

Submitted electronically via [ODSplan@od.nih.gov](mailto:ODSplan@od.nih.gov)

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Dear Dr. Thurn,

The Consumer Healthcare Products Association (CHPA)<sup>1</sup> appreciates the opportunity to provide the Office of Dietary Supplements (ODS) with comments on their Draft Strategic Plan for 2016-2021. Many of our member companies market dietary supplement products and as such we have an interest in ensuring that ODS fulfills its mission of “*conduct[ing] and support[ing] scientific research and provid[ing] 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.*”

ODS has identified a comprehensive set of strategic goals and within each, a set of strategies developed to accomplish those goals. Our comments below are directed broadly towards three of the four goals identified by ODS - expanding the knowledge base on dietary supplements; fostering development and dissemination of research resources/tools; and translating dietary supplement research into useful information. We have also incorporated into these comments our view on the questions for which ODS has requested feedback in the Draft Strategic Plan, including whether the strategic goals are adequate; whether ODS is meeting stakeholder needs; whether certain ODS programs/activities should be prioritized and ways to effectively provide useful information to the ODS user community (*e.g.*, consumers, investigators, practitioners, industry, media, policy makers, government). As you progress through the planning process we

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<sup>1</sup> CHPA, founded in 1881, is the 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. [chpa.org](http://chpa.org)

hope that you will find these comments helpful. We are happy to have further discussions regarding these comments including any potential collaborative efforts identified herein.

ODS is to be commended for identifying a very comprehensive set of strategic goals which cut across a variety of disciplines and sectors. We fully support ODS efforts in the area of enhancing the quality of dietary supplement research to further the understanding of mechanisms by which dietary ingredients and dietary supplements produce beneficial effects. One area of particular interest is research on the effects of multivitamins/minerals on general health within the elderly population. The U.S. currently has a rapidly growing aging population who would benefit from having information accessible to them on the potential health benefits of these products as well as pertinent safety information.<sup>2</sup> CHPA is also encouraged to see that ODS will work with the Institutes and Centers of NIH, including the National Center for Complementary and Integrative Health, to conduct research into the health importance of dietary supplements as well as utilize systematic reviews to address safety and efficacy issues.

It is critical that consumers have access to truthful information regarding the potential benefits of all health products they use, including dietary supplements. Research shows that a significant percentage of US adults take some form of dietary supplement in order to support a healthy lifestyle.<sup>3</sup> In addition to use of multivitamin/multimineral products, consumers are also relying on additional forms of complementary and alternative medicine including probiotics and herbals.<sup>4</sup> The 2015 Dietary Guidelines Advisory Committee Report identified a number of “shortfall” nutrients, or those that may be under-consumed either across the population or in specific groups relative to IOM-based standards.<sup>5</sup> By identifying the best approaches to measuring and correcting these gaps, ODS could contribute to the health and well-being of significant segments of the population.

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<sup>2</sup> Qato DM, Wilder J, Schumm LP, Gillet V, Alexander GC Changes in Prescription and Over-the-Counter Medication and Dietary Supplement Use Among Older Adults in the United States, 2005 vs 2011, 2016 JAMA Int Med 176(4): 473-482

<sup>3</sup> Bailey RL, Gahche JJ, Miller PE, et al. Why US adults use dietary supplements, 2013, JAMA Int Med. 173(5): 355-361.

<sup>4</sup> Wu CH, Wang CC, Tsai MT, et al., Trend and pattern of herb and supplement use in the United States: Results from the 2002, 2007, and 2012 National Health Interview Surveys, *Evid-Based Comp Alt Med*, Epub Dec 2014

<sup>5</sup> [Scientific Report of the 2015 Dietary Guidelines Advisory Committee](#)

We also strongly support ODS use of scientific workshops to disseminate information to a diverse set of stakeholders on the current state of science within the dietary supplement field, including the identification of any knowledge gaps. It is especially critical for ODS to make available any new research findings related to dietary supplements, dietary ingredients or analytical methods to dietary supplement manufacturers. As a number of different organizations and associations<sup>6</sup> are now focusing on dietary supplement quality it is important that ODS add their voice to these discussions. Research conducted by ODS on dietary supplement usage patterns, including their use with over-the-counter (OTC) medicines, will also help CHPA develop helpful, consumer friendly online information.<sup>7</sup>

In our 2015 comments to ODS<sup>8</sup> we expressed our support for research efforts seeking to further define the role of prebiotics and probiotics in human health and disease, including ODS support for an evidence-based review of probiotic safety as well as promotion of the NIH Human Microbiome Project. We believe activities such as this are crucial to developing a greater understanding of the relationship between nutrition and the microbiome and how prebiotics and probiotics could potentially benefit a number of health conditions.

