assuring that scientifically valid analytical methods and authentic and well-characterized reference materials are available to stakeholders, the AMRM program evaluates the reource needs of the dietary supplement community, maintains a repository of tools

To accomplish its goals the AMRM Program coordinates multiple complementary activities with NIH ICOs, government agencies, and private sector organizations.

- Analytical method innovation and validation are supported through an Interagency Agreement with the USDA Agricultural Research Service and Administrative Supplements to NIH-funded grants through partner NIH ICOs.
- Improved accuracy, precision, and reliability of analytical measurements are promoted through the development of methods, standards and reference materials under an Interagency Agreement with the National Institute of Standards and Technology (NIST) and contracts with other national metrology institutes and commercial organizations.
- The joint coordination and conduct of laboratory quality assurance programs with NIST collects information on stakeholder priorities and provides research scientists, clinical labs, industry analysts, and regulators a means to evaluate their measurement systems and capabilities, identify and resolve problem areas, and improve performance and harmonization across analytical communities.

and information, and provides guidance to investigators on questions of natural product integ rity to support the NIH-wide rigor and reproducibility initiative.

AMRM staff also participate in numerous external educational, standard setting, and consensus building activities in the dietary supplement and natural product research and analytical communities to promote analytical rigor and reproducibility, and thus support the translation of dietary supplement research to protect and improve public health. These multifaceted AMRM activities have fostered creation and dissemination of a substantial body of resources for dietary supplement research, with new validated methods, certified reference materials, analytical laboratory guidance documents, and novel research publications produced annually.

CARBON Program Overview

The purpose of the CARBON Program (a collaborative partnership between ODS, the National Center for Complementary and Integrative Health (NCCIH), and the National Institute on Aging (NIA) is to coordinate and promote collaborative, transdisciplinary research on the safety, effectiveness, and mechanisms of action of botanical dietary supplements that have a high potential to benefit human resilience and health. An explicit goal of the program is to foster development of transdisciplinary research teams focused on investigation of the health effects of chemically complex botanicals.

The CARBON program utilizes uses different types of awards, with synergistic but separate individual goals.

- The Botanical Dietary Supplement Research Center (BDSRC) components of the Consortium aim to fill gaps in the foundational data needed for the design of highly rigorous and informative clinical trials of the effects on resilience of the most promising botanical dietary supplements.
- The Natural Product Technology, Methodology, and Productivity Optimization (NP-TEMPO) Center is developing approaches expected to accelerate mechanistic research on these complex natural products, leveraging collaborations with other research groups to beta-beta test various applications of the NP-TEMPO approaches. The Natural Product Magnetic Resonance Database is developing a unique resource, a repository dedicated to serving as a repository for (only) natural product NMR spectra, while providing a growing suite of powerful tools for assigning, refining, and comparing molecular structure assignments and metadata. This repository with its associated tools provides an important new resource to support the rigor and progress of natural products research.
- The Pilot Projects Increasing the Impact of CARBON is a competitive initiative to increase the impact of research in the BDSRC by leveraging their well-characterized products and advanced methods to enable less experienced botanical dietary supplements researchers to strengthen their own research portfolios and toolkits while also providing new information that contributes to the BDSRC specific aims.

Launched in 1999 as the NIH Botanical Research Centers Program, each renewal cycle has had an overarching theme developed by coordinating with partner NIH ICOs to create one or more funding opportunity announcement(s) FOA(s) with the goal of addressing broad research questions of high interest to all the partner organizations. The focus of the current BDSRCs is investigation of the mechanisms through which botanicals may modulate human resilience. Each BDSRC is required to provide an atmosphere, personnel, and resources that promote collaboration between experts in the identification and characterization of botanicals and their chemistry, experts in *in vitro* and *in vivo* model systems used to study mechanisms of resilience to stress, aging, or infection, and experts in the design and conduct of clinical trials. These collaborations strengthen the rigor of the research and enhance both innovation and the eventual utility of the research for clinical trial design.

Population Studies Program Overview

The Population Studies Program evaluates the use of dietary supplements by the U.S. population and specific population subgroups and the contributions that dietary supplements make to nutritional status. Research is focused on describing the use of dietary supplements, including specific supplements taken, amount consumed, and duration of use. This program uses data from nationally representative surveys and other large population-based studies to conduct research and characterize emerging issues such as changing patterns in use of these products. Staff also lead efforts to address methodological issues in assessing dietary and dietary-supplement intakes, and importantly, total nutrietnt intakes from foods and supplements, in epidemiological and other large studies.

The Population Studies Program accomplishes its goals through program activities focused on:

- **Dietary Supplement Use**
  - Characterizing and evaluating dietary supplement use
  - Estimating total nutrient intakes from all sources (foods, beverages, and dietary supplements)
- **Nutritional Status of specific nutrients in the U.S. Population**
  - Vitamin D
  - Iodine
  - Folate
  - Vitamin B-12
  - Iron
- **Methodological Issues in Assessing Dietary Supplement Use**
  - Reviewing of food frequency questionnaires used to assess dietary supplement use
  - Analyzing dietary-supplement use by lactating women in the Human Milk Composition study
- **Development and Use of Assessment Tools**
  - Developing new methods to collect data from NHANES on the use and composition of infant formula from NHANES
  - Determining best methods to assess iodine intake from foods and salt
  - Consulting on dietary assessments in studies of pregnancy and offspring
  - Providing input on dietary assessment in the NIH All of Us Research Program and for the *Dietary Guidelines for Americans* planning guide.
- **Development and Use of Validated Biomarkers of Nutrient Exposure and Status**
  - Working with a laboratory at the CDC National Center for Environmental Health (NCEH) to develop new biomarkers of omega-3 fatty acids in blood and forms of folate in red blood cells
  - Working with the CDC NCEH to develop new tests for markers of inflammation and iron status
  - Collaborating with the CDC Division of Nutrition, Physical Activity and Obesity to identify biomarkers of iodine status

Dietary Supplement Databases

ODS funds and leads the development of three databases. The first two, the Dietary Supplement Ingredient Database (DSID) and the Dietary Supplement Label Database (DSLD), contain information on the composition of many dietary supplements for sale in the United States. Using these databases together with food composition databases makes it possible to estimate the total daily intakes of nutrients and other bioactive substances from both foods and dietary supplements. The third ODS-supported database, Computer Access to Research on Dietary Supplements (CARDS), contains information on research projects pertaining to dietary supplements funded by the USDA, DoD, or NIH since 1999.

ODS continues to develop and expand the utility of dietary supplement databases:

- The DSLD is a repository for all the information on the product label (composition, claims, manufacturer contact information, etc.) of dietary supplements. The database has data from overmore thanabout 125,000 labels, and data from another 1,000 labels is added each month. DSLD data is being used to compare nutrient needs/dietary intake gaps with multivitamin/mineral and prenatal supplements.
- The DSID contains analytically derived information on the amount of labeled ingredients of many dietary supplements offered for sale in the United States It currently includes adult, child, and prenatal multivitamin/multimineral supplements and omega-3 fatty acid products.
- Since 2010 the Federal Dietary Supplement Database Working Group* has developed criteria for choosing botanicals and other dietary ingredients of public health interest to add to the DSID that do not have established recommended intakes but that should be analytically evaluated.
- Them CARDS Database ensures that all data is easily accessible and includes dietary supplement-related projects funded through FY2019, with FY2020 projects in review.

