

# Dietary Supplements **sector**



**Convention**

## Dietary Supplements Sector of the USP Convention: Kick-off meeting Wednesday, March 10<sup>th</sup>, 2021 Agenda

### Goals and anticipated outcomes

- Dialogue on the opportunities, challenges and dynamics in the Dietary Supplements Sector.
- Identify and capture insights about priority topics, specifically bolstering transparency in the global supply chain.

### Wednesday, March 10<sup>th</sup>, 3:00-4:30PM

1. Chair welcome remarks
2. Convention President remarks
3. Convention Stakeholder Engagement remarks
4. Dietary Supplements Sector Overview
5. Guest Panel on Increasing Transparency and Consumer Awareness About Dietary Supplements
  - a. Opening remarks and moderator discussion
    - i. Larry Freedman, Vice President, Operations, Clarion Brands
    - ii. Nancy Glick, Director of Food and Nutrition Policy, National Consumers League
    - iii. Robin Marles, Ph.D., Chair, Botanical Dietary Supplements and Herbal Medicines

Expert Committee
  - b. Audience Q&A (15-20 min)
6. Member discussion
  - a. In the dietary supplements space, what regulatory reform ideas are priorities at your organization?
  - b. What broader issues as to trust and/or quality in dietary supplements are concerns for your organization?
7. Closing remarks and follow-up

## Pre-reading Content

COVID-19 required dietary supplement manufacturers to reassess their production lines and equipment  
*Nutritional Outlook* (February 26, 2021)

<https://www.nutritionaloutlook.com/view/covid-19-required-dietary-supplement-manufacturers-to-reassess-their-production-lines-and-equipment>

New NABP Report Explores How Pharmacists Can Safeguard Patients from Risky Dietary Supplements  
National Association of Boards of Pharmacy (January 19, 2021)

<https://nabp.pharmacy/news/news-releases/new-nabp-report-explores-how-pharmacists-can-safeguard-patients-from-risky-dietary-supplements/>

Dietary Supplements: Update on Regulation, Industry, and Product Trends

The Council on Science and Public Health, American Medical Association (November 2020)

<https://www.ama-assn.org/system/files/2020-10/nov20-csaph03.pdf>

What Supply Chain Transparency Really Means

Alexis Bateman and Leonard Bonanni, *Harvard Business Review* (August 20, 2019)

<https://hbr.org/2019/08/what-supply-chain-transparency-really-means>

Policy Principles

*Dietary Supplements Quality Collaborative*

<https://dsqcollaborative.org/wp-content/uploads/2020/04/DSQC-Policy-Principles.pdf>

## Registered Attendees

(as of March 9, 2021)

### Featured Speakers

**Dennis E. Doherty, M.D.**

Professor Emeritus  
University of Kentucky, College of Medicine  
President, USP Convention

**Larry Freedman**

Vice President, Operations  
Clarion Brands

**Nancy Glick**

Director, Food and Nutrition Policy  
National Consumers League

**Robin Marles, Ph.D.**

Chair, Botanical Dietary Supplements and Herbal Medicines  
USP Expert Committee

**Jay Sirois, Ph.D.**

Senior Director, Regulatory & Scientific Affairs  
Consumer Healthcare Products Association  
Chair, Dietary Supplements Sector of the USP Convention

**Shelley Whiddon, M.A.**

Senior Director, Operations, Convention and Stakeholder Engagement  
USP

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### Attendees

**Lauren Bloomberg**

Senior Director, Communications and Media Relations  
Consumer Healthcare Products Association

**Amy Cadwallader, Ph.D.**

Director, Science and Drug Policy  
American Medical Association

**Steven Casper, Ph.D.**

Ethnobotanist  
U.S. FDA

**Philip Coggins**

National Pharmacy Program Manager  
Veterans Healthcare Administration

**James Griffiths, Ph.D.**

Senior Vice President, International and Scientific Affairs  
Council for Responsible Nutrition

**Marianne Ivey, Pharm.D.**

Professor Emerita  
University of Cincinnati

**Nailah John**

Program Associate  
National Consumers League

**Holly E. Johnson, Ph.D.**

Chief Science Officer  
American Herbal Products Association

**Mary Ann Kliethermes, Pharm.D.**

Director of Medication Safety and Quality  
American Society of Health-system Pharmacists

**Adam Kuszak, Ph.D.**

Director, Analytical Methods and Reference Materials Program  
NIH Office of Dietary Supplements

**Deborah McKenzie, M.S.**

Senior Director, Standards & Official Methods  
AOAC International

**Steve Mister, Esq, C.A.E.**

President & CEO  
Council for Responsible Nutrition

**Rahul Pawar, Ph.D.**

Research Chemist  
U.S. FDA Center for Food Safety and Applied Nutrition

**Lawrence Perez, Ph.D.**

Senior Chemistry Reviewer  
U.S. FDA

**Gretchen Powers**

Senior Director Marketing & Member Experience  
Council for Responsible Nutrition

**Maureen Schanck**

Professional Affairs Manager  
National Association of Boards of Pharmacy

**John Troup, Ph.D**

Vice President, Scientific Affairs & Dietary Supplements  
Consumer Healthcare Products Association

**Kristin Willemsen M.S.**

Vice President, Scientific & Regulatory Affairs  
Food, Health and Consumer Products of Canada

