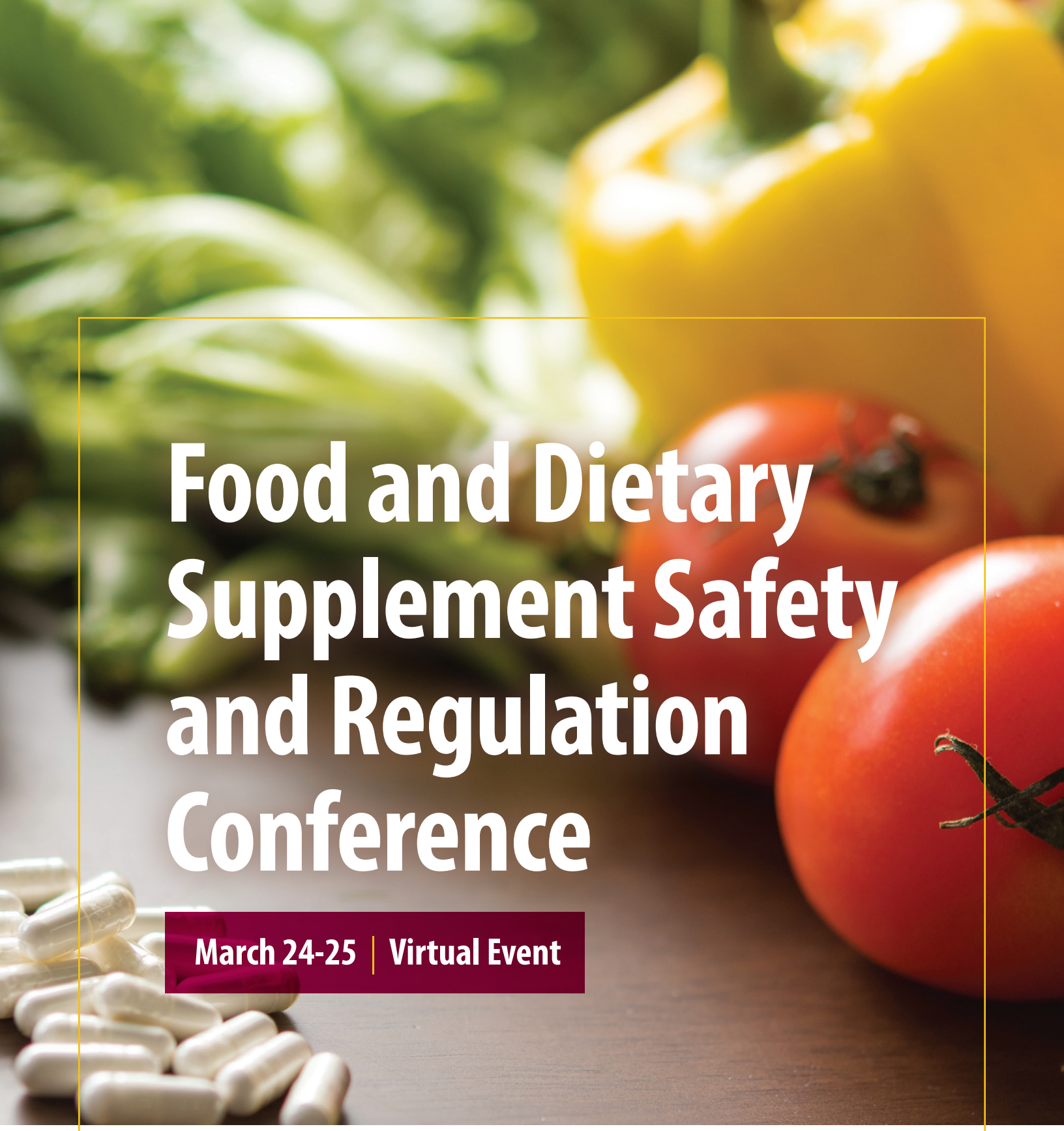

Food and Dietary Supplement Safety and Regulation Conference

March 24-25 | Virtual Event

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Elizabeth Fawell, Hogan Lovells US LLP

Andrea Ferrenz,Campbell Soup Company

Neal Fortin, Michigan State University College of Law

Ryan Gooley, Stericycle

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Food and Dietary Supplement Safety and Regulation Conference

For the Food and Dietary Supplement Industries

March 24-25, 2021

Wednesday, March 24

11:20 – 11:40 AM **Technology and Connection Support Session**
First virtual conference? Unsure about technology? Join FDLI staff for this informal, open session to make sure your audio and technology are prepared for the day's sessions and to answer your questions about the virtual platform.