*The working group consists of representatives from ODS, NLM, NCI, USDA, CDC, FDA, DoD, and NIST.

Resilience and Health Studies Program

Resilience and Health Program Activities:

- An Interagency Agreement (IAA) with the Uniformed Services University of the Health Sciences, (USUHS) DoD Center for Health and Military Performance (CHAMP), "Dietary Ingredients to Minimize Environmental Heat Injury," investigated the ability to mitigate mitochondrial damage, with select dietary ingredients, following exposure of mice to acute heat stress.
- An IAA with CHAMP titled, "Dietary Supplement Ingredients Promoted for Immune Health," was initiated in response to increased (pandemic related) inquiries of the benefits and risks associated with the use of new products or new uses/immune health claims for previously marketed products.
- The Trans-NIH Resilience Working Group was established to enhance collaboration and coordination of the resilience research agenda across all of NIH. ICO's representing the core working group include NCI, NCCIH, NIA, National Heart Lung and Blood Institute (NHLBI), National Institute of Nursing Research (NINR), National Institute on Minority Health and Health Disparities (NIHMD), and ODS. A website with an agreed upon definition and conceptual model of resilience and a resilience research decision tool is available on the ODS website.
- An analysis of ODS Resilience grants (2018-2020) was completed to facilitate criteria development for resilience study designs and to identify common measures of resilience.

The Resilience and Health Studies Program focuses on elucidating biochemical mediators of resilience to help gain a better understanding of how physiologic adaptations to biological, environmental, and psychosocial stressors may impact nutrient status and overall health status in individuals. The program helps to address key questions that are relevant to the mission of ODS such as: when should a change in nutrient status or altered biochemical markers represent a beneficial adaptation to a stressor versus a detrimental imbalance to

the system (or a combination of both); and, when do individual nutrient variations require intervention with dietary supplements? The program encourages researchers to identify opportunities to study "resilient" special populations (active duty military, centenarians, survivors within high-risk populations) that are typically under-represented in scientific investigations. The program also promotes a better understanding of protective factors of health that lead to resilient health outcomes and determine the impact that protective factors have on disease risk factors. ODS coordinates the Trans-NIH Resilience Working Group enhancing resilience research collaborations across NIH.

Iodine Initiative

Iodine is an essential nutrient and a component of thyroid hormone. The iodine status (i.e., adequacy or deficiency) of populations and individuals varies with geography, iodine content of the food supply, and use of iodized salt and dietary supplements. Although iodine deficiency is rare in the United States and Canada, it can have serious effects. ODS originally developed its Iodine Initiative in 2011 in response to concerns that some pregnant women in the United States might have inadequate iodine intakes at a time of high physiologic demand. Six NIH-sponsored workshops have provided expert opinion on public health issues and research needs. In addition, the *Scientific Report of the 2020 Dietary Guidelines Advisory Committee* has identified a number of iodine-related concerns. ODS seeks to address these identified research and resource needs by supporting research and methodology development to provide a scientific base for understanding how best to improve iodine status in individuals with low to moderate risk of deficiency.

Iodine Program Highlights:

- **Iodine Content of Foods and Dietary Supplements:** Develop a database of the iodine content of foods and dietary supplement content database with the USDA, and the FDA.
- **Characterization of U.S. Population-Level Iodine Intake.** Analyzed the NHANES data to determine the proportion of pregnant women advised by physicians to take supplements containing iodine (80%). Partially supported NHANES to gather information on household usage of iodized salt and other types of salt, total individual dietary intake of iodine from foods and supplements, exposure to iodine uptake inhibitors, and thyroid status as indicated by clinical laboratory measurements. Estimates of the dietary iodine intake of individuals participating in NHANES will be derived using the newly released USDA, FDA and ODS-NIH Database of the Iodine Content of Common Foods.
- **Analytical Methods, Reference Materials, and Standards for Assessing Iodine Status:** ODS supports the development of certified reference materials that researchers can use to support measurements of iodine in foods and dietary supplements, as well as and thyroxine and triiodothyronine in serum.

Mary Frances Picciano Dietary Supplement Research Practicum

ODS offers the Mary Frances Picciano Dietary Supplement Research Practicum, a 2.5-day annual educational opportunity to provide fundamental knowledge of dietary supplements to faculty, students, and practitioners with a serious interest in this subject. This intensive practicum provides a thorough overview and grounding about issues, concepts, unknowns, and controversies about dietary supplements and supplement ingredients. It also emphasizes the importance of scientific investigations to evaluate the efficacy, safety, and value of these products for health promotion and disease prevention and how to carry out this type of research.

Practicum Ffaculty and participants

- The faculty consists of experts from NIH, academic institutions, federal regulatory agencies such as the U.S. Food and Drug Administration, and practicing stakeholders. Participants also hear from various stakeholders—the dietary supplement industry, consumer advocacy groups, and media—who study, advocate, regulate, or educate about dietary supplements.
- The practicum is open to selected faculty, graduate students, and research practitioners in health-related disciplines such as nutrition, food science, pharmacy, pharmacology and pharmacognosy, exercise science and kinesiology, medicine, dentistry, nursing, and complementary and alternative medicine. Primary candidates are full-time academic faculty, research practitioners, doctoral students, postdocs, and fellows.

Federal Working Group on Dietary Supplements

The federal working group consists of representatives from federal agencies that share information and discuss issues, initiatives, and research related to dietary supplements and serves as a means of communication between ODS and its federal partners in several ways:

- to co-fund research investigations within the NIH;
- to expand opportunities for research-investigator training; and
- to strengthen collaborative efforts involving dietary supplement research, education, and communication across the government.

Federal Working Group on Dietary Supplements Members

- Most NIH ICOs
- Agency for Healthcare Research and Quality (AHRQ)
- Administration for Community Living
- CDC
- Consumer Product Safety Commission
- DoD
- Department of Justice
- Department of Veterans Affairs
- FDA
- FTC
- Health Resources and Services Administration
- National Aeronautics and Space Administration
- NIST
- HHS Office of Disease Prevention and Health Promotion
- U.S. Agency for International Development
- USDA

The federal working group was established in part on the basis of a Congressional law that specifies that ODS serve as an advisor to federal health agencies on issues related to dietary supplements. It also exists in response to a goal in the ODS Strategic Plan to expand and conduct outreach efforts that inform and educate about

supplements.The federal working group has met twice a year since 2005, generally in April and October. It also maintains periodic contact via email and other means as appropriate.

ODS Communications Program

The ODS Communications Program provides helpful, up-to-date information on dietary supplements through various channels, including social media platforms:

- ODS communications' staff respond directly to media inquiries and questions from the public about dietary supplements.
- Fact sheets on dietary supplement ingredients (the most frequently viewed materials on the ODS website) include more than two dozen facts sheets on nutrients such as vitamin D and magnesium with detailed versions including references directed to health care professionals as well as easy-to-read versions for consumers in both English and Spanish.
- Additional fact sheets are available on dietary supplements such as multivitamin/mineral products and on supplements marketed for specific purposes (such as weight loss and athletic performance).
- The ODS website provides detailed descriptions of ODS program areas and activities, including the Analytical Methods and Reference Materials program, and the vitamin D, iodine, and iron initiatives.
- The ODS website includes information that is particularly relevant to the scientific research community: research-funding opportunities, a listing of funded grants, and dietary supplement research, label, and ingredient databases.
- Through the ODS website, users can sign up to receive e-newsletters, such as *ODS Update* (directed to professional audiences) and *The Scoop* (for consumers), as well as email blasts on special topics.
- ODS posts information daily about dietary supplements andor nutrition on Twitter and Facebook.

