U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF FOODS AND VETERINARY MEDICINE
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Responsible Innovation in Dietary Supplements
Public Meeting Speakers' and Panelists' Biographies

Steven Tave, Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA

Steven Tave is the Director of the Office of Dietary Supplement Programs (ODSP) in FDA's Center for Food Safety and Applied Nutrition (CFSAN). He was named ODSP's first permanent Director in November 2016 after serving as Acting Director beginning in March 2016. Previously, Steve was the Acting Director of the Office of Unapproved New Drugs and Labeling Compliance in CDER's Office of Compliance, where he led a multidisciplinary staff with responsibility for operations and regulatory actions with respect to misbranded and unapproved new drugs, including compounded drugs, fraudulent drugs, homeopathic drugs, marketed unapproved drugs, and over-the-counter drugs. Steve began his career as an attorney and practiced law for almost 15 years, both as a litigator in FDA's Office of Chief Counsel and in the private sector. He received his law degree from the University of Virginia School of Law and his bachelor's degree from Northwestern University.

Cara Welch, Ph.D., Special Assistant to the Deputy Commissioner of Policy, Legislation, and International Affairs, Office of the Commissioner, FDA

Cara Welch is currently on detail as a Special Assistant to the Deputy Commissioner for Policy, Legislation, and International Affairs in the Office of the Commissioner, specifically working on the foods portfolio. In her permanent role, Dr. Welch is the Senior Advisor for the Office of Dietary Supplement Programs (ODSP) in FDA's Center for Food Safety and Applied Nutrition (CFSAN). In ODSP, Dr. Welch works on new policies and programs involving regulatory compliance matters for the dietary supplement industry. She joined FDA in 2014 as a chemist and utilizes her background to provide guidance on ODSP's research program. Prior to FDA, Dr. Welch was the Senior Vice President of Scientific and Regulatory Affairs at the Natural Products Association. Welch earned her Ph.D. in Medicinal Chemistry from Rutgers University working with traditional medicinal African plants.

Scott Bass, Head, Global Life Sciences Team, Sidley Austin LLP

Mr. Bass heads Sidley Austin's Global Life Sciences team, coordinating pharmaceutical, medical device, food and dietary supplement matters in the U.S., Europe, and Asia. He is ranked internationally among the top authorities on FDA-related enforcement and regulatory issues and was the lead industry negotiator and one of the principal drafters of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Mr. Bass is widely regarded as a visionary thinker for how dietary supplements are regulated to balance consumer safety with providing broad consumer access to these products.

Manon Bombardier, Director General of Natural and Non-prescription Health Products Directorate, Health Products and Food Branch, Health Canada

Manon Bombardier is the Director General of Natural and Non-prescription Health Products Directorate, Health Products and Food Branch of Health Canada since October 2016. Before joining Health Canada, Manon served as Chief Compliance and Enforcement Officer at the Canadian Radio-television and Telecommunications Commission (CRTC). As a senior member of the Commission, she was responsible for the Compliance and Enforcement of the telemarketing rules and the Canadian Anti-Spam Legislation.

From 2000 to 2013, Manon served in several leadership roles at Environment and Climate Change Canada, including as Director General of Environmental Enforcement where she oversaw the environmental surveillance and enforcement functions under the Canadian Environmental Protection Act, and previously as Director of National Support Programs at the Canadian Environmental Assessment Agency. Prior to that period, she conducted research at the Qc regional laboratory of Environment Canada and led the establishment of two new environmental toxicology laboratories in the National Capital Region.

Manon holds a PhD in Environmental Toxicology (Université de Metz, FR, 2007) and a MBA (Hautes Etudes Commerciales, 2001).

Dr. Pieter Cohen, Associate Professor of Medicine, Harvard Medical School

Dr. Pieter Cohen, a graduate of Yale School of Medicine, is an Associate Professor of Medicine at Harvard Medical School and a practicing internist at Cambridge Health Alliance (Somerville, Massachusetts) who routinely recommends dietary supplements to his patients. His area of research is the safety of dietary supplements. Along with analytic chemistry colleagues he has spent the last decade exploring the boundaries between drugs and supplements. His work has been published in the *New England Journal of Medicine*, *JAMA*, *JAMA Internal Medicine*, *American Journal of Public Health* and *Annals of Internal Medicine*."

