

Submitted electronically via ODSplan@od.nih.gov

March 6, 2015

Paul M. Coates, Ph.D.
Director, Office of Dietary Supplements
National Institutes of Health
610 Executive Blvd., Rm. 3B01
Bethesda, MD 20892-517

Dear Dr. Coates,

The Consumer Healthcare Products Association (CHPA)¹ appreciates the opportunity to provide the Office of Dietary Supplements (ODS) with comments on their Strategic Plan 2010-2014 Progress Report. Several of our member companies market dietary supplement products and as such we have an interest in ensuring that ODS fulfills its mission of “strengthen[ing] knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population”. 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.

Our comments touch on several of the goals identified by ODS in the Progress Report. As you progress through the planning process we 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.

¹ CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements (chpa.org).

Research balance between traditional nutrients and probiotics/herbals

Research shows that a significant percentage of US adults take some form of dietary supplement in order to support a healthy lifestyle.² In addition to use of multivitamins/multimineral products, consumers are also relying on additional forms of complementary and alternative medicine including probiotics and herbals.³ Recent data from the 2012 National Health Interview Survey (NHIS)⁴, a health questionnaire developed by NCCIH and the NCHS and administered every 5 years as part of the NHIS, found that US adults' use of probiotics or prebiotics increased between 2007 and 2012.

Probiotics are live microorganisms which confer a health benefit on the host when administered in adequate amounts. Utilizing a number of different endpoints, studies have found that digestive health is a core benefit of many probiotic species including Bifidobacterium, Lactobacillus and Saccharomyces. Many of the beneficial effects have been shown to be strain dependent thus accurate identification of strains is important. There are approximately 100 trillion resident microbes in the adult gut and the corresponding genome (microbiome) has been estimated to contain 150-fold more genes than the host genome.⁵

Because of this, we are encouraged by ODS support of these research efforts which seek to further define the role of prebiotics and probiotics in human health and disease. ODS has noted that it will provide support for an evidence-based review of probiotic safety through the Agency for Healthcare Research & Quality (Goal 1) as well as promote use of the NIH Human Microbiome Project (Goal 2), a comprehensive characterization of the human microbiome and analysis of its role in human health and disease. We believe such activities 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.

² Bailey RL, Gahche JJ, Miller PE, et al. Why US adults use dietary supplements, 2013, *JAMA Int Med.* 173(5): 355-361.

³ 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

⁴ Clarke TC, Black LI, Stussman BJ, et al. Trends in the use of complementary health approaches among adults: United States, 2002-2012. National health statistics reports; no 79. Hyattsville, MD: National Center for Health Statistics. 2015.

⁵ Qin J, Li R, Raes J, Arumugam M, Burgdorf KS, Manichanh C, et al. A human gut microbial gene catalogue established by metagenomic sequencing. *Nature* 2010;464:59-65.

Provide research to help determine appropriate claim support for dietary supplements

Under the law, manufacturers of dietary supplement products have three different categories of claims that can potentially be used for dietary supplements: health claims, structure/function claims, and nutrient content claims. All claims must be truthful and not misleading. The most common of these types of claims, a structure/function claim, describes the role of a nutrient or a dietary supplement intended to affect the structure or function of the body, the mechanism of how it helps to maintain that structure or function, or general well-being. Federal law, enforced by both the FDA and the Federal Trade Commission (FTC), requires that companies marketing dietary supplements have competent and reliable scientific evidence to substantiate the label claims provided on their products as well as in advertising. CHPA members marketing dietary supplements support current regulations and are committed to advertising in a responsible manner. Claims that sound too good to be true likely are, and we encourage consumers to learn more about all the dietary supplements they are taking (or considering) by speaking with their healthcare professional.⁶

CHPA is encouraged to see that ODS (Federal Working Group on Dietary Supplements) has partnered with the Federal Trade Commission (among others) in order to promote the exchange of information about dietary supplements through seminars, workshops, and other working groups. It is critical that consumers have access to truthful information regarding the potential benefits of all health products they use, including dietary supplements. In a recent opinion,⁷ the FTC sought to impose a rigid substantiation rule (requiring multiple randomized controlled trials to support a particular claim) for health-related advertising claims. This type of requirement for all products could potentially deprive consumers of useful information as there are other means to evaluate the relationship between diet and disease (*e.g.*, epidemiologic studies). In some situations, clinical trials may also be difficult to perform or unethical. Jointly with the Council for Responsible Nutrition, CHPA filed an amicus brief (August 2013)⁸ in the case of POM

⁶ <http://www.chpa.org/FAQsDS.aspx>; <http://otcsafety.org/en/health-and-wellness/dietary-supplements>

⁷ Opinion of the Federal Trade Commission In the Matter of POM Wonderful LLC, Docket No. 9344, available at <http://www.ftc.gov/opa/2013/01/pom.shtm>.

⁸ Brief of Amici Curiae Consumer Healthcare Products Association and Council for Responsible Nutrition in Support of Petitioners' Request for Reversal; August 21, 2013.

