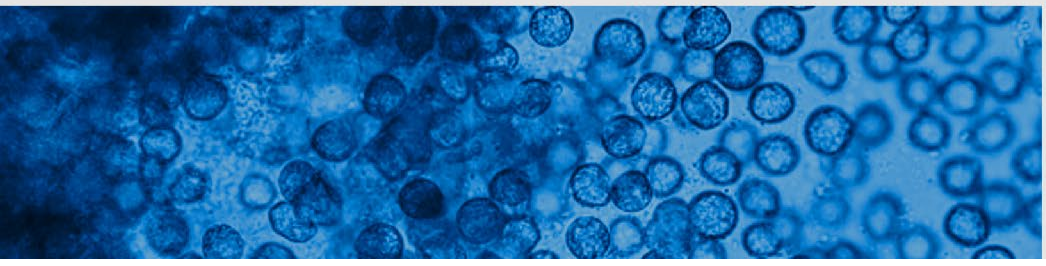
National Institutes of Health
Office of Dietary Supplements

NIH Office of Dietary Supplements STRATEGIC PLAN

2025-2029

A Blueprint for a Coordinated Dietary Supplement Research Agenda at NIH



Foreword

Dietary supplements are widely available and used by more than one-half of adults and one-third of children in the United States to fill nutrient gaps and optimize health. Despite this common use, there is much to understand about the health impacts of dietary supplements. The Office of Dietary Supplements (ODS), located within the Division of Program Coordination, Planning, and Strategic Initiatives in the Office of the Director, at the National Institutes of Health (NIH), is charged with ensuring that the public has confidence in the science that informs their decisions to use dietary supplements. ODS fulfills its mission through funding, promoting, and coordinating scientific studies of dietary supplements to understand their impact on the health of Americans. For 30 years ODS has been a trusted primary source of scientific information, tools, resources, and support to consumers, healthcare professionals, practitioners, researchers, and industry partners.

Last year, Dr. Stefan M. Pasiakos began his tenure as the new director of ODS, and he and the team at ODS have outlined a visionary framework for creating an expansive dietary supplement research agenda. NIH enthusiastically welcomes this new strategic plan that will promote greater collaboration and coordination of innovative dietary supplement research with the Institutes, Centers, and Offices (ICOs) across NIH. The strategic plan clearly articulates ODS's scientific cross-cutting themes of diverse populations, healthy lifespan, and resilience, along with the strategic priorities that will establish a framework for new, collaborative dietary supplement initiatives across NIH and the Federal government. Plans to develop and communicate enhanced research methodology guidelines will help advance and harmonize the field of dietary supplement research.

With a talented staff and plans for strengthening and developing close partnerships with the ICOs, I am confident that ODS will contribute greatly to the scientific understanding of dietary supplements and how they impact the health of our nation.

Tara A. Schwetz, Ph.D.
Deputy Director for Program Coordination, Planning, and Strategic Initiatives
National Institutes of Health

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A Message from the Director

Since joining the NIH Office of Dietary Supplements (ODS) as its new director in July 2023, my primary focus has been to establish a strategic vision that positions ODS as the premier organization, authority, and convening body for advancing the study of dietary supplements. My vision for ODS emphasizes objectivity and innovation. It prioritizes collaboration and coordination across NIH while maintaining our long-standing partnerships with other federal agencies and leading dietary supplement trade organizations. We remain committed to the American public as the honest broker for advancing dietary supplement science and fostering public health knowledge.

I am pleased to introduce the ODS Strategic Plan for 2025-2029, "A Blueprint for a Coordinated Dietary Supplement Research Agenda at NIH." The plan reimagines ODS with new priorities, programs, and scientific interest areas. These all build upon our competencies and ongoing activities to address a renewed mission to coordinate collaborative, innovative and cutting-edge dietary supplement research across NIH and other federal agencies to foster knowledge and optimize health across the lifespan.

The new ODS structure includes three key areas: research, research capacity, and operations and resources. The Biological, Population, and Analytical Sciences Research Programs all promote interoperability and reflect the broad scientific disciplines necessary to address contemporary public health needs relevant to dietary supplements. These programs will converge to develop cutting-edge research initiatives of broad interest across NIH pertaining to diverse populations, healthy lifespan, and resilience. To support these new efforts, we include research capacity programs. We will strengthen rigor and reproducibility of dietary supplement science with a focus on methodological best practices and will facilitate an efficient, agile, and robust research portfolio by strategizing funding opportunities. Operations and resources programs support all ODS activities with communications, data resources, partnership development, program assessment, and other administrative needs.

This strategic plan reflects the collaborative work of the dedicated and passionate staff that comprise the ODS, with input and expertise provided by our colleagues and partners across NIH, other federal agencies, leading dietary supplement trade organizations, the broader scientific field of dietary supplements and nutrition, and the public. It is a blueprint for new opportunities to forge successful collaborations and advance the field with our many partners. ODS embraces the structure and the foundation the new strategic plan provides for the coordination of dietary supplement research and the translation of findings that will inform nutrition and public health guidance and most importantly, the public's choices for the safe and effective use of dietary supplements.

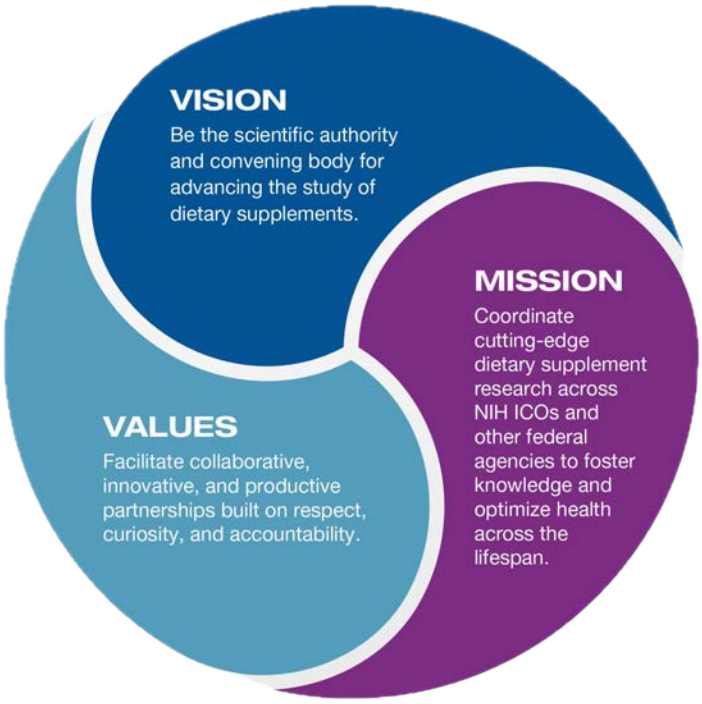
Stefan M. Pasiakos, Ph.D.
Director, Office of Dietary Supplements
National Institutes of Health

Introduction

Overview of the Office of Dietary Supplements

The dietary supplement market now includes more than 100,000 products and about one-half of adults and one-third of children and adolescents in the United States use dietary supplements. Yet questions remain about their cellular mechanisms, metabolism, efficacy, safety, and effects on health. To address these questions, the Office of Dietary Supplements (ODS) leads the scientific exploration of dietary supplements across the National Institutes of Health (NIH). In this new strategic planning period (2025–2029), ODS will continue to identify dietary supplement research priorities based on public health importance and will use research coordination and funding to address critical gaps in knowledge. ODS also will continue to translate scientific advances for researchers, health professionals, public health policy decision-makers, industry leaders, and the public. This strategic plan provides a blueprint for how ODS will help to inform and shape the dietary supplement research agenda at NIH.

Figure 1: ODS Reimagined



To provide a foundation for and stimulate new dietary supplement research opportunities, ODS has refined its vision, mission, and values (Figure 1), prioritizing strategically selected areas of study for collaborations within the office and with other NIH Institutes, Centers, and Offices (ICOs); federal agencies; and partners in the dietary supplement research community. ODS is in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the Office of the Director at NIH. ODS is positioned with its renewed

mission *to coordinate cutting-edge dietary supplement research across NIH ICOs and other federal agencies to foster knowledge and optimize health across the lifespa*n.