ODS has communicated the science of dietary supplements to diverse audiences through its information products– primarily a library of fact sheets on ingredients in supplements. Most of these products are available on the ODS website, accessed by more than 1.5 million people per month.

C. Key Accomplishments from the Strategic Planning Period 2017-2020

The following is an overview of key ODS program accomplishments in the period of 2017 – 2020 by ODS goal and specific objectives for each ODS program. This summary supplements activities and scientific strategies described in sections above. Please refer to staff publications and presentations posted on the ODS website for additional information.

GOAL 1: Expand the scientific knowledge base on dietary supplements by stimulating and supporting a full range of biomedical research and by developing and contributing to relevant initiatives, workshops, meetings, and conferences.

Objectives	Key Accomplishments
Grants Program • To support innovative research that evaluates the health effects of dietary supplements • To increase the exposure to and awareness of research on dietary supplements among researchers in related fields	• Co-funded 247 grants valued at $40.8 million across 13 NIH ICs
CARBON Program • Develop methods and data required to understand and test the biological effects of inherently complex natural products, especially botanicals, both food and non-food, on resilience in humans or other animal models	• 69 publications resulted from CARBON program support • 5 new CARBON centers were funded in 2020
Population Studies • Characterize patterns of dietary supplement use in the U.S. population • Determine the contribution of dietary supplements to the nutritional status of the population and subgroups • Identify nutrients requiring additional research	• Iodine: USDA-FDA database, National Institute of Child Health and Human Development (NICHD) Notice of Special Interest (NOSI), Federal Interagency Working Group • Collaborated with NHANES on folate, vitamin D, iron, and iodine (populations: infants to older adults; data collection methods, analyses) • Collaborated with USDA, National Center for Health Statistics (NCHS), HHS, National Academies of Sciences, Engineering, and Medicine (NASEM), CDC, Centers for Medicare and Medicaid Services (CMS), FDA, NCI, Administration on Aging (AoA) and others on dietary supplement use across the lifespan • Vitamin D Standardization Program resulted in 90+ publications; certification program at CDC; accuracy-based Vitamin D External Quality Assessment Scheme (DEQAS), and standard reference materials (SRMs) available at NIST
Resilience & Health Studies Program • Foster collaboration between ICOs around resilience research • Collect data on commonalities related to resilience outcomes, phenotype patterns, and measurements of resilience	• Trans-NIH Resilience Working Group: conceptual development retreat, conceptual model, research tools, website • Planning of joint program with NCCIH • Collaborations with CHAMP and others

GOAL 2: Enhance the dietary supplement research workforce through training and career development.

Objectives	Key Accomplishments
Grants Program • To enhance the dietary supplement research workforce through training and career development opportunities	• 26 ODS Scholar projects (NIH early career scientists) and 90 administrative supplements • 2 Milner fellows
CARBON Program • To provide training opportunities to postgraduate and graduate students **AMRM Program** • To promote advances in analytical laboratory proficiency and capability by supporting outreach and education in chemical and biological characterization of dietary supplements and their bioactive ingredients	• CARBON and AMRM contributed to training of 83 postgraduates and 50 graduate students
Dietary Supplement Research Practicum • To offer brief course in fundamental knowledge of dietary supplements to academics, Ph.D. students, and postdoctoral fellows; healthcare practitioners; and other professionals with advanced biomedical degrees	• 772 practicum attendees 2017-2019, and 2021 (academic faculty, PhD students, postdocs, healthcare practitioners and other biomedical professionals). Due to Covid the 2020 practicum was cancelled.

GOAL 3: Foster development and dissemination of research resources and tools to enhance the quality of dietary supplement research.

Objectives	Key Accomplishments
CARBON Program • To develop methods that will be directly applicable to the biological effects of animal- and plant-derived foods and fermented foods	• CARBON supported the development of 20 new methods
AMRM Program • To catalyze analytical method development and validation for quantitative and qualitative characterization of dietary supplements and their ingredients • To advance development of reference materials for dietary ingredients and natural products.	• AOAC International's method standardization contract resulted in 30+ method performance requirement documents and 15+ Official Methods of Analysis • AMRM collaborators (i.e., NIST, National Research Council Canada, private sector) produced 35+ reference materials specific to dietary supplement ingredients/metabolites • AMRM supports NIST to administer laboratory quality assurance programs to help laboratories improve accuracy of analytical measurements (cumulative 35 exercises conducted to date
Population Studies • Improve data collection and analysis tools for total nutrient consumption (food and dietary supplements)	• Collaborated with USDA to develop database of iodine content of food, beverages, and dietary supplements • Collaborated with NHANES on data collection methods for infant formula and iron and iodine status in pregnant/lactating women and infants
AMRM, CARBON and Population Studies • To enhance rigor and reproducibility of dietary supplement research	• Developed a complete renovation of the AMRM and CARBON program websites, providing ODS stakeholders with summaries and ready access to seminal publications, validated analytical methods, certified reference materials, and database resources resulting from these programs • Published an updated product integrity page on the ODS website titled *The Importance of Natural Product Characterization and Integrity for Dietary Supplement Research*
Dietary Supplement Label Database (DSLD) Program • Maintain and expand database with labels of products sold in the United States • Perform program and policy research and inform stakeholders of findings • Provide training to researchers via presentations, posters, articles in peer reviewed journals	• DSLD includes over 125,000 labels • Analyzed DSLD data to compare nutrient needs/dietary intake gaps with multivitamin/mineral and prenatal supplements
Dietary Supplement Ingredient Database (DSID) Program • Maintain DS ingredient database complementary to the DSLD • Conduct analyses of DS ingredient concentrations and composition • Support use of the DSID database for public health research	• Analyzed DSID data to develop precise estimate of nutrient intake through dietary supplements
CARDS Program	• CARDS includes NIH dietary-supplement related projects 2002-2020

• Maintain a database of all federally-funded dietary supplement research • Ensure that data collected for database is easily accessible by stakeholders • Increase the use of the CARDS database	• Strategies being developed to identify non-NIH federally-funded dietary supplement-related research

GOAL 4: Translate dietary supplement research findings into useful information for consumers, health professionals, researchers, and policymakers.

Objectives	Key Accomplishments
Communications Program • Provide and promote the use of the most current, accurate, and useful information about dietary supplements to our audiences • Support ODS Scientific Staff and Programs • Monitor tech environment for most recent advances and evaluate their usefulness for ODS	• ODS website averages more than 1.5 million visits and 2.5 million page-views per month • ODS responded to 539 public inquiries in 2020 • Hosted 36 seminar speakers (2017-2020) • Social media: 10,000 Facebook followers; 16,000 Twitter followers • Products: ODS Update more than 11,000 subscribers; The Scoop more than 21,000 subscribers; Videos 94,700 views • Facts sheets (health professionals and consumers) continuously reviewed, updated and new ones developed • New webpages added for CARBON and the Trans-NIH Resilience Working Group • Presentations and publications 2017-2020: 146 presentations at national/international conferences and 155 publications • ODS increased the number of its subscribers more than 4-fold in a six month period following its use of GovDelivery by Granicus.