11:45 AM–12:00 PM **FDLI Welcome**
Amy Comstock Rick, President & CEO, FDLI
Steven Armstrong, Senior Regulatory Advisor, Haynes and Boone LLP and Chair, FDLI Food and Dietary Supplement Conference Planning Committee

12:00–12:45 PM **Keynote Address**
Sharon Lindan Mayl, Senior Advisor for Policy, Office of Food Policy and Response, United States Food and Drug Administration (FDA)

12:50–1:50 PM **Evaluating the Food Safety Modernization Act (FSMA) Proposed Rule for Food Traceability**
As part of the New Era of Smarter Food Safety Blueprint, and as required by FSMA, FDA has proposed a new rule establishing additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold certain foods. Panelists will review the components of the proposed rule, then discuss its potential benefits, including improved food safety and outbreak response, against the additional costs it would impose on parties in the supply chain.

Laurie Beyranevand, Director and Professor of Law, Center for Agriculture and Food Systems, Vermont Law School
Rebecca Goldberg, Associate Chief Counsel, FDA Office of the Chief Counsel
Bryan Hitchcock, Senior Director, Food Chain & Global Food Traceability Center, The Institute of Food Technologists (IFT)
Moderated by **Allen Sayler,** Senior Director of Food Consulting Services, EAS Consulting Group

1:50–2:10 PM **Break**

2:10–2:55 PM **Produce Safety: New Approaches to a Persistent Public Health Problem**
Contaminated produce remains one of the leading causes of recalls in the United States, and recently FDA has increased its efforts to combat this problem. This discussion will cover year-over-year trends in produce-related

recalls, the impact of FSMA implementation on produce safety, FDA's recent push to react to and post information on outbreaks more quickly, and remaining challenges to reducing the amount of contaminated produce that reaches consumers.

William (Bill) Marler, Managing Partner, Marler Clark
Jennifer McEntire, Senior Vice President, Food Safety and Technology, United Fresh Produce Association
Moderated by **Steven Armstrong,** Senior Regulatory Advisor, Haynes and Boone LLP and Chair, 2021 Food and Dietary Supplement Safety and Regulation Conference Planning Committee

3:00–3:45 PM **Update on Allergen Labeling and Recalls**

Allergen labeling continues to be a hotly debated topic, and undeclared allergens continue to be a frequent cause of both food and dietary supplement recalls. Attendees will hear the latest updates on efforts to include sesame in mandatory allergen labeling, standardize label warning language, and modernize the allergen listing process, as well as recent examples of and trends in allergen-related recalls.

Evangelia Pelonis, Partner, Keller & Heckman LLP
Anita Roach, Vice President of Health Innovation Strategies & Corporate Ventures, Food Allergy and Research Education (FARE)
Moderated by **Neal D. Fortin,** Director, Institute for Food Laws and Regulations, Michigan State University and Professor, Department of Food Science and Human Nutrition, Michigan State University College of Law

3:45–4:00 PM **Break**

4:00–5:00 PM **Examining FDA's Increased Use of Warning Letters for Food and Dietary Supplements**

Warning letters remain a vital tool for FDA, and their many uses span enforcing FSMA compliance to protecting consumers from impermissible claims of COVID-19 prevention and treatment. Learn from industry experts how FDA has utilized warning letters during the pandemic, including increased specificity in Foreign Supplier Verification Program (FSVP)-related warning letters and issuing inspection violation citations based on record reviews alone and without conducting in-person inspections. Panelists will also make predictions on whether these trends are likely to continue post-pandemic and future FDA enforcement priorities.