Historically, ODS has organized its work around specific objectives called out by legislation— the Dietary Supplement Health and Education Act (DSHEA) of 1994 (see Appendix A). Going into its fourth decade, ODS will evolve to expand its capabilities and accomplish its mission by emphasizing collaboration across NIH ICOs and implementing an organizational structure that enables it to:

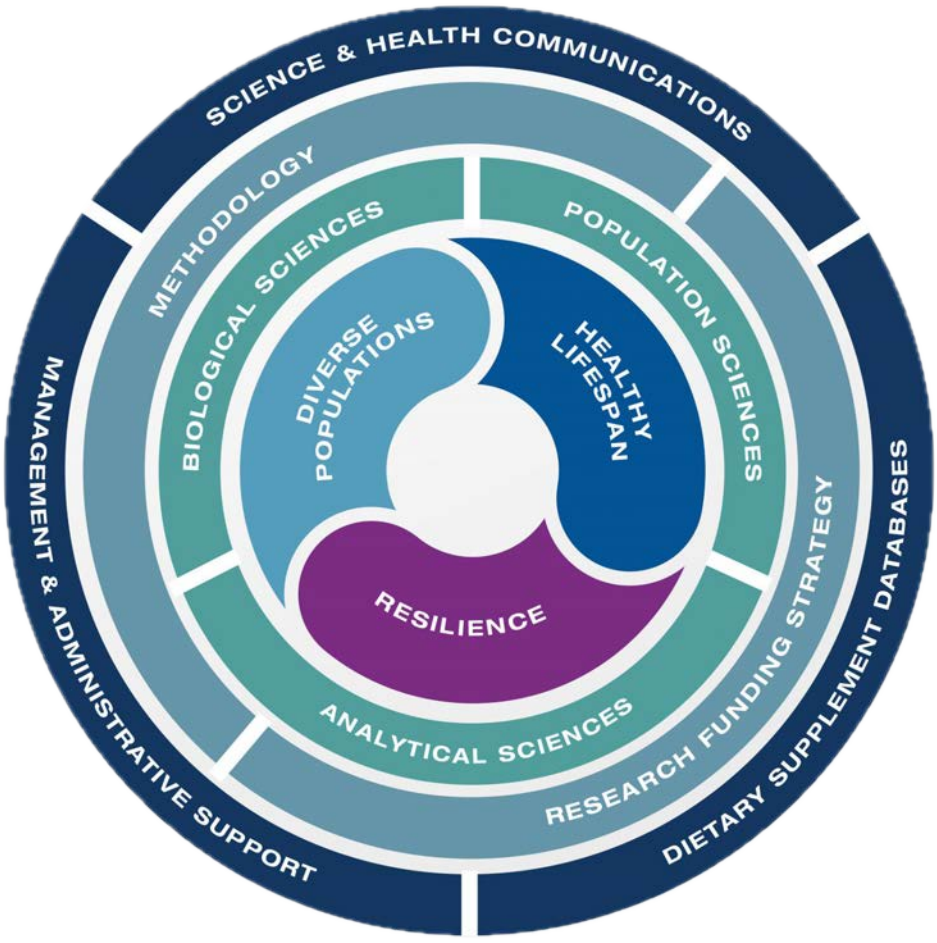
1. Create a priority-based organizational culture that empowers collaboration.
2. Convene working groups comprised of subject matter experts to identify knowledge gaps of shared and timely interest.
3. Engage with NIH ICOs and other federal agencies to develop new research initiatives to address identified knowledge gaps.
4. Leverage all viable funding mechanisms to support new research and partnerships.
5. Disseminate ODS accomplishments, findings of relevant dietary supplement studies, and related nutrition and public health advances to a variety of US and global audiences.
6. Provide access to and support of dietary supplement databases.

The ODS structure and research approach introduces interoperability across ODS programs. Appendix B includes an organizational chart that includes a leadership team who will work together to support all ODS programs and staff. Each program, led by a program director, will include staff who will collaborate across multiple programs, promoting communication within the office. This organizational structure supports all staff by standardizing communications, improving efficiencies, simplifying decision processes, and promoting accountability.

Strategic Plan Framework

To foster a culture that stimulates and supports collaboration, communication, innovation, and timely and effective dissemination of findings, ODS will synergize around joint strategic priorities, building upon existing strengths, enabling professional and organizational growth, and expanding the ODS sphere of influence across NIH. There will be eight interconnected priority-based programs, with ODS staff serving on multiple program teams. Their collective core competencies will motivate and facilitate new focused partnerships and engagements with NIH ICOs, other federal agencies, and other dietary supplement researchers to support the program areas of research, research capacity, and operations and resources (Figure 2). ODS has identified diverse populations, healthy lifespan, and resilience as cross-cutting themes around which new research initiatives will be developed. These themes reflect topics of high interest across NIH that intersect with dietary supplement research. Subsequent sections of the strategic plan provide extended details describing the new ODS research, research capacity, and operations and resources programs and cross-cutting themes.

Figure 2: ODS Interconnected Programs



The strategic priorities that align with the programs depicted in Figure 2 include:

Research Priorities:

- Biological Sciences: Advance the study of the biological effects of dietary supplements on health across the lifespan.
- Population Sciences: Advance the study of population-based dietary supplement use, related nutrient intake, and their effects on health.
- Analytical Sciences: Advance the study of the composition, quality, stability, safety, and efficacy of dietary supplements and their ingredients.

Research Capacity Priorities:

Methodology: Strengthen and harmonize the methodologies applied to dietary supplement research.

Research Funding Strategy: Strategize ODS research funding mechanisms.

Operations and Resources Priorities:

Science and Health Communications: Communicate advances in dietary supplement science, promote ODS activities, and amplify ODS messages.

Dietary Supplement Databases: Maintain and ensure access to public use dietary supplement databases.

Management and Administrative Support: Coordinate and support ODS program evaluation, workforce development, and day-to-day ODS operations.

Priority Setting and Strategic Planning

Priority setting in ODS is a dynamic process that considers public health needs, knowledge gaps, and changing trends in the dietary supplement marketplace and consumer use of these products. Priority setting occurs when developing a strategic plan, but also continues as programs refine their focus and set goals and objectives. Key questions used to determine knowledge gaps and set research priorities include:

- What is the nature and prevalence of the public health issue?
- Do we know to what extent the population is exposed to a dietary supplement or nutrient?
- How are biomarkers of nutritional exposure status, and bioavailability of dietary supplements and their constituent 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 than the methods currently used?
- What is the evidence for the health effects of dietary supplements? What amounts of dietary supplement intake, relevant to dietary consumption, are safe and produce an observed biological effect or health outcome?

Priority setting for this strategic plan began with a reexamination of subject matter expert feedback to an interim plan (2022–2026), followed by an iterative ODS staff priority-setting process to delineate areas of scientific emphasis and opportunity. This process established the three broad program areas of research: research capacity, and operations

and resources and the priorities for each. It also produced key cross-cutting themes to advance research on dietary supplements.

The next priority-setting step will be to collaborate with NIH ICO staff with diverse disciplinary backgrounds to identify knowledge gaps in dietary supplement research that relate to the cross-cutting themes and NIH ICO interests. This information will be used to structure meetings with subject matter experts to prioritize focus areas that will serve as the basis for new ODS research across all cross-cutting themes.

Appendix C presents a full description of the strategic planning process followed for the development of the ODS 2025–2029 plan. The planning process includes:

- Review of past achievements and subject matter expert feedback
- Development of new ODS vision and mission, strategic priorities, and objectives
- Review by the NIH Dietary Supplement Research Coordinating Committee (DSRCC) and other subject matter experts
- Feedback and approval from NIH leadership

Implementation of the Strategic Plan

The overarching goal for this strategic plan period is to increase the interoperability and cross-functional nature of ODS. Thus, staff will work interactively across the different research programs. These interactions will promote communication and collaboration, ensuring a critical mass of diverse expertise and opinions are used to develop new initiatives and activities.

Continuous program assessment and evaluation are key tools for program development and implementation. Each ODS program will develop an implementation plan for achieving its objectives that will include program activities, required program inputs, anticipated outcomes, and assessment measures. A timeline with milestones will accompany each plan and will be used to adjust a course as needed based on program progress.

Leveraging Partnerships

Collegial partnerships with NIH ICOs, other federal agencies, academic experts, and industry researchers help ODS expand fundamental knowledge of dietary supplements and, in turn, help partners identify best practices for applying that knowledge for the betterment of the health of the U.S. populations. These partnerships expand the range of subject matter expertise, enhance initiative collaborations, allow for pooled resources, and provide opportunities for feedback and dialogue. ODS staff participate in working groups with the NIH 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 will expand their participation to include other groups such as the Sexual & Gender Minority Research Office (SGMRO) research coordinating committee. These relationships allow ODS to engage more actively in and promote expanded diversity, equity, inclusion, and

accessibility (DEIA) in dietary supplement research. ODS will continue to foster these partnerships by developing strategic liaisons with partner groups and sharing key dietary supplement research findings to inform their work.