Wonderful *vs.* the FTC regarding the standards used to assess whether an advertising health claim is false or misleading and what constitutes adequate substantiation for such claims.

We believe that ODS could play a leadership role in this area 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 biomarkers or other biological measures to help in providing claim substantiation. We also believe it would be helpful for ODS to undertake a more vocal role in speaking out about what constitutes valid scientific evidence to support claims.

Enhance awareness of Botanical Research Centers

The Strategic Plan notes that ODS established six Botanical Research Centers which they administer in partnership with the National Center for Complementary and Integrative Health (NCCIH). The goal of the BRC Program is to “promote collaborative, integrated, interdisciplinary study of botanicals, particularly those found as ingredients in dietary supplements, and to conduct research of high potential for being translated into practical benefits for human health”. We applaud the goals outlined by the centers and believe that ODS should ensure that work performed by the centers is widely disseminated. By so doing, we believe ODS would enhance its role as an authoritative source for information on botanical products. Consumers would also benefit from a greater understanding of the potential health benefits of botanicals and those in the scientific community would become more aware of potential collaborative opportunities. CHPA also endorses continued efforts by ODS to support examination of the practical implications of herb-drug interactions in a scientifically robust manner.

As the BRC contain experts within the field of botanical research we feel it would be helpful if they were to be more vocal regarding issues of adulterated dietary supplements. This problem is of concern to all responsible stakeholders in the dietary supplement industry and having an authoritative voice could help to drive those who purposely spike their products with illegal ingredients out of business.

ODS should also consider speaking out more or offering technical assistance on issues related to herbal supplements. An example is the recent controversy surrounding the New York Attorney General's analysis of herbal dietary supplement products and his claims that the products were adulterated. Other organizations including FDA⁹ and USP¹⁰ 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. Of note, although DNA barcoding may not be a validated approach for botanical identification or quantitation, it is a relevant and validated approach for quality control when used appropriately for other applications. Experts within the various BRC areas could contribute to the discussion by informing consumers of what constitutes a valid test for botanicals and what common analytical practices are used. This could help to dispel some of the sensationalistic stories hitting the media and thus contributing to the negative impression about the dietary supplement industry.

Communication to the Public – Collaborative Efforts

Since its establishment in 1995, ODS has realized the benefits of communicating with a wide range of representatives from the scientific community as well as the public in order to develop a sound research plan and support the widespread dissemination of knowledge. We encourage ODS to continue this effort and to enhance their outreach to consumers as well as the scientific community on the benefits of dietary supplements.

CHPA has significant experience in communicating with the public and is willing to help in this regard. For instance, we could help circulate the ODS Update to CHPA members and potentially reach additional consumers through our webpages. ODS has noted that due to the success of the ODS Update, a separate electronic newsletter targeted specifically to consumers would be beneficial. We believe this is an excellent idea and offer our help in developing and maintaining this type of effort.

⁹ FDA Does Not Use Testing Behind New York Enforcement On Major Retailers' Herbals, *The Tan Sheet*, February 6, 2015

¹⁰ [DNA Testing of Herbal Supplements - Does it Work or Doesn't It?](#), Nandakumara Sarma, February 12, 2015

The CHPA Educational Foundation, 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 OTCsafety.org, the online home of the CHPA Educational Foundation.

CHPA Educational Foundation Programs include the following:

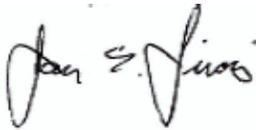
- **Up and Away and Out of Sight:** an educational program to remind families of the importance of safe medicine storage to prevent young children from getting into medicine when they shouldn't. It is led by the Centers for Disease Control and Prevention (CDC) and the CHPA Educational Foundation, in partnership with the PROTECT Initiative. A full list of partners and campaign resources is available at UpandAway.org.
- **Know Your Dose:** this campaign educates patients and consumers about safe and effective use of acetaminophen, the most commonly used drug ingredient in the United States. The campaign is organized by the Acetaminophen Awareness Coalition—a group of consumer organizations, health organizations, and healthcare provider organizations, including the CHPA Educational Foundation. The U.S. Food and Drug Administration's Safe Use Initiative and the CDC both serve as coalition advisors. The coalition provides information to consumers as they are making healthcare decisions in pharmacies, health clinics, physician offices, and online.
- **Treat with Care:** this program 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. Timed around cold and flu season, "Treat with Care" efforts have included print and radio public service announcements; ads and content in popular parenting media; posters and brochures for doctors' offices, clinics and pharmacies; and a

national media tour with "Grey's Anatomy" star Chandra Wilson. [Treat with Care brochures](#) in English and Spanish can be downloaded or ordered at no charge on OTCsafety.org.

Enhance engagement with dietary supplement trade associations

As ODS is actively 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 Strategic Plan for 2015-2019. 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. Through more frequent collaborative efforts with industry, ODS would obtain more regular feedback and be better positioned to take advantage of opportunities. 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 black ink that reads "Jay Sirois". The signature is written in a cursive style with a large initial "J" and "S".

Jay Sirois, Ph.D.