D. New Initiatives 2022-2026

ODS's activities are built upon the successful development of programs since the office's inception and continue to reflect the mandate set by the DSHEA. However, new knowledge, technologies, and public health concerns take some programs in new directions and necessitate the development of new programs. Examples of how ODS is planning to expand its directions in the next five years include the following:

- ODS will examine relevant NIH programs and best practices and implement approaches to enhance diverse participation in all of the Office's collaborative, outreach, education, training, and funding efforts.
- ODS will explore additional mechanisms to support the training of a more diverse cohort of postdoctoral researchers through collaboration with other NIH ICOs and federal agencies.
- ODS will continue to coordinate the development and dissemination of analytical methods including, but also extending beyond, the measurement of individual nutrient ingredients in dietary supplement products. Directions in which efforts will be extended include the measurement of suites of constituents used to discriminate between plant species, as well as to describe the chemical constituents associated with biological activities of interest and improve efforts at ingredient (and product) standardization. The latter may aid in identifying more or less active preparations of a product. Additionally, ODS will continue to pursue collaborations and other approaches towards the identification and measurement of biomarkers of nutrient exposure and status in blood and other biological specimens.
- In consultation with relevant ICOs, ODS will assemble, brief, and convene an expert panel to consider critical gaps and needs in research on chemically complex botanical and other natural products, and the ways in which the current CARBON Program contributed to advancing the field over the 2015-2021 period. Input from the expert panel will be utilized in developing concepts for future CARBON initiatives.
- ODS will establish a joint trans-NIH Resilience and Health Research Program with NCCIH as the principle IC partner.
- A Resilience scientific interest group (SIG) will be established to facilitate broader outreach across NIH and to enhance collaborations that might improve harmonization and data sharing initiatives on all aspects of resilience.

III. Scientific Stewardship

A. Priority Setting

Priority setting is a dynamic process within ODS and considers public health needs, knowledge gaps, and changing trends in the dietary supplement marketplace (comprising more than 80,000 products and thousands of ingredients) and consumer use of these products. Key questions are used to determine what new initiatives are needed and how the work should be approached. These questions include:

- What is the nature and intensity of the public health issue?
- Is the prevalence of the population exposure to a nutrient or other supplement ingredient known? Is it too low or too high? What is the evidence?
- How are biomarkers of nutritional exposure, status, and bioavailability of dietary supplement ingredients and metabolites measured? Are there concerns about the reliability of the measurements? Are new methods available or on the horizon that might provide more useful information?
- What is the evidence for the health effects of dietary supplements? What levels of dietary supplement intake, relevant to dietary consumption, produce an observed biological effect or health outcome?
- How should ODS and the research community identify and fill gaps in knowledge?
- How should ODS and its partners translate the results of research for policymakers, clinicians, and the public?
- How can ODS reach out to the greater NIH community to acquire and communicate information as well as knowledge gaps and to coordinate and support trans-NIH efforts to fill those gaps?

Because ODS was not granted the authority and administrative infrastructure to make its own grant awards and directly issue requests for applications (RFAs) it must depend on coordination and collaboration with NIH ICOs that have their own research and funding priorities. ODS staff rely on extensive interactions with ICOs to assist in setting research priorities and monitor dietary supplement research expenditures by other ICOs through NIH portfolio databases to identify promising areas of collaboration. In addition, ODS staff work with ICO program staff to develop initiatives, develop and contribute to relevant workshops, and publish key findings from workshops and other meetings. Lastly, through close communication and interactions across NIH and with the ODS-sponsored FWGoDS, ODS staff capture insights into emerging public health issues related to dietary supplements and use the insights gained in communication and coordination of research support across NIH.

Working closely with the DPCPSI Office of Portfolio Analysis and taking advantage of other resources, ODS will measure the success of its activities to address its five goals based on the

impact of publications in the peer-reviewed literature arising from co-funded grants, research tools developed, information pieces written, initiatives and workshops developed by staff, and manuscripts published by ODS and other NIH staff. ODS will assess the impact of these results over time as they inform policy and influence health practices related to dietary supplements. ODS programs and initiatives also undergo periodic external evaluations and lifecycle assessments. Programs are sunsetted when workshops, the peer-review literature, or portfolio analyses indicate that needs have been met or priorities have shifted.

B. Rigor and Reproducibility

Dietary supplements commonly contain mixtures of vitamins, minerals, and/or other natural products such as botanical constituents. Even supplements marketed as having a single active ingredient such as an extract of the leaf of a plant may be complex preparations containing numerous unique phytochemicals in a milieu of thousands of other chemical compounds. Relatively simple single chemical entity products may occur in the marketplace as different chemical isomers (e.g., resveratrol, vitamin E) or as a unique formulation marketed for its purportedly enhanced bioavailability (e.g., curcumin). In addition to this complexity, there are tens of thousands of supplement products available in the U.S. market that are combinations of one or two to dozens of active dietary ingredients. Dietary supplements used in biomedical investigations must therefore be rigorously identified and characterized to know exactly what is being studied. The end product of this characterization process is assurance of product integrity and enhanced ability to understand and potentially learn from any variability in outcomes associated with changes in product composition or matrix. Critical parameters of product integrity must include the source, identity, composition, purity, and stability of the dietary supplement that is being investigated, as described, for example, on ODS' newly updated page of related resources for dietary supplement research . ODS works with all its collaborators and funding recipients to assure the product integrity of dietary supplements under investigation has been carefully considered and appropriately documented to ensure experimental rigor and enhance research reproducibility.

The ODS AMRM Program plays a large role in enhancing experimental rigor and research reproducibility with its goal to enhance the analytical foundation for biomedical research on the health effects of nutrients, botanical constituents, and their metabolites in dietary supplements and biological samples. In addition to disseminating information and resources (publications, certified reference materials, laboratory quality assurance exercises) to assure that analytical methods and reference materials are available to stakeholders, the AMRM program assesses community resource needs and provides guidance to ODS grant awardees and co-funding IC partners for demonstrating the integrity of natural product interventions used in research, which supports the NIH-wide rigor and reproducibility initiative. To accomplish these goals the AMRM Program coordinates multiple complementary activities with NIH ICs, government agencies, and private sector organizations.

- Analytical method innovation and validation are supported through an Interagency Agreement with the USDA Agricultural Research Service and administrative supplements to NIH-funded grants through partner NIH Institutes and Centers.
- Improved accuracy, precision, and reliability of analytical measurements are promoted through the development of methods, standards, and reference materials under an Interagency Agreement with NIST and contracts with other national metrology institutes and industry organizations.
- The joint coordination and conduct of laboratory quality assurance programs with NIST collects information on stakeholder priorities and provides research scientists, clinical labs, industry analysts, and regulators a means to evaluate their measurement systems and capabilities, identify and resolve problem areas, and improve performance and harmonization across analytical communities.

In addition to these ODS-organized efforts, AMRM staff participate in numerous educational, standard setting, and consensus building activities in the dietary supplement and natural product research and analytical communities to promote analytical rigor and reproducibility, and thus support the translation of dietary supplement research to protect and improve public health. These multifaceted AMRM activities have fostered creation and dissemination of a substantial body of resources for dietary supplement research, with new validated methods, certified reference materials, analytical laboratory guidance documents, and novel research publications produced yearly.