The NIH DSRCC was established in 2022 to increase collaboration among NIH ICOs whose programs include work that focuses on dietary supplements and the intersection of dietary supplements, natural products, and nutrition research. Members include program staff from each NIH ICO who have research related to dietary supplements in their NIH extramural portfolios as well as representatives from key federal agency partners with shared interests in dietary supplement research. The DSRCC provides research coordination through the exchange of programmatic and scientific information, collaborative planning, and the implementation of relevant activities and initiatives with a focus on scientific gaps in dietary supplement research along with emerging and cross-cutting dietary supplement research areas related to each ICO's programmatic interests, mechanisms to promote collaborative initiatives across NIH and within the federal government, and programmatic and policy issues and activities that impact ODS or to which ODS can contribute. Through the DSRCC and other collaborations, ODS has developed stable, collegial, and productive relationships with select ICOs, external groups, and federal agencies whose research interests are clearly aligned with ODS. Although the type of collaboration varies, they help ODS increase its influence on dietary supplement biomedical research. Throughout this strategic plan period, ODS intends to increase its collaborations with NIH ICOs and external colleagues to identify topics for new work that address the selected cross-cutting themes.

Creating a Dietary Supplement Research Agenda

Cross-Cutting Themes

The ODS cross-cutting themes include diverse populations, healthy lifespan, and resilience. Although these themes are presented individually below, they integrate not only with the different ODS strategic priorities but also with each other. For example, initiatives on health and resilience across different life stages will include research that focuses on segments of the diverse U.S. populations. While we highlight these three themes, there are additional relevant factors that we will consider in new research initiatives. These include issues that impact nutrient status and health outcomes such as climate change, or factors that facilitate dietary supplement research such as the use of cutting-edge methodologies including artificial intelligence. It is with this interactive lens that ODS will deepen the knowledge of dietary supplements and health.

Diverse Populations

A focus on diverse populations and dietary supplement research stresses the importance of improving the health of all Americans through research on disease prevention and health

promotion, considering the different genetic traits in the population. Diverse populations include those designated by NIH as populations with health disparities such as racial and ethnic minority groups, people with lower socioeconomic status, underserved rural communities, sexual and gender minority groups, and people with disabilities. Additionally, we include people of different ages, sex, gender, geographic locations, health status, primary language, and citizenship status. Prevention research explores biological, behavioral, physical, social, and community environmental factors, along with health outcomes to inform health-related guidelines, policies, and regulations. Understanding the use of dietary supplements and their effects on health outcomes in the United States requires investigation into their use and associated health outcomes identified in the many diverse populations and the various intersections of these groups within the United States.

Knowing that biological research findings cannot be accurately extrapolated from one subgroup of the population to the next, each population group needs to be understood on its own. The ODS work on the Vitamin D paradox in Black Americans is one example of the importance of discovering the different responses to a nutrient's intake found among different population groups. The paradox is that despite markedly low measures of vitamin D status in Black Americans, the incidence rates of falls, fractures, or osteopenia are significantly lower compared to White Americans with similar vitamin D status. The consensus among experts that Black Americans gain no skeletal benefits from high doses of vitamin D supplementation and that high levels of the biomarker of vitamin D status, serum 25-hydroxyvitamin D or 25(OH)D, in this population could very well be associated with adverse effects highlights the importance of identifying lower and upper tolerance limits in the dietary reference intakes for nutrients for different subgroups.

Another example of ODS work highlighting the need to understand diverse populations focuses on populations at greatest risk for food insecurity, which is the limited or uncertain availability of nutritionally adequate and safe foods or the limited or uncertain ability to acquire acceptable foods in socially acceptable ways. Resulting from an array of factors that include many social determinants of health such as low economic status, neighborhood environment, access to healthy food, lack of transportation, cost of food, and housing costs, food insecurity disproportionately impacts Black non-Hispanic, Hispanic, and American Indian/Alaska Native households. Studies have documented higher rates of diabetes, hypertension, obesity, heart disease, and other chronic diseases among adults living with food insecurity and that adults living with food insecurity have lower intakes of vitamin A, vitamin B6, calcium, magnesium, and zinc from diet alone. Analyses of National Health and Nutrition Examination Survey (NHANES) data that included dietary supplement intake found a higher prevalence of micronutrient inadequacy among adults living with food insecurity for copper; potassium; niacin; and vitamins C, D, E, and K in both men and women, with inadequate levels of selenium only in men.

To better understand diverse populations ODS will expand its research on how the consumption of dietary supplements affects food insecurity and nutritional status of subpopulations within racial or ethnic groups at greatest risk including children, older adults, and those living with long-term chronic illness. This may include investigations that characterize the multiple factors that influence the complex relationship between food

insecurity, diet, and specific health outcomes in vulnerable populations. Initiatives addressing the theme of diverse populations also will include work investigating how dietary supplements modulate the responses to biological mechanisms and exposomes (environmental and lifestyle exposures) that influence the health of diverse populations.

ODS recognizes that there is a need to better understand both the distinctive health characteristics and attributes of minority racial and/or ethnic groups who have historically been underrepresented in biomedical research and the impact of social determinants on health outcomes and interventions to address them among designated health disparity populations. This requires improved methods for recruitment of these groups in research studies and the development of appropriate data collection methodologies. The Methodology Program includes this as one of its objectives for this strategic planning period.

ODS has participated in the development of several funding opportunities that focus on diverse populations including three notices of special interest (NOSI): Stimulating Research to Understand and Address Hunger, Food and Nutrition Insecurity, Increasing Uptake of Evidence-based Screening in Diverse Populations Across the Lifespan, and Implementation Science to Advance Maternal Health and Maternal Health Equity for the IMPROVE Initiative. Other funding opportunities ODS has participated in include an initiative on Multi-Sectoral Preventive Interventions that Address Social Determinants of Health in Populations that Experience Health Disparities and another on Mobile Health: Technology and Outcomes in Low and Middle Income Countries.

New research initiatives on diverse populations will consider factors that include differences in biological mechanisms and outcome measures, community- and population-level dietary patterns, access to food and dietary supplements, and attitudes surrounding use of nutritional and non-nutritional dietary supplements (e.g., botanicals, probiotics). Variables to be addressed include sex, gender, racial, ethnic, and health status differences, and their intersectionality, that impact the utilization of and access to nutrients and phytochemicals in supplements and conventional food and how these might influence health in diverse populations and across the lifespan.

Healthy Lifespan

Throughout life, people experience different stages of physical and cognitive growth and development. Each stage, including pregnancy, lactation, infancy, childhood, adolescence, adulthood, menopause, and old age, includes changing nutritional needs and potential concerns. For example, during infancy and childhood, recommended intakes of macronutrients and most micronutrients are higher relative to body size compared with those during adulthood. In older adults, some nutrient needs increase while others are reduced. At all stages of life nutrient inadequacies, and in some instances excessive intakes are associated with adverse health effects, although the effect of dietary supplementation on health optimization across the lifespan continues to be debated.

The Institute of Medicine's (now the National Academy of Medicine) Food and Nutrition Board established estimated average requirements and adequate intakes as age- and gender-specific nutrient intake goals. The Dietary Guidelines for Americans 2020–2025 (DGA) identified calcium, potassium, dietary fiber, and vitamin D as dietary components of public health concern for the general U.S. population because low intakes are associated with risk of chronic disease. Conclusions from an analysis of 2003–2018 NHANES data suggest that nutrient intake and the percentage of the population meeting nutritional recommendations among U.S. adults have changed little over time and suggest that dietary supplement intake may assist many U.S. adults in meeting nutrient requirements.

This conclusion is supported by other analyses of NHANES data that indicate that dietary supplements are used across all age groups and contribute to increased intakes of nutrients and decreased population prevalence of inadequacy and, for a small proportion of the population, nutrient excess. An analysis of NHANES data from 2017 to 2018 showed that more than half of U.S. adults used any dietary supplement in the past 30 days and with age there is an increase in the use of any dietary supplements and the number of supplements used. The data also show that approximately one-third of children and adolescents used dietary supplements in the past 30 days. Analyses from earlier years found slightly less than one-fifth of infants and toddlers used dietary supplements as did approximately three-fourths of pregnant and lactating people.