**USP Staff****Marissa Brykman, J.D.**

Director, U.S. Regulatory Policy

**Shawna Embrey, M.S.L.**

Senior Director, Growth Programs

**Darcy Gentleman, Ph.D.**

Senior Stakeholder Engagement Manager

**Kit Goldman, Ph.D.**

Director, Dietary Supplements and Herbal Medicines

**Carrie Harney, J.D.**

Senior Director, U.S. Government and Regulatory Affairs

**Tony Lakavage, J.D.**

Senior Vice President, Global External Affairs, USP  
Secretary, USP Convention and Board of Trustees

**Elana Pate**

Project Coordinator

**Nandakumara Sarma, Ph.D.**

Director, Dietary Supplements and Herbal Medicines

**Amy Sonderman, M.P.A.**

Director, USP Convention and Stakeholder Engagement

**Joy Titus- Young**

Deputy Director, USP Convention and Stakeholder Engagement

## Speaker Biographies

(in order of speaking)

**Jay Sirois, Ph.D.**, is the Senior Director, Regulatory & Scientific Affairs for the Consumer Healthcare Products Association (CHPA). His responsibilities include cooperation programs within the U.S. FDA, ingredient safety, and dietary supplement programs. Prior to joining CHPA in 2011, Dr. Sirois worked at the Pharmaceutical Development Group as a Director of Scientific Research and Clinical Studies. His experience extends to pharmaceutical, medical device, dietary supplement regulatory affairs, pharmacovigilance, prescription to OTC switch, product safety, and clinical research. A member of the Regulatory Affairs Professional Society and reviewer for the journal *Neurotoxicology*, Dr. Sirois gained his Ph.D. in pharmacology and toxicology from Michigan State University.

**Dennis E. Doherty, M.D.**, is the USP Convention President and member of the Board of Trustees for the 2020-2025 cycle. For over 20 years, he has contributed to USP's success in fulfilling its mission of improving global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. A Professor Emeritus of Medicine at the University of Kentucky, Dr. Doherty is an academic pulmonologist who has been the Principal Investigator in basic research and clinical studies, with more than 190 publications on lung inflammation, obstructive lung disease, and pulmonary fibrosis. He has also served as a division chief, department chairman, an officer and board member of several national professional societies. After earning his undergraduate degree at Johns Hopkins University, Dr. Doherty attended The Ohio State University College of Medicine. He went on to a distinguished career at several noted institutions including University of Colorado College of Medicine, University of Kentucky College of Medicine, and the Veterans Administration Medical Center. Dr. Doherty cites receipt of the 2015 Ohio State College of Medicine Academic Achievement Award as one of his proudest achievements.

**Anthony Lakavage, J.D.**, is Senior Vice President, Global External Affairs, and Secretary, USP Convention and Board of Trustees. In his role, Mr. Lakavage oversees Global Communications, U.S. and International Public Policy and Regulatory Affairs, Global Stakeholder Engagement and the USP Quality Institute. As secretary to the USP Convention, Mr. Lakavage works closely with the 500 member organizations comprising the USP Convention. As Secretary to the Board, he supports the Board's work on organization strategy, and financial and risk management. Prior to joining USP, Mr. Lakavage worked in the medical technology sector serving as Worldwide Vice President, Public Affairs, at Becton Dickinson. He has also held a variety of U.S. and international public policy and government affairs leadership roles for GlaxoSmithKline, Gilead Sciences, Chiron Corporation and Applied Biosystems. Earlier in his career, he worked for Pennsylvania Lt. Gov. Mark Singel and Missouri Congressman Alan Wheat. Mr. Lakavage earned his B.A., *cum laude*, in International Politics from Saint Joseph's University, and his Juris Doctorate, *cum laude*, from the Temple University School of Law – where he served on the Temple Political & Civil Rights Law Review staff. He is admitted to the bar in Pennsylvania and New Jersey.

**Larry Freedman**, is Vice President Operations at Clarion Brands LLC where he has responsibility for supply chain, quality and regulatory. Prior to Clarion Brands, he was at Insight Pharmaceuticals where he served in various roles from Director Business Innovation to Director Technical Operations and ultimately as Senior Director Operations and Sourcing. In total, Mr. Freedman has close to 20 years of experience in the OTC consumer healthcare industry managing supply chain and the quality of products supplied.

**Nancy Glick**, is Director of Food and Nutrition Policy at the National Consumers League (NCL), having joined the staff there in September 2020. She works closely with the executive director and stakeholder organizations, developing policy positions and mounting education and advocacy campaigns on issues including food insecurity, food safety, eliminating

food waste, food fraud, obesity and diet-related diseases, and improving labelling. Prior to joining NCL, Ms. Glick was Director of Health Affairs and Advocacy at the global public relations firm MSL, building on career roles in public relations. Her previous work included serving as a press officer at the U.S. FDA, handling food, cosmetic, drug, and consumer issues and agency announcements about product recalls.

**Robin Marles, Ph.D.**, is the Senior Scientific Advisor, Bureau of Nutritional Sciences, Food Directorate, Health Canada. He advises on safety, quality and health claims for botanical, nutrient, and functional food ingredients. A volunteer with the United States Pharmacopeia, Dr. Marles chairs the Botanical Dietary Supplements and Herbal Medicines Expert Committee. Previously, at Health Canada's Natural Health Products Directorate (2003–2013), he was the Science Advisor for drafting the Natural Health Products Regulations; Manager of product licensing premarket safety, efficacy, and quality assessment; Director for NHP clinical trial authorization, health risk assessment, and monograph development; and Senior Science Advisor for NHP policy.