C. Addressing Health Equity and Disparities in Research

To adequately address health equity and disparities in dietary supplement research it is vital to understand the differences that exist between different subgroups of the population that might impact nutrient uptake, absorption and utilization, and might influence nutrient consumption, from supplements as well as from food. ODS has active working relationships with the Tribal Health Research Office (THRO), Office of Research on Women's Health (ORWH), and the National Institute on Minority Health and Health Disparities (NIMHD) and use these liaison positions to actively inform funding ICOs of our interest in co-funding and admin supplements in their areas and to collaborate on relevant projects when possible. For example, ODS staff participated in a project with ORWH preparing an journal article on *Physiological Need for Calcium, Iron, and Folic Acid for Women of Various Subpopulations During Pregnancy and Beyond.* ODS also co-sponsored an expert panel meeting with the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute on Aging (NIA), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) on the vitamin D paradox in Black Americans. The paradox is that despite markedly low (or "deficient") measures of vitamin D status in Black Americans, the incidence of falls, fractures, or osteopenia are significantly lower compared to White American counterparts with similar vitamin D status. While ODS cannot put out RFAs, staff develop nutrient-specific programs (e.g. Vitamin D or iodine) to fill both the knowledge gaps and the health disparities associated with the gaps. The ODS

populations studies program characterizes supplement use in groups such as infants and toddlers, females of reproductive age, pregnant women, and older adults, evaluating dietary supplement use in relation to demographics, lifestyle, health status, and disease risk. Future work can include investigations of additional subpopulation groups (for example, by race/ethnicity, rural/urban, underserved populations, military/civilian groups, family status, immigrant status or health status).

As part of its communications efforts, ODS has worked to prepare some materials in both English and Spanish. Future communication efforts targeting the general population may consider utilizing an array of communication strategies to ensure that diverse populations have easy access to relevant and valuable ODS information. For professional audiences, a recent webinar hosted by ODS focused on dietary supplement use among Hispanics/Latinos living in the US is an example of how to address knowledge gaps. ODS will continue to invite researchers who are able to speak about health equity and dietary supplements. Through the new DSRCC, ODS will serve as a facilitator and catalyst of research on dietary supplements that creates a better understanding of health differences to achieve health equity among our population. Similarly, the ODS grant and funding program can help to support research that leads to a better understanding of dietary supplements diverse populations. ODS efforts to train and increase the dietary supplement workforce will support the development of programs for diverse researchers who are underrepresented in science.

D. Partnerships and Collaborations

ODS has developed stable, productive relationships with select ICOs, external groups, and federal agencies whose research interests are clearly aligned with ODS (see Appendices B for a complete list of ODS liaisons and interactions). Though the type of collaborations vary, they help ODS increase its impact/influence on dietary supplement biomedical research.

- ODS has built solid relationships with ICOs, such as NCCIH through the CARBON Program and with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) through several joint funding opportunities based on a mutual interest in nutrition research.

- ODS also regularly participates in co-funding activities with 13 ICOs and has funded ODS Scholars from 8 ICOs.

- ODS's relationship with CDC's NHANES program has provided valuable and clinically relevant information for the research community as a resource leading to numerous highly cited publications on important differences in folic acid, iodine, and vitamin D status in the U.S. population and subgroups.

- ODS's support for the USDA's DSID, Food Composition Lab, and special databases such as the flavonoid database, and interagency agreements with NIST have yielded

many useful outputs including reference materials, standards, and assays for the research community.

- ODS has developed a collaboration with the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP) on their safety-focused Botanical Dietary Supplements program. ODS and NIEHS NTP continue to routinely communicate, and NIEHS is a sign-on partner for ODS's current FOAs.

- ODS also participates in a number of other trans-agency working groups, including the Federal Dietary Reference Intakes Steering Committee and the Joint Agency Nutrition Working Group, and convenes and leads the FWGoDS and the Trans-NIH Resilience Working Group.

- ODS has co-authored papers, hosted numerous ICO staff for ODS seminars, and has co-funded workshops with a wide range of ICOs include the Vitamin D Paradox workshop (NIMHD, NIA, NIDDK), the Enhancing Natural Product Clinical Trials workshop (NCI, NIA, National Institute on Alcohol Abuse and Alcoholism (NIAAA), NIEHS, and the Office of Research on Women's Health (ORWH) and the Trans-NIH Resilience Workshop (NINR, NCCIH, NCI, NHLBI, NIMHD, NIA).

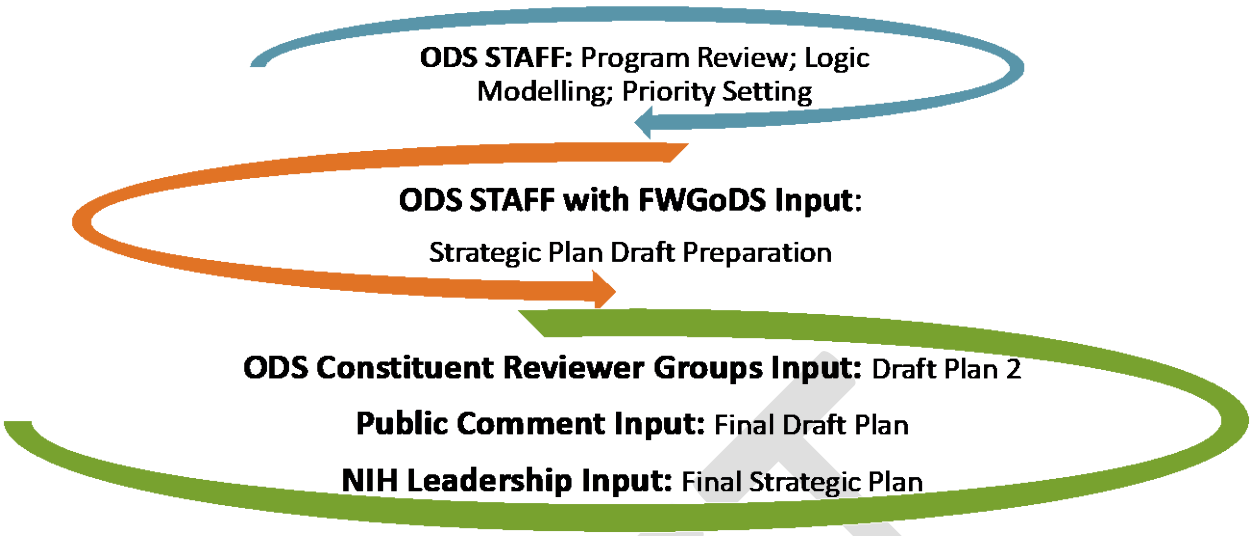
IV. Strategic Planning Process

Since its inception, ODS has used a deliberate planning process to develop five-year strategic plans. The strategic plan serves multiple purposes for ODS. The planning process provides ODS management and program directors with an opportunity to evaluate their progress over the prior five-year period and to determine how to best optimize their work going forward. This evaluation process focuses on questions such as:

- What are we trying to achieve?
- What activities have we pursued and what have we accomplished?
- What activities should we implement or continue to pursue to achieve our intended impact?
- How do we determine success?

The following (as depicted below) describes the strategic planning process used to build the ODS 2022-2026 strategic plan with key steps including:

- ODS individual program review of accomplishments and program goals
- ODS office review of accomplishments and program goals
- Stakeholder review



ODS individual program review of accomplishments and program goals

Since 2017 ODS has used an annual reporting process to ensure that it continues to meet its objectives while responding to emerging public health issues throughout the five-year strategic planning period. These reports are available on the ODS website and provide a basis for receiving feedback from key stakeholders. These stakeholders include NIH IC leadership, representatives of the scientific community, industry, other federal agencies, and the public. Gathering the data for these reports provided staff with the opportunity to review their activities and accomplishments on a quarterly and annual basis.