The identification of nutrients of concern and the simultaneous widespread use of dietary supplements across all age groups call for additional investigations to understand associations between dietary supplement use, disease prevention, and health optimization at the different ages and life stages and the biological mechanisms through which dietary supplements impact health. Work that ODS has helped to support includes grants such as Alpha Lipoic Acid as a Maternal Supplement in Obese Pregnancies (the National Center for Complementary and Integrative Health [NCCIH]), Botanicals Enhancing Neurological and Functional Resilience in Aging (NCCIH), Impact of Prenatal Vitamin A Deficiency on Cell Fate Alterations in Adult Airway Hyperresponsiveness (the National Heart, Lung, and Blood Institute [NHLBI]), The Nutritional Immunology Across the Lifespan Conference (the National Institute of Allergy and Infectious Diseases [NIAID]), and Long-Term Effects and Safety of DHA Supplementation in Toddlerhood for Children Born Preterm (the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development [NICHD]).

The effects of dietary supplements on various chronic diseases or conditions remain unclear as does the understanding of how dietary supplements interact with other dietary supplements, medications, and lifestyle factors such as sleep, physical activity, and overall dietary intake. Age and sex-limited population-based analyses to identify nutrients and chronic diseases or conditions of greatest concern can be used to inform new biological science initiatives on the mechanisms through which select dietary supplements influence specific chronic diseases or conditions at specific life stages. Analytical science-related initiatives may seek to understand factors in supplements that influence their uptake and metabolism and ability to influence nutritional status, considering their interactions with other dietary supplements, medications, or lifestyle factors. Some diseases and conditions

to be considered may include mucosal immunity, digestive diseases, autoimmune or immune-mediated diseases, and cardiorespiratory and cardiovascular diseases. Longevity and factors affecting lifespan and quality of life also may be considered including obesity, physical activity, cardiometabolic dysregulation, sarcopenia, and age-related physical and cognitive function decline.

Resilience

A focus on dietary supplements and resilience supports ongoing resilience research efforts at NIH and the U.S. Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion's Federal Plan for Equitable Long-Term Recovery and Resilience (Federal Plan for ELTRR). Given the high-level focus on resilience throughout the HHS and ODS's recently demonstrated success in coordinating resilience research efforts across the NIH through its coordination of the Trans-NIH Resilience Working Group, the ODS will devote resources to clearly delineating the role of dietary supplements in advancing the science of resilience.

The Trans-NIH Resilience Working Group definition of resilience encompasses the capacity to resist, adapt to, recover, or grow from a challenge. It suggests that over time, a system's response to a challenge might show varied degrees of reactions that likely fluctuate in response to the severity of the challenge, the length of time exposed to the challenge, and/or innate biological factors. The ODS Resilience and Health Studies Program began developing a resilience initiative by exploring resilience outcomes in investigations of dietary supplement ingredients as part of its efforts to address evidence gaps pertaining to the benefits (and/or harms) of dietary supplement use. Inconsistent methods, endpoints, and study design strategies have contributed to the heterogeneity in the scientific literature of potential benefits of dietary supplements. Resilience as an ODS cross-cutting theme will promote the use of resilience research frameworks that focus on enhancing protective pathways to investigate the effects of dietary supplements on health. With the understanding that resilience outcomes can be attributed to pathways that are unique and unrelated to any disease pathway, studies of dietary supplements that are intentionally designed to explore resilience outcomes may expand our understanding of the mechanisms by which dietary supplement ingredients provide potential health benefits.

The resilience research framework developed by the ODS-led Trans-NIH Resilience Working Group differs from previously published resilience models due to its intentional focus on the system rather than the stressor. The framework allows for the notion that different stressors and risks can be constant occurrences, and an understanding of the factors that strengthen or protect a system despite exposures to stressors and risks allows for a multipronged approach to health optimization. A special issue of Stress & Health titled "Harmonizing the Science of Resilience," led and co-authored by the ODS Resilience and Health Studies Program, includes contributions from 32 authors from across NIH ICOs, scientists from the United States Army Research Institute of Environmental Medicine (USARIEM), and researchers from academia. To identify measures and metrics necessary to fully capture the protective pathways that elicit resilience and optimize human health across the lifespan that can appropriately be applied to dietary supplement research, ODS

organized a workshop titled “Coordinating Measures and Metrics to Advance the Biomedical Science of Resilience.”

While developing a resilience research category for the Research Condition and Disease Categorization (RCDC) system, ODS identified 819 resilience research grants in 2023 with representation from 12 NIH ICOs. Among the resilience grants co-funded by ODS are research on Neuroprotective Effects of Antioxidants from Select Botanicals (NCCIH), Biomarkers of Dietary Flavonoid Intake, Carbonyl Stress, and Metabolic Risk (the National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK]), Botanicals Enhancing Neurological and Functional Resilience in Aging (The National Institute on Aging [NIA]), and Influence of Botanical Dietary Supplements on Biological and Behavioral Resilience (NCCIH). Work focused on dietary supplements and resilience may include mechanistic studies of dietary supplement ingredients, clinical studies that explore potential biomarkers of resilience, and studies of diverse populations to facilitate discovery of new protective pathways influenced by dietary supplements.

Research

Goal: To coordinate and support dietary supplement research based in biological, population, and analytical sciences.

ODS research programs include the Biological, Population, and Analytical Sciences Programs. Each program draws upon the knowledge gained from current ODS programs whose activities will be included where appropriate in the new priority-based programs. The ultimate goal of each program is to coordinate the development of broad research initiatives that leverage the expertise of NIH and other dietary supplement researchers. The objectives for each research program for 2025–2029 include:

Objective 1: Conduct extensive research reviews to identify dietary supplement research knowledge gaps.
Objective 2: Collaborate with NIH ICO program staff to identify research topics of interest that address knowledge gaps and align with ODS cross-cutting themes and NIH ICO focus areas.
Objective 3: Coordinate the development of dietary supplement research initiatives for each cross-cutting theme in the scientific disciplines of biological, population, and analytical sciences.

Research Priority 1: *Advance the study of the biological effects of dietary supplements on health across the lifespan*

Currently, about one-half of adults and one-third of children and adolescents in the United States consume dietary supplements. Some use them to address known nutrient deficiencies while others consume them to improve their health or to prevent future health problems. The focus on biological sciences reflects the importance of understanding how dietary supplements affect health and the intrinsic and extrinsic

factors that may modulate those effects. Basic science, translational, and clinical research initiatives will be central to answering key biological questions.

For decades, ODS has been supporting NIH ICO efforts to advance the understanding of how dietary supplements affect health. For example, ODS, in collaboration with NIAID, recently supported *The Nutritional Immunology Across the Lifespan Conference*. This conference, which was held by the Federation of American Societies of Experimental Biology during their 2023 Science Research Conference Series, brought together subject matter experts from diverse disciplines to focus on identifying research gaps that, if addressed, would delineate the intersection of nutrition with innate and adaptive immunity across the lifespan. In another example, ODS partnered with NIDDK to support the *Ethnic Differences in Iron Absorption Study*, a project that took a multidisciplinary approach to study genetic mechanisms that modulate iron homeostasis to better understand disease risk and optimize dietary iron intake recommendations for diverse populations. The *Manganese in Inflammatory Bowel Disease Study* is a project supported by ODS and NIDDK that seeks to define the roles of dietary manganese and single nucleotide polymorphism in the manganese transporter SLC39A8 in the maintenance of gastrointestinal health. The data generated from this trial will provide the evidence base for novel therapeutic trials testing the efficacy of diet or supplemental manganese on digestive health in individuals at high risk of inflammatory bowel disease.

Through an intra-agency agreement with the National Eye Institute (NEI), *The Age-Related Eye Disease Studies* (AREDS and AREDS2) clinical trials tested whether taking a mix of dietary supplements (including vitamin E, vitamin C, and beta-carotene) could prevent or slow the development of cataracts and age-related macular degeneration (AMD). Although the supplement formulations tested did not prevent AMD onset or affect cataracts, they did reduce the risk of developing advanced AMD by about 25 percent. AREDS2 also tested a version of the AREDS dietary supplement formulation without beta-carotene because beta-carotene supplementation has been shown to increase the risk of lung cancer in smokers and former smokers. Results from the trial showed no significant differences in the risk of advanced AMD when beta-carotene was removed from the supplement formulation.