Andrea Ferrenz, Food Law Counsel, Campbell Soup Company
Susan J. Hewlings, Director of Scientific Affairs, Nutrasource Pharmaceutical and Nutraceutical Services
John F. Johnson, Partner, Shook, Hardy & Bacon LLP
Moderated by **Elizabeth Barr Fawell,** Partner, Hogan Lovells

Thursday, March 25

11:20 – 11:40 AM **Technology and Connection Support Session**
First virtual conference? Unsure about technology? Join FDLI staff for this informal, open session to make sure your audio and technology are prepared for the day's sessions and to answer your questions about the virtual platform.

11:50 AM–12:00 PM **FDLI Welcome**
Steven Leslie, Assistant Director, Educational Programs, FDLI

12:00–12:45 PM **Featured Presentation and Q&A**

Vasilios (Bill) Frankos, Senior Vice President of Global Product Science, Safety, and Compliance, Herbalife International of America, Inc.

12:50–1:50 PM **Dietary Supplements: Regulatory Challenges and Litigation Risks**
Already a growing product category, the pandemic has further accelerated consumer interest in dietary supplements. This panel will feature perspectives on the most pressing issues in the dietary supplement space, including what differentiates dietary supplements from drugs and foods, nuances in the new dietary ingredient notification process, regulatory risks, and recent trends in both class action and Prop 65 litigation.

Megan Olsen, Vice President and Associate General Counsel, Council for Responsible Nutrition
Judith M. Praitis, Partner, Faegre Drinker Biddle & Reath LLP
Jack Wenik, Member, Epstein Becker & Green, P.C.
Moderated by **Robert Durkin,** Of Counsel, Arnall Golden Gregory LLP

1:50–2:10 PM **Break**

2:10–2:55 PM **Navigating the Patchwork of State Hemp and CBD Regulation**
In the absence of additional federal guidance, there remains great deal of variation among state regulations for products with hemp-derived CBD. Panelists will survey the current "state" of these laws and requirements, including variations in testing and lab accreditation requirements, and predict what federal CBD regulation and enforcement will look like under the Biden administration and with a new FDA Commissioner, including whether Congress will step in and pass new legislation on hemp-derived CBD products.

Daniel R. Dwyer, Partner, Kleinfeld, Kaplan & Becker, LLP
Daniel McGee, Former Chief Legal Officer, Solari Hemp
Moderated by **Sam Dietle,** Senior Associate, Hogan Lovells LLP

3:00–3:55 PM **Considerations for Using Third-Party Certification for Ensuring Product Safety**
From Good Manufacturing Practices (GMPs) compliance to supplier inspections to ingredient and finished product testing, food and dietary supplement

manufacturers rely heavily on third party certifiers to ensure their finished products are safe. This discussion will address how industry reliance on third parties has changed after the high-profile recalls from 2009-2011 (Peanut Corporation of America, Quality Egg, and Jensen Farms). Speakers will also discuss recent issues with dietary ingredient contamination, and the extent that domestic and international companies can and should rely on third parties when it comes to product safety assurance.

Tara Couch, Senior Director, EAS Consulting Group
Karil L. Kochenderfer, Principal, LINKAGES
Moderated by **Jacqueline J. Chan,** Partner, Kleinfeld, Kaplan & Becker, LLP

4:00–4:55 PM **Bioengineering, Cell-Cultured Products, and the Challenge of Regulating at the Same Pace that Technology Advances**

Technology tends to outpace regulation in all product categories, and food and dietary supplements are no exception. Topics will include Federal Bioengineered Disclosure Standard definitions in light of evolving gene-editing technology, pending challenges faced by FDA and USDA for regulating cell-cultured meat and seafood, and big-picture suggestions for how regulatory bodies can keep pace with rapidly evolving technology.