In preparation for the development of the strategic plan, ODS program staff engaged in a logic modeling process to further review program accomplishments and determine future program directions. Each program director and program staff developed a logic model that included the following:

- Key stakeholders (who has an interest in the work being done?)
- Underlying program assumptions (why is the program necessary?)
- External influencing factors (what factors influence the success of the program?)
- Program objectives and activities (what is the program trying to accomplish and how?)
- Program inputs (what is needed for the program to exist?)
- Program outputs and assessment measures (what are the tangible results and how are they measured?)
- Program short- and long-term outcomes and assessments measures (what is the program trying to add to the field of dietary supplement research and how will it be measured?)

ODS office review of accomplishments and program goals

Upon completion of all program logic models, the individual program data was compiled and an ODS-wide logic model was developed. The ODS logic modelling process included the

presentation of compiled information and staff deliberations on each of the data categories (above). Together, staff considered overall ODS goals and objectives, activities, inputs needed, and outputs and assessment measures to be used. These discussions and the final ODS logic model served as the basis for the initial development of ODS's goals and objectives for the 2022-2026 ODS strategic plan.

Stakeholder review

ODS is committed to engaging the NIH ICO leadership, representatives of the scientific community, industry, other federal agencies, and the public in the strategic planning process. For the 2022-2026 strategic planning process, ODS incorporated various stakeholder review strategies to complete the plan. These include presenting the key goals and program objectives to the FWGoDS, establishing partner review groups (external, NIH and federal partners), and gathering feedback from other interested stakeholders by issuing a request for public comment.

The first presentation of the agreed upon ODS mission, goals, program accomplishments, and future direction was made to the FWGoDS in April 2021. Members of the working group were invited to comment on public health issues related to dietary supplements, existing knowledge gaps, or other areas that ODS can help address or do differently to meet the needs of stakeholders. Following this meeting, ODS constructed a final set of goals and completed a first draft version of the report.

In August, 2021, ODS established four expert review panels, Academic Expert Panel, Industry and Association Expert Panel, NIH Partner Expert Panel and Federal Partner Expert Panel (see Appendix C for a list of all expert panel members). Academic and Industry and Association Expert Panels included academic researchers, health professionals, leadership from related professional associations and members of the dietary supplement industry, while the NIH and Federal Partner Expert Panels included partner NIH ICO program directors and partner federal agency program directors outside of NIH (CDC, FDA, HRSA, NIST, USAID, USARIEM, USDA, and USUHS). Members of all groups had the opportunity to review a PowerPoint overview of ODS's strategic plan and a draft of the written plan. They were asked to respond to three questions:

- Are there emerging public health issues that ODS can help address?
- Are there existing knowledge gaps that ODS can help address?
- Is there anything that ODS can do differently to meet the needs of its stakeholders?

All reviewer feedback was received by early December 2021 and was used to stimulate discussion among ODS staff regarding potential changes to the draft strategic plan.

[Note: the following steps will be accomplished in early 2022]

An additional feedback strategy was a widely publicized request for public comment that linked to an online version of the draft strategic plan and the recorded overview presentation posted on a dedicated ODS webpage. Stakeholders were alerted to the availability of the these materials and asked to provide comments to ODS through a Federal Register notice. ODS publicized the notice through its listserv, a notice on its website, and direct email with colleagues and other program contacts. Stakeholders were asked to comment on new directions that ODS might pursue and on ways in which ODS can continue to meet stakeholders' needs.

All the feedback gathered through these different stakeholder feedback activities were used to revise the ODS 2022-2026 strategic plan. Upon completion of a final draft, the plan was shared with partner NIH ICO directors and the DPCPSI leadership. Their comments were incorporated into a final version of the strategic plan.

Appendix A: ODS Mandates in the Dietary Supplement Health and Education Act (DSHEA) of 1994 and Subsequent Congressional Language

ODS purpose:

- 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

ODS responsibilities:

- 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
- Collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources
- 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, and the Commissioner of the Food and Drug Administration 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
- Compile a database of scientific research on dietary supplements and individual nutrients
- Coordinate funding relating to dietary supplements for the NIH

Congressional mandates to ODS subsequent to DSHEA:

- Develop a botanical research center initiative (1999)
- Conduct evidence-based reviews of the efficacy and safety of dietary supplements (2001)
- Accelerate the validation of analytical methods and reference materials for dietary supplements (2001)
- Support the development of a dietary supplement label database (2004)

***Definition of a dietary supplement (from DSHEA)*:**

- A product (other than tobacco) that is intended to supplement the diet and 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 humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combination of these ingredients
- Intended for ingestion in pill, capsule, tablet, or liquid form
- Not represented for use as a conventional food or as the sole item of a meal or diet
- Labeled as a dietary supplement

B. ODS Interactions with NIH and Other Federal Partners and Non-Governmental Organizations

NIH, Other Federal Agency and Non-Governmental Organization Committees and Groups with an ODS Staff Liaison
NIH
NIH Prevention Research Coordinating Committee
NIH Nutrition Research Coordinating Committee
NIH Nutrition Research Coordinating Committee Nutrition Strategic Plan
NIH Education Subcommittee
NIH Nutrition Research Taskforce
NIH Prebiotic/Probiotic Working Group
NIH Diabetic Complications Working Group
NIH Obesity Research Task Force
NIH Working Group on Bone Diseases
NIH Microbiome Working Group
NIH Nutrition and Obesity Working Group
NIH Guide Liaison Working Group
NIH High-Risk, High-Reward Working Group
NIH Coordinating Committee for Research on Women's Health
NIH P&E Officers
NIH GPRA Performance Measures Working Group
NIH Dietary Supplement Special Interest Group
NIH Mitochondrial Disease Special Interest Group
NIH Medical Rehabilitation Research Coordinating Committee
NIH Program Leadership Committee
NIH Multi-morbidity Special Interest Group
NIH GeroScience Special Interest Group
Trans-NIH Sleep Research Coordinating Committee
NIH Inflammation Special Interest Group
DPCPSI Program Office Directors
Communication Directors
Social Media Collaboration
Press Officers
MedlinePlus Advisory
Science Writers (SWANIH)
NIH QVR Steering Committee
NIH eRA Database Users Group
NIH OD Sharepoint Users Group
ECHO Obesity Diet and Nutrition Subgroup
All of Us Research Program
Tribal Heath Research Coordinating Committee
Infant Feeding Practices Study III Planning Committee
Automated Self-Administered 24-hr Recall (ASA24) team
Research, Condition, and Disease Categorization (RCDC)Working Group