ODS also partnered with the Department of Defense (DoD) Consortium for Health and Military Performance (CHAMP) on systematic reviews exploring dietary supplements, immune health, and resilience outcomes and led interagency agreements (IAAs) to explore mechanisms and effectiveness of dietary supplement ingredients and their potential to minimize environmental heat injury.

The Biological Sciences Program will emphasize work across NIH ICOs, facilitating collaborations that enhance our knowledge of the role that dietary supplements play in health and the mechanisms through which they work. Knowledge gaps will be identified that reflect on:

- Underlying biological states and mechanisms that influence a system's cellular, molecular, physiologic, and behavioral/psychological response to stress or disease
- Protective pathways, disease prevention, and health promotion

- Interactions of diet, dietary supplement use, individual health behaviors, and exposomes that impact health

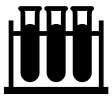
Research Priority 2: *Advance the study of population-based dietary supplement use, related nutrient intake, and their effects on health*

Adequate nutritional intake is critical for optimal health and development throughout the lifespan. Developing a complete profile of the nutrient intake, including the intake of nutrients from food as well as dietary supplements, along with a profile of the nutritional and health status of the U.S. population and its subgroups is vital for the development of effective nutrition policy.

ODS's collaborations with the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS), Division of Health and Nutrition Examination Surveys (DHANES) have advanced our ability to describe total nutrient intakes that include both dietary supplements and food as well as biochemical markers of nutrient status of public health concern for the U.S. population. The current ODS Population Studies Program has supported the development of population-based data collection methods and tools for investigating dietary supplement usage patterns in diverse population subgroups. For example, these collaborations resulted in developing new methods to collect data on the use and composition of infant formula from NHANES; determining the best methods to assess iodine intake from foods and iodized salt; consulting on dietary assessments in studies of pregnancy and offspring; developing and improving dietary supplement questionnaires, including the support of validation studies of questionnaires; and providing input on dietary assessment in the Dietary Guidelines for Americans planning guide.

Population sciences will remain key for identifying nutrient and other bioactive deficiencies or excesses that might impact the health of the whole U.S. population or subgroups within it and for hypothesis generation that will inform new biological and analytical sciences research. Combining population data from NHANES, the NIH *All of Us Research Program*, the Environmental influences on Child Health Outcomes (ECHO) program, and other epidemiological surveys that include dietary supplement data with findings from biological and analytical research will help inform future supplementation recommendations in the United States. With the intent to better address health disparities and advance health equity, future work will include investigations of additional subpopulation groups (e.g., by race/ethnicity, rural/urban, ability/disability, underserved populations, military/civilian groups, family status, immigrant status, or health status). Population-based nutrition and health outcome initiatives will seek to address knowledge gaps in:

- Diet and dietary supplement use and patterns, their interactions and implications for nutrient deficiencies and excesses, health outcomes, lifestyle behaviors such as physical activity and sleep, and dose-related effects of dietary supplements
- Nutrient requirements and dietary reference intake (DRI) gaps
- Nutrient intake, food security, and nutritional and health status disparities



Research Priority 3: *Advance the study of the composition, quality, stability, safety, and efficacy of dietary supplements and their ingredients*

Dietary supplements commonly contain mixtures of vitamins, minerals, and/or other natural products such as botanicals. Even supplements marketed as having a single active ingredient, such as an extract of the leaf of a plant, may in fact be complex preparations containing numerous unique phytochemicals in a milieu of hundreds or even thousands of other chemical compounds. Relatively simple single-chemical entities may occur in products in the marketplace as different chemical isomers (e.g., cis- or trans-resveratrol, vitamin E as a mixture of tocopherols and tocotrienols) or as a unique formulation marketed for its purportedly enhanced bioavailability (e.g., chemical modifications of curcumin). In addition to this complexity, there are tens of thousands of supplement products available in the U.S. market that are combinations of two to dozens of purported active dietary ingredients. Dietary supplements used in biomedical investigations must therefore be rigorously identified and characterized to know exactly what is being studied, and their dissolution and disintegration must be known to ensure that they are bio-efficacious. This characterization is needed to ensure product integrity and enhanced ability to understand and learn from any possible variability in outcomes associated with changes in product composition. Critical parameters of product integrity include authentication of identity and assessments of the composition, purity, and stability of the dietary intervention(s), as described, for example, on ODS's page of related resources for dietary supplement research. The ODS Analytical Methods and Reference Materials (AMRM) Program has developed and expanded the availability of reliable, scientifically valid analytical methods for quantitative and qualitative characterization of dietary supplements and their ingredients.

In partnership with NCCIH, ODS supports the Consortium for Advancing Research on Botanical and Other Natural Products (CARBON) Program to promote collaborative, transdisciplinary research on the safety, effectiveness, and mechanisms of action of botanical dietary supplements that have a high potential to benefit human health and to support the development of methods and resources that will enhance the progress of this research. A CARBON Program, the Natural Product Technology, Methodology, and Productivity Optimization Center, focused on developing methods to accelerate research on complex natural products such as botanicals for human health and on collaborations to develop applications of these methods. A Natural Products Nuclear Magnetic Resonance (NMR) Open Data Exchange facilitated the accessibility and utility of natural product chemical structure data. The ODS-supported pilot projects collaborated with these centers to extend understanding of products studied in the Botanical Dietary Supplements Research Centers or to leverage methods in use in the CARBON Program for early phase research relevant to natural product dietary supplements.

The knowledge gained and resources developed through the AMRM and CARBON Programs will propel the analytical sciences program forward to identify product integrity research gaps and develop new initiatives that address the three cross-cutting themes and focus on:

- Dietary supplement ingredients, composition, quality, and integrity

- Dietary supplement safety, bioavailability, bio-convertibility, and bio-efficacy
- Biomarkers of nutritional status and dietary supplement intake

Research Capacity

Goal: To support the development of NIH dietary supplement initiatives that incorporate research methods guidance and make the best use of all available NIH funding mechanisms.

Research Capacity Programs will serve as integrated resources for the research programs as they identify knowledge gaps and develop new collaborative initiatives. To ensure that research methods used in ODS-funded initiatives are appropriate and rigorous, the ODS methodology program will work with experts at NIH and in the field to develop a harmonized set of research methods best practices that can confidently be applied to a variety of dietary supplement research projects. In addition, the research funding strategy program will strategize with ODS staff to create the best approaches for supporting each new initiative to increase interest, responsivity, and accountability while maximizing the potential of the anticipated research impacts and outcomes.

Objective 1: To develop best practices for basic and clinical dietary supplement research and assist in their application across ODS-supported research initiatives.
Objective 2: To support the development of ODS research initiatives through the identification of appropriate funding mechanisms.

Capacity Priority 1: *Strengthen and harmonize the methodologies applied to dietary supplement research*

Dietary supplement research spans cell, animal, clinical, and population-based studies with numerous areas of focus. For example, studies to evaluate the health effects of dietary supplements—primarily for promoting health and reducing the risk of disease—focus on the underlying biological mechanisms by which they do so and the safety and effectiveness of dietary supplement interventions. This includes preclinical and translational research to inform future clinical trials. Research on exposure to dietary supplements among the diverse populations in the United States uses population-based survey data that capture nutrient and dietary supplement intake. The correlation of dietary supplement intake with health outcomes depends on the identification and measurement of biomarkers of nutrient exposure, status, and function in relation to chronic disease in populations and individuals.

The ability to compare, reproduce, and replicate published research results is essential for building scientific knowledge, and for dietary supplement research this requires the development of best practice guidance for research methodology and techniques that can be applied to a variety of research paradigms with a focus on research design, intervention development, measurement, and analysis.

ODS has set the groundwork for developing research best practices that can be applied to various types of dietary supplement research through the work of the AMRM, CARBON, Resilience, Population Studies, and Dietary Supplement Ingredient Database (DSID) Programs. The ODS AMRM Program has enhanced the foundation for biomedical research on the health effects of nutrients and 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 well-characterized reference materials are available to interested parties, the AMRM Program evaluates the resource needs of the dietary supplement community, maintains a repository of tools and information, and provides guidance to investigators on questions of natural product integrity to support the NIH-wide rigor and reproducibility initiative.