Gregory Jaffe, Director of the Project on Biotechnology, Center for Science in the Public Interest (CSPI)
Kelly G. Laudon, Of Counsel, Jones Day
Larisa Rudenko, Research Affiliate, Program of Emerging Technologies (PoET), Massachusetts Institute of Technology (MIT) and Co-Founder, Biopolicy Solutions, LLC
Moderated by **Jessica P. O'Connell,** Partner, Covington & Burling LLP

4:55 – 5:00 PM **Closing Remarks and Adjournment**

Food and Dietary Supplement Safety and Regulation Conference
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Speaker Biographies

STEVEN ARMSTRONG is an independent consultant specializing in food law and regulation. He has over 20 years of experience counseling leading consumer products companies on regulatory and marketing matters and is currently serving as Senior Regulatory Advisor for Haynes & Boone, LLP. Mr. Armstrong served as the Chief Food Law Counsel at Campbell Soup Company for 10 years before retiring in 2016. At Campbell, he advised businesses throughout the company on food safety, food policy, labeling and regulatory compliance, including matters involving FDA, USDA, and food agencies around the world. He led the company's crisis management team. Prior to Campbell, Mr. Armstrong served as a regulatory and marketing counsel for Unilever US and Colgate-Palmolive Company. Before attending law school, Mr. Armstrong worked as a reporter and editor at several newspapers, including the Miami Herald. He earned his JD degree from Columbia University and did his undergraduate work at Harvard. From 2014-17, Mr. Armstrong served on the Board of Directors of the Food and Drug Law Institute. He is a recipient of FDLI's Distinguished Service Award and frequently speaks and writes on food law and policy issues.

LAURIE BEYRANEVAND is the Director of the Center for Agriculture and Food Systems and a Professor of Law at Vermont Law School. Laurie has published scholarly articles and book chapters that focus on the connections between human health and the food system. Her work has been cited in petitions to major federal agencies, books, blogs, and articles, and she has been quoted in Politico, Mother Jones, the Christian Science Monitor, Climate Wire, the Washington Post, Food Tank, and E & E Greenwire, among others. Laurie is an appointed member of the Food and Drug Law Institute and Georgetown Law School's Food and Drug Law Journal Editorial Advisory Board, a founding member of the Academy of Food Law and Policy, and the former Chair of the Agriculture and Food Law Section of the American Association of Law Schools. She is admitted to the New York and Vermont State Bars, as well as the US District Court, District of Vermont.

JACQUELINE J. CHAN is a partner at Kleinfeld, Kaplan & Becker LLP. She advises all sizes of food companies from start-ups to global entities throughout the product lifecycle, including labeling, advertising/promotion, enforcement risk assessment, post-marketing obligations, and regulatory strategy and compliance. She serves as an active member of her clients' teams, working to find solutions to meet both legal and business goals. Using her knowledge of today's litigation trends, Ms. Chan helps develop new products, label claims, promotional campaigns, and advertising materials. She is currently keeping an eye on issues related to plant-based foods, standards of identity, sustainability/environmental claims, and challenges to ingredient claims.

TARA LIN COUCH, Senior Director for Dietary Supplement and Tobacco Services at EAS Consulting Group, is an analytical/organic chemist with exceptional analytical abilities and more than 30 years of diverse laboratory and regulatory experience in academic, field, contract, and manufacturing environments. She is a sought-after expert on issues pertaining to quality control (QC) in both pharmaceutical and dietary supplement manufacturing, as well as the tobacco industry. As a consultant, Dr. Couch assists with the development, improvement and implementation of quality systems that are scientifically sound, efficient, practical, and compliant with FDA regulations. She also performs mock FDA inspections, gap analyses, and contractor and laboratory audits. Dr. Couch provides GMP (good manufacturing practice) and laboratory trainings via seminar, webinar and on-site presentations.

SAM DIETLE is a senior associate at Hogan Lovells US LLP where she provides practical legal solutions and regulatory guidance to all segments of the food and dietary supplement industry. Her practice is primarily focused on regulatory considerations for novel ingredients, labeling and advertising issues, and claims substantiation. Since the passage of the 2018 Farm Bill, the focus of Sam's work has been helping companies navigate the complex federal and state regulatory schemes for hemp-derived ingredients, including cannabidiol.