NIH, Other Federal Agency and Non-Governmental Organization Committees and Groups with an ODS Staff Liaison
Other Federal Agencies Interagency Committee on Human Nutrition Research (ICHNR) ICHNR Dietary Reference Intakes (DRIs) Subcommittee DRI Steering Committee Joint Health Canada-US DRI Working Group Federal Working Group on Dietary Supplements Joint Agency Nutrition Working Group (NIH/FDA) Joint Agency Microbiome Group (NIH/FDA/NIST) U.S. Preventive Services Task Force National Health and Nutrition Examination Survey (NHANES) National Food and Nutrient Analysis Program (NFNAP) Steering Committee DoD, Consortium for Health and *Military* Performance (*CHAMP*) USDA, *Beltsville Human Nutrition Research Center* (*BHNRC*) Inter-Agency Modeling and Analysis Group National Collaborative on Childhood Obesity Research National Institute of Standards and Technology Botanical Safety Consortium (FDA, NIEHS, NTP) DHHS B-24 Consortium DHHS Human Milk Composition Consortium USDA/DHHS2020-2025 Dietary Guidelines for Americans Federal Interagency Iodine Group
Non-Governmental Organizations NASEM Food Forum AOAC International Stakeholder Panel on Dietary Supplements U.S. Pharmacopeia (USP) Convention Activities USP Probiotic Working Group NSF International - American National Standards Institute (NSF-ANSI) Joint Committee on Dietary Supplements International Life Sciences Institute (ILSI) Microbiome Working Group North American Mitochondrial Disease Consortium American Heart Association Nutrition Committee Micronutrient Forum NIH/NICHD-Gates Foundation Research Collaboration

Description of Key Interactions with NIH, Federal and Non-Governmental Organization Partners	
NIH ICO or Federal Agency	**Description**
FDA Office of Dietary Supplements Program	Regular conference calls for both offices to exchange updates on issues of mutual interest and provide clarification or information on current issues
FIC, NCCIH, NCI, NHLBI, NIA, NIAAA, NIAMS, NICHD, NIDDK, NIEHS, NINDS	Co-funded grants
NCI, NHLBI, NIAID, NIDDK, NIEHS	Support NIH intramural scientists to study the role of dietary supplements and/or their ingredients in health promotion and disease prevention
NCCIH, NCI, NIDDK, NIEHS	Administer an FOA for single-lab validation studies of analytical methods for dietary ingredients and/or their metabolites
NCCIH	Jointly prepare FOAs, oversee existing grantees/projects, and plan and coordinate annual meeting.
CDC National Center for Health Statistics	Jointly evaluate biomarkers of iodine status and iron status
Joint Agency Microbiome Working group - NIH, FDA and NIST.	Promote trans-agency collaborations in advancing microbiome-related science
CDC National Center for Health Statistics	Support CDC in preparation of report on blood vitamin D status for NHANES 2011-2014.
CDC Division of Nutrition, Physical Activity and Obesity	Participate in Obesity-Diet and Nutrition Task Force work focusing on the Environmental Influences on Child Health Outcomes (ECHO) project.
Federal working groups for Human Milk Initiative	Co-chair the "measures of human milk" working group and the data working group.
CDC National Center for Health Statistics	Collaborate closely with NHANES Planning Branch on the collection and processing of dietary supplements in the survey.
CDC National Center for Health Statistics	Coordinate quarterly meetings with the NHANES program to discuss current and future projects.
CDC National Center for Health Statistics	Collaborated on publication on supplement usage in children younger than 24 months as reported in 2007-2014 NHANES.
CDC National Center for Health Statistics	Collaborated on new biomarkers of red blood cell folate and an omega-3 fatty acid index to be implemented in the 2019-2020 NHANES.
CDC National Center for Health Statistics	Collaborated on the development of a method for measuring iron status and inflammation using a low volume of blood from children younger than one year in the 2019-2020 NHANES and possibly for the National Children's Study blood samples being evaluated for pregnancy iron status screening.
CDC National Center for Health Statistics	Work with NHANES Planning Branch to develop method to collect accurate infant and toddler formula information collected in 2019-2020.

Description of Key Interactions with NIH, Federal and Non-Governmental Organization Partners	
NIH ICO or Federal Agency	**Description**
CDC National Center for Health Statistics	Proposed approach for estimation of dietary iodine intake for inclusion in the upcoming NHANES surveys
USDA Nutrient Data Laboratory	Interagency agreement to develop a database on the iodine content of salt, foods, beverages, and dietary supplements.
CDC/DNPAO and NCHS, NIST, FDA, USDA	Participate in Iodine Interagency Working Group coordinated by CDC.
NIH-FDA Joint Agency Nutrition Working Group	Semi-annual meeting of nutrition leaders from NIH and FDA to facilitate high-quality nutrition research to improve public health.
NINDS	Co-funded grant for North American Mitochondrial Disease Consortium researchers to develop patient registries, establish natural histories, and investigate dietary supplement-relevant interventions in primary mitochondrial disorders.
NIST	Organizing a workshop on development of reference materials for metabolomic analysis of fecal samples.
DoD Uniformed Services University of the Health Sciences, Center for Health and Military Performance	Funded and is overseeing an interagency agreement on "Dietary Ingredients to Minimize Environmental Heat Injury."
Trans NIH Research Condition and Disease Categorization working group	Initiated the development of an NIH-wide RCDC fingerprint for research related to the microbiome; participated in the development of an NIH Nutrition Research Strategic Plan with the DRI subcommittee.
FDA, USDA, NCI (Office of Cancer CAM and Nutrition Science Research Group), NIA, NIAAA, NIEHS, and ORWH	Led workshop on Enhancing Natural Product Clinical Trials with participation and/or input from other ICOs and federal agencies.
NIST Material Measurement Laboratory, Chemical Sciences Division	Develop innovative analytical methodology for supplements, support and/or mentor postdoctoral researchers
NIST Material Measurement Laboratory, Chemical Sciences Division	Design and conduct quality assurance exercises with participating external laboratories to enhance analytical capacity for supplement and nutrition research.
NIST Material Measurement Laboratory, Chemical Sciences Division	Partner to develop and distribute reference materials.
USDA Food Composition and Methods Development Laboratory	Develop and validate methods for the authentication and characterization of botanical ingredients and supplements, support and/or mentor postdoctoral researchers
FDA, NIEHS National Toxicology Program, private sector supplement manufacturers and trade associations	Participate in activities of the Botanical Safety Consortium
National Library of Medicine (NLM) and work group (NCI, USDA—ARS, CDC NHANES, FDA, DoD—USUHS, NIST)	Developed and updated DSLD database with NLM and with advisement from the working group. DSLD provides information on product ingredients,

Description of Key Interactions with NIH, Federal and Non-Governmental Organization Partners	
NIH ICO or Federal Agency	**Description**
	manufacturers, and other claims from dietary supplement labels. Coordinate interagency meetings.
NLM and work group (NCI, USDA – ARS, CDC NHANES, FDA, DoD—USUHS, NIST)	Collaborates with working group to develop, launch and expand DSID
NIH OD - Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)	Contribute to DPCPSI Spotlight
NIH-wide communications and nutrition groups including the NIH Communications Directors, NIH Press Officers groups, NIH Social Media Collaboration Team, NIH Consumer Health Content Committee, and the Nutrition Education Subcommittee of the Nutrition Research Coordinating Committee	Committee participants
Federal Working Group on Dietary Supplements	Communications team organizes meetings of the Federal working groups twice yearly and ODS staff present research and updates as requested.
NIH Communications vehicles	Prepare Monthly Report to the NIH Director; BRAIN topic; NIH Week Ahead Report; HHS 30-Day Look Ahead Report; Trans HHS Collaborations; Trans NIH Collaborations
ILSI North America	Gut microbiome committee member;organized workshop on healthy gut microbiome
United States Pharmacopeia (USP)	Government liaison for USP probiotic expert panel
United States Pharmacopeia (USP)	Observer to USP Expert Panels on Botanical Dietary Supplements and Herbal Medicines and Non-Botanical Dietary Supplements
NSF International — American National Standards Institute	Participant on the Joint Committee on Dietary Supplements
AOAC International	Stakeholder Panel on Dietary Supplements (2013-2018) – convened representatives from 32 different academic, government, and industry organizations, deliberated analytical method requirements for dietary supplement ingredients prioritized by an Advisory Panel