Sandra Eskin, Project Director, Food and Dietary Supplement Safety, The Pew Charitable Trusts

Sandra Eskin is the Project Director for Food and Dietary Supplement Safety at The Pew Charitable Trusts in Washington, D.C. Before joining Pew, she spent nearly 20 years as a public-policy consultant to numerous consumer and public-interest organizations, providing strategic and policy advice on a broad range of consumer-protection issues, in particular, food and drug safety, labeling, and advertising. She has served as a member of numerous federal advisory committees, including ones related to consumer information on prescription drugs, meat and poultry safety, and foodborne illness surveillance. Before joining Pew, Ms. Eskin was the Deputy Director of the Produce Safety Project (PSP), a Pew-funded initiative at Georgetown University. While at PSP, Ms. Eskin was a senior scholar with the O'Neil Institute for National and Global Health Law at Georgetown University. She has written numerous reports and articles on food-safety topics. Ms. Eskin received her J.D. from the University of California, Hastings College of the Law, and her B.A. from Brown University.

Daniel Fabricant, Ph.D., President and CEO, Natural Products Association

Daniel Fabricant, Ph.D. is President and CEO of the Natural Products Association (NPA), the nation's largest and oldest trade organization representing the natural products industry, including dietary supplements, foods, personal care products and more. He is responsible for implementing board

policy for the advancement and protection of the natural products industry, while overseeing every aspect of the association's programs and activities.

Immediately prior Dr. Fabricant served as the Director of the Division of Dietary Supplement Programs at the U.S. Food and Drug Administration (FDA), where he directed agency policy, public affairs and regulatory action regarding regulation of the dietary supplement industry. Dr. Fabricant holds a Ph.D. in Pharmacognosy from the University of Illinois at Chicago, where he has served as an adjunct professor in the Department of Medicinal Chemistry and Pharmacognosy since 2009.

Loren Israelsen, President, United Natural Products Alliance

Mr. Israelsen is the founder and President of the United Natural Products Alliance (UNPA), a trade association of dietary supplement companies committed to safety, science and quality. He has been deeply involved commercial, regulatory and political issues facing the global dietary supplement industry since 1980. He served as president of Nature's Way Products and has held industry positions including vice president/general counsel to the American Herbal Products Association, co-founder of the European American Phytomedicine Coalition (EAPC), industry liaison to FDA's Expert Advisory Committee on Ephedra, industry advisor to the Office of Dietary Supplements (ODS), expert panel member on IFT's Functional Food Report and sat as an expert panel member to the Department of Defense / RAND study on dietary supplement use among military personnel. He was also an active participant in the introduction and passage of the Dietary Supplement Health and Education Act of 1994.

Laura MacCleery, Policy Director, Center for Science in the Public Interest

Laura MacCleery is a passionate and skilled advocate for public health and has worked to advance transparency, fairness and democracy for twenty years. She is Policy Director of Center for Science in the Public Interest, a leading public health advocacy organization, and has been at CSPI since 2016. A graduate of Stanford Law School, she spent nine years at Public Citizen, including serving as Director of Congress Watch. She was Deputy Director for Democracy Programs at the Brennan Center for Justice for three years, followed by Director of Legislative Affairs at the Center for Reproductive Rights, leading the development of their D.C. office. She was also Vice President for Policy and Mobilizations at Consumer Reports/Consumers Union. She is the author or editor of more than 100 comments to regulatory dockets and 30 major research-based reports, and has testified in state legislatures, the U.S. Congress, and Brussels. She has appeared on national and local television and radio, published dozens of opinion editorials and blog posts, spoken at numerous conferences, rallies and other events, and been quoted frequently in the press.

Michael McGuffin, President, American Herbal Products Association

Michael McGuffin is the President of the American Herbal Products Association (AHPA) and has been active in the herbal industry since 1975. He has owned and managed both retail and manufacturing businesses in this field. Michael also serves on the boards of the American Herbal Pharmacopoeia and United Plant Savers, and on the Advisory Board of the USC School of Pharmacy Regulatory Science Master's Degree Program. In addition, he is the managing editor of AHPA's *Botanical Safety Handbook*, first (1997) and second (2013) editions, and of *Herbs of Commerce*, 2nd edition (2000). Michael was presented the Cliff Adler "Heart in Business" award in 1994 and the Nutrition Business Journal Award for Efforts on Behalf of Industry in 2004 and in 2011. He was inducted into New Hope Natural Media's "Hall of Legends" in March 2013.