ODS could also play a leadership role in the area of dietary supplement research by fostering discussion among industry and other stakeholders as to what type(s) of “valid scientific evidence” are required for substantiation of structure/function claims. This could be undertaken by convening workshops focusing on the development of biological measures to help in providing claim substantiation and taking a more vocal role in speaking out about what constitutes valid scientific evidence to support claims. The identification of nutritional biomarkers<sup>9</sup> also represents an exciting area of research which could potentially indicate

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<sup>6</sup> For example, USP has recently convened the ‘Dietary Supplement Quality Collaborative’, a diverse set of stakeholders whose stated goal is to advance the quality and safety of products marketed as dietary supplements in the United States in the interest of protecting public health.

<sup>7</sup> Available at [CHPA.org](http://CHPA.org) and [KnowYourOTCs.org](http://KnowYourOTCs.org)

<sup>8</sup> CHPA comments on the ODS Strategic Plan 2010-2014 Progress Report, available at <http://www.chpa.org/Submissions.aspx>

<sup>9</sup> Pfeiffer CM, Schleicher RL, Johnson CL, Coates PM Assessing vitamin status in large population surveys by measuring biomarkers and dietary intake - two case studies: folate and vitamin D Food & Nutr Res 56 5944 - DOI: 10.3402/fnr.v56i0.5944

sensitive subpopulations or individuals lacking in a particular nutrient in addition to reducing the bias of self-reported dietary intake errors.

An additional goal identified by ODS is translating their research into useful information for consumers, health professionals and policymakers. ODS has made available a wide variety of information on dietary supplements aimed at both consumers and researchers. In our 2015 comments to ODS, we suggested enhancing outreach to various stakeholders, supporting an enhanced role for ODS as an authoritative source for information on dietary supplement products. We reiterate our support for an enhanced role of ODS in dissemination of information to various stakeholders, particularly regarding the issue of adulterated dietary supplements<sup>10</sup> and the use of validated analytical techniques to determine dietary supplement quality.

This problem is of concern to all responsible stakeholders in the dietary supplement industry as sensationalistic media stories and examples demonstrating cases where manufacturers have been involved in criminal behavior cast a shadow on the entire industry. While the majority of dietary supplement manufacturers are responsible and manufacture products according to regulations, there are unfortunately those who add undeclared or illegal ingredients to their products and market them illegally masquerading as dietary supplements. Through media outreach as well as the provision of helpful information regarding the potential health benefits of dietary supplements, ODS could use its authoritative voice to help consumers avoid purchasing these illegal products. This type of information would also be useful to healthcare professionals as well as policymakers as they often represent sources of information to consumers and should have access to up-to-date and accurate information on the health benefits of dietary supplement products. CHPA, through its educational foundation, has significant experience in building collaborations to communication with the public and is willing to partner with ODS in this regard. This could be accomplished through a variety of mechanisms including circulation of the ODS Update and other ODS activities to CHPA members or collaborative efforts to produce consumer friendly information on supplement benefits as well as safety information.

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<sup>10</sup> Marcus DM, Dietary supplements: What's in a name? What's in the bottle? *Drug Test & Anal.* 2016, 8(3-4): 410-412

ODS also notes that it will continue to compile information on dietary supplement labeling in the Dietary Supplement Label Database, a publicly available database launched in 2013. We encourage ODS to provide information on the public utility of this database and to ensure that regular updates are enacted so that users access up to date information.