To facilitate the use of appropriate and rigorous research paradigms for investigating the safety and efficacy of dietary supplements and their ingredients, ODS supports and organizes workshops on the latest knowledge and emerging approaches in the study of dietary supplements. For example, one workshop focused on the unique challenges of translating natural products research to clinically useful trial outcomes and another, co-sponsored by ODS, focused on assessing the safety of botanical dietary supplements. ODS also encourages the development and use of appropriately validated biomarkers of nutrient status in ODS-supported studies of the health effects of dietary supplement ingredients. In addition, as described in the Population Sciences Program section above, ODS helps to develop tools to evaluate dietary supplement use more precisely in national health surveys and other large cohorts in collaboration with CDC's National Center for Health Statistics (NCHS) and the U.S. Department of Agriculture's (USDA) Agriculture Research Service (ARS) Human Nutrition Research Center (HNRC).

Expanding upon the existing ODS methodological resources, the Methodology Program will work to strengthen the reproducibility and reduce the heterogeneity in dietary supplement research. It will:

- Establish best practices needed to bolster experimental design and methodological rigor applied to ODS- and NIH-funded dietary supplement research
- Serve as a resource to ODS research programs and NIH ICO partners to ensure that guidelines for methodological rigor are appropriately delineated in funding announcements and applied during grant reviews
- Develop equitable population-based research designs and data collection tools to ensure adequate representation of diverse subpopulations and comprehensive demographic data collection to accurately capture diverse identification.
- Develop dietary supplement assessment methodology that links dietary supplement and nutrient intake data with food and supplement composition data
- Develop methodological training courses/curricula with analytical science experts from academia, industry, and government

Capacity Priority 2: *Strategize ODS research funding mechanisms*

Strong partnerships within NIH and across the federal government have been instrumental in helping ODS achieve its mission throughout the years. Going forward, ODS will increase its focus on coordinating and initiating collaborations across NIH ICOs, in addition to continuing many of its partnerships across other government organizations and communities that are key to the ODS mission. A critical factor will be the identification of the best funding mechanism available that facilitates efficiency in the development of ODS -supported research initiatives. There are a variety of funding mechanisms that ODS and its ODS Grants and Funding Program have used to support research on dietary supplements in collaboration with many NIH ICOs. The main funding approaches that have been used to build the ODS's research investment portfolio include:

- Co-funding support of investigator-initiated grants (i.e., those submitted under general NIH funding announcements or parent announcements)
- Administrative supplements for research and training grants proposing an expanded component related to dietary supplements
- Collaboration with NIH ICOs and co-funding of targeted research (i.e., topic-specific initiatives that have dollar set-asides)
- Collaboration with the NIH intramural laboratories and offices in support of special programs, such as ODS Research Scholars awards for early career scientists and the NIH Bench-to-Bedside Program

In addition to these mechanisms, ODS has used inter- or intra-agency agreements (e.g., with CDC for the NHANES Dietary Supplements and Nutritional Biochemistry Component/Study and with USDA for a project on validated methods for authentication of botanical supplements and ingredients), research contracts (e.g., contracts to build, expand, and optimize the Dietary Supplement Label Database [DSLD]), and funded workshops and conferences to advance the science of dietary supplements (e.g., National Academies of Sciences, Engineering, and Medicine [NASEM] for the Food Forum). ODS will explore additional funding opportunities such as Other Transactions that may be appropriate for new initiatives.

With a depth of knowledge about the wide array of funding mechanisms available, the ODS Research Funding Strategy Program is well positioned to facilitate the development of new research initiatives and will:

- Strategize with research program staff to jointly select the best funding options for each new initiative, aiming to diversify ODS funding approaches across all programs
- Train ODS research program staff in the development of NIH funding opportunities, contract development, and IAAs
- Coordinate ODS-wide collaborative processes for determining funding awards
- Develop feedback mechanisms to gather research progress and findings for all ODS-supported projects

Operations and Resources

Goal: To support ODS programs and develop and disseminate dietary supplement research findings and research resources to ODS audiences.

The Operations and Resources Programs will work together to support ODS research staff as they develop initiatives and to translate and disseminate research findings and products. Databases developed with ODS support will be maintained and made available to researchers and other audiences. Program efficiency and accountability will be enhanced through the identification and implementation of the best NIH analysis and evaluation tools for ODS programs. These tools will help program staff develop priority-based portfolio analyses and assess the progress of ODS programs and research initiatives, empowering determinations of when they have accomplished their goals and identifying new directions and priorities to be addressed. The operations and resources programs also will support the NIH DSRCC, expert panel meetings, workshops, and the Mary Francis Picciano Dietary Supplement Research Practicum. The programs include the Science and Health Communications Program, the Dietary Supplement Database Program, and the Management and Administrative Support Program.

Objective 1: To translate and disseminate dietary supplement research findings to researchers, health professionals, government officials, policymakers, and consumers.
Objective 2: To support and maintain publicly accessible dietary supplement databases for use in dietary supplement research.
Objective 3: To support ODS research and research capacity programs using program analysis and evaluation tools available at NIH.
Objective 4: To coordinate collaborations and partnerships with NIH and federal agencies to inform research and public health policy related to nutrients and other ingredients in dietary supplements.
Objective 5: To support ODS staff in the development of dietary supplement workshops and training.

Operations and Resource Priority 1: *Communicate advances in dietary supplement science, promote ODS activities, and amplify ODS messages.*

To fully achieve its mission of supporting innovative and cutting-edge research on dietary supplements to foster knowledge and optimize the health of the population, the importance of pertinent science and health communications from ODS cannot be overstated. Communicating and translating the latest dietary supplement science to key audiences is one of the collective goals of all ODS programs and activities.

Communications activities include raising awareness about the research accomplishments of ODS and its partners; promoting its events and programs; and managing website, newsletters, and social media resources to distribute up-to-date and

relevant research findings and resources to NIH ICOs, federal government, academic and industry researchers, health professionals, policymakers, and consumers.

The ODS website is the key communication vehicle that provides a wealth of information on dietary supplements to diverse audiences. ODS program information and research resources are available to NIH, external research communities, and beyond. In addition, the ODS website provides access to an up-to-date online library of ODS-developed professional and consumer fact sheets (in English and Spanish) on dietary supplements, a linked list of ODS staff co-authored peer-reviewed research and review publications, ODS newsletters, videos, and other evidence-based resources. Through the 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 regularly on social media about dietary supplements and/or nutrition. Over the past strategic planning period, ODS has updated the website's functionality, navigation, and design and added new webpages to reflect ODS program and research resources development. The newest communication-products include the monthly ODS Director's Message and revamped ODS Update. The Director's Message highlights key ODS accomplishments and provides an opportunity to raise awareness of significant advances in the scientific field of dietary supplements and the role they may have in health optimization. ODS Update newsletter for health professionals highlights recent developments in dietary supplement science.

The communications team supports ODS staff and their programs, seminars, workshops, and conferences. They also coordinate the response to information requests from the media, health care providers, policymakers, and the public. The team also coordinates with NIH ICO communication teams and participates in broader NIH-wide communications activities.

ODS dietary supplement information materials for the public include some in both English and Spanish. For example, ODS has a dedicated webpage containing dietary supplement information for consumers in Spanish. This webpage includes Spanish versions of the ODS Dietary Supplement Fact Sheets for consumers, consumer videos in Spanish about dietary supplement use, a dietary supplement and medicine record in Spanish, and links to other federal resources on dietary supplements in Spanish. In addition, all ODS videos have closed captioning to accommodate people with hearing impairments. ODS also provides audio-described videos for speaker presentations from the Mary Frances Picciano Dietary Supplement Research Practicum and select ODS Seminar Series presentations. Audio-described videos allow people without vision or with low vision to understand visual media.

Future communication efforts targeting the general population may consider using an array of communication strategies to ensure that diverse populations have easy and equitable access to relevant and valuable ODS information. For enhancing knowledge among professional audiences on health diversity, disparity, and equity as related to dietary supplements,

The Science and Health Communications Program will:

- Communicate key ODS messages about activities and research findings throughout NIH and other federal and academic research communities
- Develop and maintain informational resources on dietary supplements, including fact sheets, newsletters, and videos, for diverse audiences
- Manage social media messaging and monitoring
- Respond to inquiries about dietary supplements from researchers, health care providers, consumers, and others
- Manage all aspects of media relations for ODS, including obtaining clearance for media inquiries, responding to questions from the media or coordinating response from other ODS subject matter experts, and handling media outreach and monitoring
- Maintain and improve technologies used for communicating ODS information
- Support ODS program staff in promoting new program developments, research products, and events
- Support ODS-sponsored workshops, seminars, and other meetings

Operations and Resource Priority 2: *Maintain and ensure access to public use dietary supplement databases*

There are more than 100,000 dietary supplements on the market in the United States that contain significant amounts of nutrients and often other bioactive ingredients that may affect human health as well as presumed "inert" ingredients used in product formulation. Documentation on each dietary supplement product and its composition is necessary for clinicians, researchers, and consumers to understand what is being consumed by those using dietary supplements and ultimately to understand their contribution and risks to overall nutrient intake among the U.S. population and its diverse subgroups.