George Paraskevakos, Executive Director, International Probiotics Association

George has been involved with the probiotic industry since 2007 where he served in various roles from business development to account management with a globally recognised probiotic producer. During this time, he also served on the IPA Board of Directors and had two mandates as President before taking on the association's leadership role as Executive Director in 2015. His passion for the probiotic industry is unequivocal and his persistence to have IPA continue being 'The Global Voice Of Probiotics®' has taken the association from 40 members when he took on the role to now over 100 international companies under his tutelage.

Andrew Shao, Interim Senior Vice President of Scientific & Regulatory Affairs, Council for Responsible Nutrition

Dr. Andrew Shao has spent nearly two decades in the global nutrition industry, assuming leadership roles in various nutrition, scientific, regulatory and government affairs functions. He is currently the principal at Global Nutrition Solutions, LLC and serves as interim senior vice president, scientific & regulatory affairs for the Council for Responsible Nutrition, a Washington, DC-based trade association representing the dietary supplement industry. Prior to that, Dr. Shao held several science and regulatory leadership roles at multinational companies, including Amway Corporation and Herbalife Nutrition.

Dr. Shao has advised governments around the world on science-based regulatory and policy reform on topics ranging from health claims, to risk analysis to regulation of botanicals. He is the author or co-author of over 60 peer-reviewed articles, abstracts, trade articles and book chapters, serves on the Editorial Board of several peer-reviewed journals, including Advances in Nutrition, Journal of Dietary Supplements and Journal of the International Society for Sports Nutrition. He served as Chair of the International Alliance of Dietary Supplement Associations (IADSA) Scientific Council and is a member of the American Society for Nutrition (ASN), the Institute of Food Technologists (IFT) and the Tufts Nutrition Council (TNC).

Shao holds a Ph.D. in nutritional biochemistry and M.S. in human nutrition science, both from Tufts University, and a B.A. in biology from Brandeis University.

Wes Siegner, Senior Counsel, Hyman Phelps & McNamara, P.C.

Wes Siegner provides counsel on FDA and FTC regulation of foods and dietary supplements, OTC drugs, and animal drugs and feeds. Since joining the firm in 1986, Mr. Siegner's work has encompassed a wide range of regulatory matters including product labeling, advertising and promotion, and FDA and FTC enforcement actions. Recently, he has focused on foods, dietary supplements, and OTC drugs, helping to pioneer and defend novel products in the dietary supplement, medical food, and homeopathic drug industries. Mr. Siegner has also worked extensively in the rapidly expanding area of organic food regulation, representing clients before the National Organic Program of the USDA.

Jay Sirois, Ph.D., Senior Director, Regulatory & Scientific Affairs, Consumer HealthCare Products Association

Jay Sirois is Senior Director of Regulatory & Scientific Affairs at the Consumer Healthcare Products Association (CHPA), the 138-year-old national trade association representing the leading

manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. Dr. Sirois is responsible for regulatory and scientific affairs activities, including cooperative programs with the U.S. Food and Drug Administration, ingredient safety, and dietary supplement programs at CHPA. He is experienced in pharmaceutical, medical device, and dietary supplement regulatory affairs, pharmacovigilance, Rx-to-OTC switch, product safety, and clinical research.

Dr. Sirois is the current Chair of the steering committee for the Dietary Supplement Quality Collaborative, a multi-stakeholder and cross sector collaborative aimed at improving the quality and safety of products marketed as dietary supplements. He is also a participating member in the Botanical Safety Consortium, a public-private partnership that of industry, academia and government that will promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements. He is a member of the Regulatory Affairs Professionals Society and is an ad hoc reviewer for the *Journal of Dietary Supplements* and *Neurotoxicology*. Dr. Sirois received his Ph.D. in Pharmacology and Toxicology (with a minor in Environmental Toxicology) from Michigan State University. Prior to his current role, Dr. Sirois worked at the University of Virginia and at a consulting firm in Tampa, FL.

Ashish Talati, Partner, Amin Talati & Upadhye

Ashish R. Talati leads Amin Talati's FDA practice and is one of the industry's foremost experts on FDA regulatory matters. Ashish primarily counsels clients on matters of regulatory compliance, helping them anticipate and address regulatory issues in their day-to-day business operations and strategic planning. He also advocates on their behalf before the FDA, FTC, Customs, USDA, DEA, and other federal agencies, and in court. He is considered a leading authority in the areas of Generally Recognized as Safe (GRAS) requirements and New Dietary Ingredients (NDI); Considered a creative and strategic partner by his clients, Ashish works with companies all over the globe and is a trusted advisor at every step of the product life cycle, including product formulation, safety and efficacy studies, product launch, and ongoing marketing and sales.