ROBERT DURKIN is of counsel at Arnall Golden Gregory LLP. As a former acting Director and Deputy Director of the Office of Dietary Supplement Programs (ODSP) in the FDA's Center for Food Safety and Applied Nutrition (CFSAN), he brings a wealth of knowledge and insight to his legal practice. In working with AGG clients, Bob will draw from the extensive experience he gained at the FDA where he was responsible for performing policy analysis and evaluations related to all aspects of the agency's dietary supplement programs while also providing skillful advice on compliance and enforcement issues (such as Warning Letters, seizures, injunctions, import detention/refusal, etc.). During this time, he was active in a variety of agency working groups, including: Agency-wide Marijuana Working Group, Agency-wide CBD Policy Working Group, and the Agency-wide Investigational New Drug (IND) Policy Working Group. While helping to lead ODSP, Bob also successfully led the Office through multiple GAO investigations. Just prior to joining ODSP, Bob was the acting Director of CFSAN's Food Defense Staff. In this role, Bob led a dedicated group of professionals whose duty it was to determine the best regulatory strategies to help protect our nation's food supply from intentional contamination. The Food Defense staff's work includes the implantation of the Food Safety and Modernization Act's Rule for Mitigation Strategies to Protect Food against Intentional Adulteration and determining the best ways to educate, and then regulate, industry relative to the Rule. Bob has also served in both the Commissioner's Office and the Center for Drug Evaluation and Research (CDER). While in the

Commissioner's Office, Bob managed a staff of Emergency Response Coordinators whose focus was on coordinating an over-all Agency approach to mitigate and respond to urgent health concerns related to FDA regulated commodities. While at CDER, Bob worked in the areas of health fraud, over the counter drugs, and pharmacy compounding.

DANIEL R. DWYER is a partner with Kleinfeld, Kaplan and Becker, LLP. His practice focuses primarily on representing dietary supplement, food, pharmaceutical, cosmetic, medical device, and consumer products companies on a variety of matters involving regulatory and advertising law. Mr. Dwyer has substantial expertise in Cannabis and hemp regulation, as well as pharmaceutical and controlled substance law, labeling and advertising claim substantiation, sales and marketing practices, good manufacturing practices, FDA inspections, recalls, corporate compliance programs and related matters. He regularly advises clients on developing strategies for compliance in complex legal environments.

ELIZABETH BARR FAWELL is a partner at Hogan Lovells LLP. Successfully navigating the detailed and often complex regulatory issues confronting the food industry, she helps companies understand both the rules and various risks involved to make the most informed and strategic decisions. Elizabeth has worked with every segment of the food industry, including manufacturers, distributors, retailers, restaurants, and food service operators, as well as their trade associations. Her work on behalf of food industry clients with the Food Safety Modernization Act (FSMA) since its inception and her understanding of Hazard Analysis Critical Control Point (HACCP) systems provides her with the experience and perspective needed to counsel clients on how to comply with new requirements under the law. Elizabeth is also a Preventive Controls Qualified Individual (PCQI) and has completed the FSPCA PCQI training. Elizabeth provides real-time advice during factory inspections, helps clients prepare 483 responses, and drafts inspection manuals. She assists clients in lawfully and creatively promoting their products, such as the development of labels, claims, and website and promotional campaigns. Elizabeth also supports clients in advertising disputes and with responses to FTC and Attorney General investigations. She also counsels clients on compliance with Consumer Product Safety Commission (CPSC) safety standards, testing and certification requirements, and reporting obligations.