In our 2015 comments to ODS, we encouraged ODS to provide a more active voice in public matters related to botanical dietary composition and safety. In 2015, the New York Attorney General ordered four major retailers to remove botanical dietary supplement products from shelves based on DNA barcode testing, claiming that products did not contain their stated ingredients and contained undeclared allergens. These investigations were supported by the use of DNA barcoding technology, a promising tool which can provide useful information when the test is conducted properly. However, scientific experts familiar with herbal products and their testing methods maintained that the DNA barcode test is not an appropriate method to determine what is in an herbal dietary supplement, thereby making these results likely inaccurate and irrelevant. Other organizations including FDA<sup>11</sup> and USP<sup>12</sup> weighed in, noting that the DNA barcode method is not recognized as a validated approach for botanical identification or quantitation and that alternate validated test methods are used to determine the authenticity of herbal supplement products. ODS should utilize their scientific standing to not only provide consumers with information regarding potentially harmful products but also to correct potential consumer confusion resulting from well-intentioned efforts which are based on bad science.

As ODS has the technical expertise to opine on these matters, and has a broad range of media outreach activities, we feel that practical consumer information provided on topics such as this, from a distinguished, scientifically-reputable source, would help to provide consumers with useful information about dietary supplement products and what to look for when purchasing products. Experts within the various Botanical Research Centers could contribute to the discussion by providing consumers and media outlets information regarding what constitutes a valid test for botanicals and what common analytical practices are used. This could help to

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<sup>11</sup> FDA Does Not Use Testing Behind New York Enforcement On Major Retailers' Herbals, The Tan Sheet, February 6, 2015

<sup>12</sup> [DNA Testing of Herbal Supplements - Does it Work or Doesn't It?](#), Nandakumara Sarma, February 12, 2015

dispel some of the sensationalistic media stories which contribute to an overall negative impression of the dietary supplement industry.

As ODS is engaged with a wide range of stakeholders regarding the compilation and dissemination of knowledge related to dietary supplements, we encourage you to more actively engage with the dietary supplement trade associations as you progress through your Draft Strategic Plan for 2016-2021. Collaborative efforts with interested stakeholders, including other scientific bodies, industry partners and dietary supplement trade associations, will help ODS maintain a strong presence in the field of dietary supplement research and provide researchers and consumers access to high-quality scientific information on the safe, beneficial use of these products as part of an overall healthy lifestyle.

CHPA is actively engaged with a number of other stakeholders within the dietary supplement space as well as with consumers, healthcare providers through the efforts of our Educational Foundation and outreach efforts. The CHPA Educational Foundation,<sup>13</sup> established in 2004, is dedicated to helping consumers lead happier, healthier lives through responsible self-care. Its mission is to be the trusted source of information on the responsible use of consumer healthcare products including OTC medicines and dietary supplements. Through media, programs, and partnerships, the foundation educates consumers on how to use, store, and dispose of OTC medicines and dietary supplements. We supply information and materials representing the latest medical and scientific thinking and research and address specific areas where we know consumers need guidance and support. All resources for consumers are available through [KnowYourOTCs.org](http://KnowYourOTCs.org), the online home of the CHPA Educational Foundation.

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<sup>13</sup> CHPA Educational Foundation Programs include [Up and Away and Out of Sight](#): an educational program to remind families of the importance of safe medicine storage to prevent young children from getting into medicine when they shouldn't; [Know Your Dose](#), a campaign that educates patients and consumers about safe and effective use of acetaminophen, the most commonly used drug ingredient in the U.S.; and Treat with Care, a program that provides parents and caregivers the information they need to safely treat their children's cough and cold symptoms with pediatric OTC cough and cold medicines

We applaud OD for undertaking a comprehensive effort to examine the benefits and safety of dietary supplement and dietary ingredients and for prioritizing the dissemination of useful information from that research to consumers and other stakeholders. Through more frequent collaborative efforts with industry, ODS would obtain more regular feedback and be better positioned to take advantage of opportunities to promote safe and beneficial dietary supplement use. We look forward to working with ODS staff on these efforts to enhance the understanding of dietary supplements and provide the research community, as well as consumers, access to more information.

Respectfully submitted,

A handwritten signature in blue ink that reads "Jay Sirois". The signature is written in a cursive style with a large initial "J" and "S".

Jay Sirois, Ph.D.