ODS supports several databases that provide a continuously increasing amount of detailed information on dietary supplements and their ingredients as well as on research being conducted on these supplements.

The DSLD was developed in collaboration with federal experts from NIH, CDC -NHANES /NCHS, the U.S. Food and Drug Administration (FDA), USDA, the Department of Commerce, and DoD. It contains virtually all information printed on dietary supplement labels including the product's Supplement Facts information; other added ingredients such as fillers, binders, and flavorings; directions for use; health claims; and any cautions that may be listed on the label. It also contains images of product labels.

The DSLD is used for many purposes. NIH researchers use it to identify all ingredients included in supplements used in dietary supplement research studies and those working with NHANES, or other epidemiological survey data use the DSLD to look up details about supplements that participants report that they are taking. Colleagues at the DoD determine if product labels list any ingredients that might adversely or positively affect health and performance, while colleagues at the FDA and Federal Trade Commission (FTC) view

Supplement Facts panels and claims listed on product labels. Health care providers examine the nutrients and other ingredients their patients obtain from the supplements they take, and manufacturers and distributors compare their products with others.

The DSID is a database of analytically validated supplement content measurements for estimating exposures to some of the most commonly consumed supplement product categories. When ODS first sought to investigate if the ingredients listed on the labels were actually present in supplement products at the labeled amounts, they found no such analytical data available. This led to a collaborative effort between ODS and the USDA Beltsville HNRC to collect a representative sampling of the most popular dietary supplement products, analyze their micronutrient content, and publish the data in the DSID. This important tool allows researchers to estimate intakes more accurately from dietary supplements in epidemiology or other population studies. To date, data are available for child, adult, and prenatal multivitamin/mineral supplements as well as calcium, vitamin D, omega-3 supplements, and caffeine. Dissolution and disintegration studies conducted as part of the catechins from DSID work on some categories of dietary supplements (e.g., calcium and green tea samples) have indicated potential sources of efficacy gaps with implications for NIH research and individual usage. Using DSLD and DSID 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 as reported in epidemiological surveys.

Another database developed and updated by ODS is the Computer Access to Research on Dietary Supplements (CARDS) database that contains information on research projects pertaining to dietary supplements funded by the NIH, USDA, and DoD since 1999. Researchers and the public use it to explore federal investments in dietary supplement research categorized according to dietary ingredient, health condition, and study type.

The Dietary Supplement Database Program will:

- Maintain, update, and ensure continued public access to these databases
- Convene a working group of NIH and federal agency partners to develop criteria for choosing botanicals and other dietary ingredients of public health interest for investigation through the DSID that do not have established recommended intakes but that should be analytically evaluated
- Link databases directly with dietary intake assessment tools to provide data on nutrient and non-nutrient contributions of dietary supplements to total intake

Operations and Resource Priority 3: *Coordinate and support ODS program evaluation, workforce development, and day-to-day ODS operations*

The Management and Administrative Support Program aims to bolster the efficiency, accountability, and productivity of the office. This will include supporting workshops or expert panel discussions convened to help inform ODS initiatives as well as supporting

workforce development, budget forecasting, program analysis and evaluation, and other day-to-day administrative activities.

Program Analysis and Reporting

Analysis and evaluation are an integral part of program planning and development and are necessary to fully understand the progress and value of ODS program activities and the dietary supplement research that ODS supports. They are used to help identify and implement program improvements to maximize efficiency and demonstrate accomplishments against goals and objectives.

In their work to identify key dietary supplement research gaps, ODS research programs begin by using tools, such as those available through the NIH Office of Portfolio Analysis (OPA), to identify NIH-funded research projects relevant to dietary supplements that have been conducted over a specified time period. These analyses also will help with the identification of potential research priority working group members and eventual initiative collaborators and allow for the characterization of research by topic, study design, intervention, and populations studied. With an interest in studying diverse populations and health disparities, portfolio analyses can identify key findings by population characteristics, gaps in the study of specific populations, and methodologies deployed to ensure the capture of data from these populations. Portfolio analyses of ODS-supported research also will help ODS assess the breadth of their NIH and other federal partner collaborations and can help identify new partners and funding opportunities.

The management and progress of ODS's expanded research programs will be aided by increased leveraging of NIH resources for evaluation and reporting. This includes utilization of the new Strategic Tracking and Reporting Tool (START) developed by the NIH Office of Evaluation, Performance, and Reporting (OEPR). START provides an analysis of strategic plan tracking, performance monitoring, evaluation, and other administrative data.

As ODS reorganizes its programs and establishes cross-functional teams, each program will develop logic models to help establish discrete program goals and objectives, short- and long-term program output and outcomes, and assessment measures. These measures will guide assessments to determine the success of a program and plan for its future:

- Key partners and parties of interest
- Underlying program assumptions
- External influencing factors
- Program objectives and activities
- Program inputs
- Program outputs and assessment measures
- Program short- and long-term outcomes and assessment measures

Additional qualitative program evaluation techniques will be applied as warranted to obtain feedback on program processes and perceived impact.

Supporting Dietary Supplement Research Workforce Development

To develop the dietary supplement research workforce, ODS offers educational opportunities that include the Mary Frances Picciano Dietary Supplement Research Practicum and the ODS Seminar Series. The Practicum is a multiday educational opportunity that provides fundamental knowledge of dietary supplements to faculty, students, and practitioners with a serious interest in this subject. It provides a thorough overview of 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 as well as how to carry out this type of research. Through the Seminar Series, ODS shares recent research developments with researchers, health professionals, trade associations, and consumers. Webinars are regularly scheduled, affording experts in dietary supplement science with an opportunity to share relevant research findings. Video recordings of some presentations are available on the ODS website.

In addition, ODS supports research and training programs that build future research capacity for studying the role of dietary supplements in health and disease prevention. The ODS Research Scholars Program is an example of a program designed to stimulate long-term career interest in pursuing dietary supplement-related research. The Management and Administrative Support Program will help to facilitate the ODS Research Scholars Program with an emphasis on recruiting a diverse set of researchers including those underrepresented in the workforce and other populations. ODS also supports NIH extramural training through career development grants, including fellowships, institutional training grants, physician-scientist training grants, and career transition grants that help investigators transition into full-time academic research careers.

Strengthening Day-to-Day Operations

Continuous improvement of administrative, budgetary, and management functions help all organizations enhance the efficiencies of their work and ensure that work is conducted in a supportive environment. At ODS this includes activities such as programmatic and officewide budget reviews; development and implementation of efficient administrative processes; and communication of DEIA principles and ODS core office values that include respect, curiosity, accountability, and open communications.

With a general focus on enhancing ODS programs and supporting ODS staff, the Management and Administrative Support Program will:

- Develop standards for program and research accountability
- Implement and train program staff in the use of program analysis tools and methods
- Expand ODS partnerships and collaborations
- Enhance existing workforce development and training opportunities
- Develop ODS operations standards to support an efficient and positive work environment

Diversity, Equity, Inclusion, and Accessibility (DEIA)

ODS is committed to supporting and promulgating the principles of DEIA in its research agenda, collaborations, and work environment. ODS commits to the principles and practices defined in the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility.

- Diversity: The practice of including the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of the American people, including underserved communities
- Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment
- Inclusion: The recognition, appreciation, and use of the talents and skills of employees of all backgrounds
- Accessibility: The design, construction, development, and maintenance of facilities, information and communication technology, programs, and services so that all people, including people with disabilities, can fully and independently use them

To truly support adherence to DEIA principles in establishing and supporting a research agenda it is imperative to begin by using them to create a supportive work environment for all employees. ODS embraces an office culture that is supportive and dynamic, a place where ideas, responsibilities, respect, and mutual support exist between leaders, staff, partners, and other interested parties. It is a place of trust built upon a shared vision, mission, and values. From this vantage point, ODS recognizes and celebrates diversity and insists upon equity, inclusion, and accessibility for all within ODS and those outside of the office with whom ODS staff interact.

