Challenges and Resources in Dietary Supplement Research:
The Role of the U.S. National Institutes of Health (NIH)

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Dr. Coates directs the Office of Dietary Supplements (ODS) at the National Institutes of Health in its mission to strengthen knowledge and understanding of dietary supplements. Through a range of initiatives made possible by an energetic and deeply knowledgeable staff, he has established ODS as a strong and authoritative voice for rigorous science in dietary supplements and related areas of nutrition. ODS addresses many of the issues in dietary supplements, from evaluation of the literature to supporting and conducting science, and translating the results of that work into reliable and effective information for the public. In 2011, he received the prestigious Conrad A. Elvehjem Award from the American Society for Nutrition for public service in nutrition. In 2013, he was made a Fellow of the American Society for Nutrition and was elected to serve a two-year term as At-Large Director of the Society. He is lead editor of the authoritative Encyclopedia of Dietary Supplements, now in its second edition, and associate editor of the American Journal of Clinical Nutrition. Prior to his career at NIH, he was on the faculty of the Children's Hospital of Philadelphia and the University of Pennsylvania School of Medicine. His Ph.D. in human genetics was awarded by Queen's University in Canada, followed by postdoctoral training in the Department of Human Genetics and Biometry at University College London.

In the United States, dietary supplements are regulated much like foods, not drugs, and this creates some challenges for research using these products and the ingredients they contain. The Office of Dietary Supplements (ODS) was established at the NIH in 1995 to address the needs for research and communication on these products. ODS has developed a number of resources that are widely used by the stakeholder community, which includes researchers, industry, government agencies, healthcare providers, and consumers.

1. The ODS Analytical Methods and Reference Materials Program develops tools – such as validated analytical methods and certified reference materials – in collaboration with other US federal laboratories to assist industry, regulators, and the research community. These include methods for measurement of ingredients in botanical products, as well as reference materials for botanical ingredients, as well as vitamins and minerals. This even extends to reference materials for biomarkers of nutritional status (e.g., vitamin D, folate, vitamin B12) in biological specimens.

2. The Vitamin D Standardization Program was developed by ODS and other agencies around the world to standardize the measurement of vitamin D status in national health surveys. It is important to assure that results of these measurements are accurate so that clinical and public health decisions can be made with confidence.

3. The ODS Evidence-based Review Program provides systematic reviews of dietary supplement efficacy and safety to inform the development of research agendas and public health policy. Examples have included: vitamin D, omega-3 fatty acids, pro-
biotics, ephedra, and multivitamins.

(4) Dietary supplement databases for dietary supplement labels and for analytically derived ingredient values provide tools for researchers. Currently, the Dietary Supplement Label Database contains labels and deconstructed data from more than 40,000 products in the U.S. marketplace.

(5) ODS funds about 100 grants per year with other Institutes and Centers at NIH on a wide variety of dietary supplement research topics.

(6) A suite of resources has been developed for consumers, most of which are available on the ODS website (http://ods.od.nih.gov/). These include fact sheets for commonly available dietary supplement ingredients and an array of other tools to help consumers make decisions about dietary supplements. ODS also answers many consumer questions.

(7) ODS has been guided by a series of five-year Strategic Plans in conducting its work. In the process of developing our next Plan, we have posted a Progress Report on our website detailing what has been accomplished in 2010-2014. We welcome input on our programs from all interested parties.