Appendix C: Strategic Plan Expert Review Panels

Academic Expert Review Panel

Chun-Tao Che, Ph.D., Norman R. Farnsworth Professor of Pharmacognosy, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago, College of Pharmacy
April Stull, Ph.D., R.D.N., Associate Professor, Department of Human Sciences and Design, Baylor University
Patrick Stover, Ph.D., Vice Chancellor and Dean for Agriculture and Life Sciences Director, Texas A&M AgriLife Research
Penny Kris-Etherton, Ph.D., Evan Pugh University Professor of Nutritional Sciences, College of Health and Human Development, Pennylvania State University
Barbara Schneeman, Ph.D., Emeritus Professor of Nutrition, Department of Nutrition, University of California, Davis
Julie Mares, MS.P.H., Ph.D., Professor, Department of Ophthalmology & Visual Sciences, University of Wisconsin

Industry and Association Expert Review Panel

Robert Marriott, J.D., Director of Regulatory Affairs, American Herbal Products Association
Duffy MacKay, N.D., Senior Vice President, Scientific & Regulatory Affairs, Consumer Healthcare Products
Dave Schmidt, Executive Director, AOAC International
Steve Mister, J.D., President and CEO, Council for Responsible Nutrition
Nancy Chapman M.P.H., R.D., President, N. Chapman Associates
Peter Lurie, Ph.D., President, Center for Science in the Public Interest

NIH Partner Expert Review Panel

Ann Berger, MS.N., M.D., Chief, Pain and Palliative Care, Clinical Center, NIH
Flora Katz, Ph.D., Director, Division of International Training and Research, Fogarty International Center, NIH
Rashmi Gopal-Srivastava, M.Sc., Ph.D., Program Director, Division of Clinical Innovation, National Center for Advancing Translational Sciences, NIH
Helen Langevin, M.D., Director, National Center for Complementary and Integrative Health, NIH
Emily Chew, M.D., Director of the Division of Epidemiology and Clinical Applications (DECA), at the National Eye Institute
Charlotte Pratt, Ph.D., M.S., R.D, FAHA, Deputy Branch Chief; Nutrition; CVH across the Lifespan, National Heart, Lung, and Blood Institute, NIH
Stephanie George, Ph.D., M.P.H., M.A., Epidemiologist and Program Director for the Molecular Transducers of Physical Activity Consortium (MoTrPAC), Division of Extramural Research, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Roger Little, Ph.D., Deputy Director, Division of Neuroscience and Behavior, National Institute on Drug Abuse, NIH

Mary Evans, Ph.D., Program Director, Division of Digestive Diseases and Nutrition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH
Donna Krasnewich, M.D., Ph.D., Program Director, Division of Genetics and Molecular, Cellular, and Developmental Biology, National Institute of General Medical Sciences, NIH
Lynn Adams, Ph.D., Health Scientist Administrator, Office of End-of-Life and Palliative Care Research, National Insitute of Nursing Research, NIH
Chhanda Dutta Ph.D., Chief, Clinical Gerontology Branch, Division of Geriatrics and Clinical Gerontology, National Institute on Aging, NIH
Diane Adger-Johnson, Ph.D., Health Science Program Officer, Division of Extramural Activities, Office of Research Training and Special Programs, National Institute of Allergy and Infectious Diseases
Mary Herron, Technical Information Specialist at National Library of Medicine, NIH
Deborah Young-Hyman, **Ph.D.,** Health Scientist Administrator, Office of Behavioral and Social Sciences Research, Office of the Director, NIH
Elena Gorodetsky, M.D., Ph.D., Health Scientist Administrator/Research Program Officer, Office of Research on Women's Health, Office of the Director, NIH

Federal Agency Partner Expert Review Panel

Christine Pfeffer, Ph.D., Chief of the Nutritional Biomarkers Branch, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention
Cara Welch, Ph.D., Acting Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services
Keriann Uesugi, Ph.D., M.P.H., Health Scientist, Division of State and Community Health, Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services
Omar Dary, Ph.D., Senior Nutrition Advisor, Nutrition Division of the Office of Health, Infectious Diseases and Nutrition, Bureau for Global Health, United States Agency for International Development
James McClung, Ph.D., Nutrition Biologist, United States Army Research Institute of Environmental Medicine
Naomi Fukagawa, M.D., Ph.D., Director, Agricultural Research Service, Beltsville Human Nutrition Research Center, USDA
Patricia Deuster, Ph.D., M.P.H., Executive Director, Consortium for Health and Military Performance, Uniformed Services University of the Health Sciences

Appendix D: Glossary

AAAS	American Association for the Advancement of Science
AHRQ	Agency for Healthcare Research and Quality
AMRM	Analytical Methods and Reference Materials Program
AoA	Admnistration on Aging
ASN	American Society of Nutrition
BDSRC	Botanical Dietary Supplement Research Center
BRC	Botanical Research Center
CARBON	Centers for Advancing Research on Botanical and Other Natural Products
CARDS	Computer Access to Research on Dietary Supplements
CDC	Centers for Disease Control and Prevention
CHAMP	DoD Center for Health and Military Performance
CMS	Centers for Medicare and Medicaid Services
CRM	Certified Reference Material
DEQAS	Vitamin D External Quality Assessment Scheme
DHHS	U.S. Department of Health and Human Services
DoD	Department of Defense
DPCPSI	Division of Program Coordination Planning and Strategic Initiatives
DRIs	Dietary Reference Intakes
DSID	Dietary Supplement Ingredient Database
DSLD	Dietary Supplement Label Database
FASEB	Federation of American Societies for Experimental Biology
FDA	U.S. Food and Drug Administration
FTC	Federal Trade Commission
FWGoDS	Federal Working Group on Dietary Supplements

HAMQAP	HealthAssessment Measurements Quality Assurance Program
IAA	Interagency Agreement
ICOs	Institutes, Centers and Offices [of NIH]
ICs	Institutes and Centers [of NIH]
NASEM	National Academies of Sciences, Engineering, and Medicine
NCATS	National Center for Advancing Translational Science
NCCIH	National Center for Complementary and Integrative Health
NCHS	National Center for Health Statistics
NCI	National Cancer Institute
NGO	Non-Governmental Organizations
NHANES	National Health and Nutrition Examination Survey
NHLBI	National Heart Lung and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NICHD	National Institute of Child Health and Human Development
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIMHD	National Institute on Minority Health and Health Disparities
NINR	National Institute of Nursing Research
NIST	National Institute of Standards and Technology
NLEA	Nutrition Labeling and Education Act
NLM	National Library of Medicine
NOSI	Notice of Special Interest
NP-MRD	Natural Product Magnetic Resonance Database
NP-TEMPO	Natural Product Technology, Methodology, and Productivity Optimization

NTP	National Toxicology Program
ODS	Office of Dietary Supplements
ORWH	Office of Research on Women's Health
RCDC	Research, Condition, and Disease Categorization
RFA	Request for Application
SIG	Scientific Interest Group
USDA	U.S. Department of Agriculture
USDOC	U.S. Department of Commerce
USUHS	Uniformed Services University of the Health Sciences