Workforce development efforts, whether they be training, career development, or support for junior and mid-level scientists, provide opportunities to close gaps for researchers investigating health disparities. This includes strengthening outreach, recruitment, and hiring efforts to facilitate a diverse workforce inclusive of individuals from underserved communities. ODS can work with the NIH Chief Officer for Scientific Workforce Diversity (COSWD) to develop appropriate recruitment protocols to help identify highly qualified, diverse candidates for open positions and can identify other opportunities to provide students from minority-serving institutes (Historically Black Colleges and Universities [HBCUs], Tribal Colleges and Universities [TCUs], and Hispanic Serving Institutions [HSIs]) with opportunities to learn about dietary supplement research at various stages of their career pathways.

As ODS broadens its collaborations to identify knowledge gaps and create new research initiatives, it will:

- Explore how to better connect with appropriate entities and research opportunities within NIH while also engaging with outside research centers (e.g., Minority Serving Institutions (MSI) Historically Black Colleges and Universities [HBCUs]) to ensure that they are aware of funding and collaboration opportunities.

- Explore how the Institutional Development Award (IDeA) Program administered by the National Institute of General Medical Sciences (NIGMS) aligns with ODS funding mechanisms and goals. IDeA is a congressionally mandated program that builds research capacity in states that historically have had low levels of NIH funding. It supports competitive basic, clinical, and translational research; faculty development; and infrastructure improvements.
- Continue to participate in NIH UNITE events. The UNITE initiative focuses on three primary domains—health disparities/minority health research (HD/MH), internal NIH workforce, and external biomedical and behavioral research workforce—that intersect and enable greater transparency, accountability, and communications across NIH and the biomedical and behavioral research community. Their events present the latest data and ideas on DEIA in the biomedical workforce and in research, and features leaders from the NIH community as well as other experts from the biomedical research community.

Appendices

A. ODS Statutory Authority in the Dietary Supplement Health and Education Act (DSHEA) of 1994

(a) ESTABLISHMENT. - The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

(b) PURPOSE. - The purposes of the Office are -

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

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

(c) DUTIES. - The Director of the Office of Dietary Supplements shall -

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

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

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

(A) dietary intake regulations;

(B) the safety of dietary supplements;

(C) claims characterizing the relationship between -

(i) dietary supplements; and

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

(II) maintenance of health; and

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

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

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

(d) DEFINITION**. -** As used in this section, the term "dietary supplement" has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act:

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or (ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement;

(3) does—

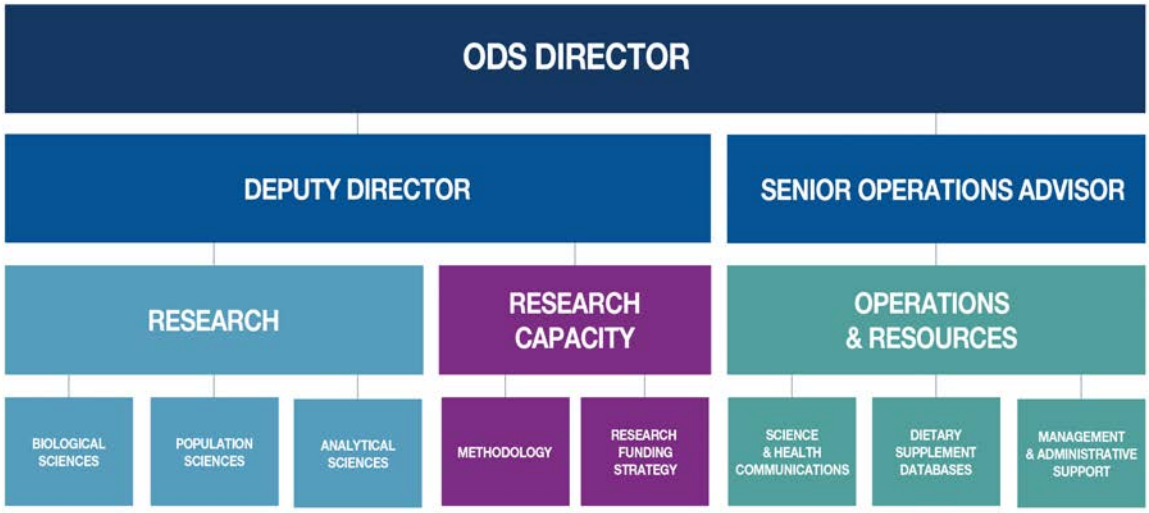
(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 5077, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

B. ODS Organizational Management



C. Strategic Planning Process

1. ODS individual program review of accomplishments and program goals

In preparation for the development of the strategic plan, ODS reviewed program progress, accomplishments, and future goals for 2025–2029.

2. ODS office mission, vision, and priorities development

Priority setting for this strategic plan began with a reexamination of expert feedback on an interim plan developed for 2022–2026 to identify all innovative ideas for program direction and ODS organizational structure. ODS staff used a small group iterative process to delineate areas of scientific emphasis and opportunity. This process established research priorities and key cross-cutting themes to advance biomedical research on dietary supplements, as presented above. ODS staff also identified core research capacity and operations and resources priorities.

3. Expert feedback

ODS is committed to engaging NIH Institutes, Centers, and Offices (ICO) leadership and representatives of the scientific community, industry, and other federal agencies in the strategic planning process. ODS gathered feedback from the Dietary Supplement Research Coordinating Committee (DSRCC) and ODS-partner review groups (NIH, federal, and external partners) on the objectives, strategic priorities, and cross-cutting themes that shape the 2025–2029 strategic plan.

4. Refinement of strategic plan

All reviewer feedback was used to stimulate discussion among ODS staff regarding potential changes to be included in the next version of the strategic plan.

5. Council of Councils review and feedback

A revised version of the plan was presented to the NIH Office of the Director Council of Councils and feedback was incorporated.

6. Public Comment

Known interested parties and the public were alerted to the availability of the strategic plan for comment 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. All feedback gathered was used to revise the ODS 2025–2029 strategic plan.

7. Finalized Strategic Plan

A final version of the plan was shared with NIH leadership for their approval and released to the public.

D. Glossary

AMRM	Analytical Methods and Reference Materials Program
AMD	age-related macular degeneration
AREDS	Age-Related Eye Disease Studies
ARS	Agriculture Research Service
CARBON	Consortium 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	Center for Health and Military Performance
COSWD	Chief Officer for Scientific Workforce Diversity
DEIA	diversity, equity, inclusion, and accessibility
DGA	Dietary Guidelines for Americans
DHANES	Division of Health and Nutrition Examination Survey
DoD	Department of Defense
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DRI	Dietary Reference Intake
DSHEA	Dietary Supplement Health and Education Act
DSID	Dietary Supplement Ingredient Database
DSLD	Dietary Supplement Label Database
DSRCC	Dietary Supplement Research Coordinating Committee
ECHO	Environmental Influences on Child Health Outcomes
ELTRR	Equitable Long-Term Recovery and Resilience
FDA	U.S. Food and Drug Administration
FTC	Federal Trade Commission
HBCUs	Historically Black Colleges and Universities
HNRC	Human Nutrition Research Center
HHS	U.S. Department of Health and Human Services
HIS	Hispanic Serving Institution
IAA	Interagency Agreement
ICOs	Institutes, Centers, and Offices (of NIH)
IDeA	Institutional Development Award
MSIs	Minority-Serving Institutions
NASEM	National Academies of Sciences, Engineering, and Medicine
NCCIH	National Center for Complementary and Integrative Health
NCHS	National Center for Health Statistics
NEI	National Eye Institute
NHANES	National Health and Nutrition Examination Survey
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	Eunice Kenney Shriver National Institute of Child Health and Human Development
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases

NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMHD	National Institute on Minority Health and Health Disparities
NMR	nuclear magnetic resonance
NOSI	Notice of Special Interest
ODS	Office of Dietary Supplements
OEPR	Office of Evaluation Performance and Reporting
OPA	Office of Portfolio Analysis
ORWH	Office of Research on Women's Health
RCDC	Research, Condition, and Disease Categorization
SGMRO	Sexual & Gender Minority Research Office
START	Strategic Tracking and Reporting Tool
TCUs	Tribal Colleges and Universities
THRO	Tribal Health Research Office
USARIEM	U.S. Army Research Institute of Environmental Medicine
USDA	U.S. Department of Agriculture