ANDREA FERRENZ is Food Law Counsel at Campbell Soup Company. Andrea began her career working in labs, first as a research assistant with the Institute for Genomic Research and then with Children's National Medical Center in Washington DC. Her undergraduate degree is in Biology from University of Mary Washington, Fredericksburg, Virginia. After attending law school at George Washington University, she was an attorney for many years with Emord & Associates PC in the Washington, DC area, representing clients regulated by the US Food and Drug Administration (and related agencies). After leaving private practice, Andrea was Legal Counsel with Celltex Therapeutics, a ground-breaking stem cell company in Houston, TX. Next, Andrea was Regulatory Director, Associate General Counsel with Innophos, Inc, a manufacturing company supplying ingredients to the food, dietary supplement, pharmaceutical and technical industries around the globe. Currently Andrea is Food Law Counsel with Campbell Soup Company working primarily with its Quality, Regulatory, R&D, and Marketing teams on some of the most iconic brands in the United States.

NEAL D. FORTIN is the Director of the Institute for Food Laws & Regulations at Michigan State University, and Professor in the Department of Food Science and Human Nutrition. Mr. Fortin teaches the courses United States Food Law, International Food Law, Codex Alimentarius, and Regulatory Leadership. He is the author of *Food Regulation: Law, Science, Policy, and Practice*, 2nd ed. Neal Fortin was the 2009 recipient of a Michigan State University Distinguished Faculty Award for his teaching. He is past President of the North Central Association of Food & Drug Officials. He served as a Commissioner for the Michigan Local Public Health Accreditation Program, the Advisory Council of the Michigan Community Health Leadership Institute, and the NSF Council of Public Health Consultants. He served on the Dietary Supplement Committee of the Food and Drug Law Institute. He has been a curriculum advisor to the International Food Protection Training Institute and the University of Catalonia. He is an emeritus member of the Association of Food and Drug Officials, the Food and Drug Law Institute, a professional member of the Institute of Food Technologists, and the State Bar of Michigan.

VASILIOS (BILL) FRANKOS serves as Senior Corporate Advisor Product Science, Safety & Compliance. He is responsible for assuring that all products sold by Herbalife are safe, meet regulatory safety requirements and that all claims are scientifically supportable. He assures Herbalife's product development activities support the company's product portfolio strategy. He retired from the US Food and Drug Administration in 2010, where he served as the Director, Division of Dietary Supplements programs. He was the lead scientist for dietary supplements for the FDA and was responsible for the full implementation of the DSHEA Act of 1994. While at FDA he also served as Special Assistant for Dietary Supplement Science Review, Staff Science Advisor in the Office of the Commissioner, and as a Senior Toxicologist in the Center for Food Safety and Applied Nutrition. Before joining the FDA, Dr. Frankos was a principal consultant with ENVIRON Corp. for

over 18 years. He holds a PhD in pharmacology and toxicology from University of Maryland Pharmacy School; an MS in molecular biology and a BA in biology from University of Maryland.

REBECCA GOLDBERG is an attorney in FDA's Office of the Chief Counsel. Since joining the office in 2009, Rebecca has advised the agency on a wide range of matters relating to foods and dietary supplements. Among her other responsibilities, Rebecca has been the lead attorney handling FSMA § 204 since the passage of the Food Safety Modernization Act in 2011. As a member of FDA's internal FSMA 204 workgroup, Rebecca has been involved in all aspects of the Food Traceability Proposed Rule and in the continued rulemaking process. Prior to joining FDA, Rebecca served as a law clerk to the Hon. Robert D. Sack of the US Court of Appeals for the Second Circuit. She received her AB in Literature from Harvard University, and her JD from Harvard Law School.

SUSAN J. HEWLINGS is the Director of Scientific Affairs at Nutrasource Pharmaceutical and Nutraceutical Services. She received her PhD in nutrition, her BS in nutrition and her MS in exercise physiology from Florida State University. She is a registered dietitian, a full- time professor at Central Michigan University, and director of scientific affairs for Nutrasource. She is Co-Founder of Substantiation Sciences LLC where she provides science and nutrition consulting services and medical writing for the dietary supplement, CBD, cannabis, and medical industries. She was formerly an assistant professor at The University of Central Florida College of Medicine, where she was responsible for integrating nutrition into a new medical school curriculum. Susan completed a fellowship studying protein and fat metabolism at The University of Texas Medical Branch/Shriners Burn Institute. She is the author of Nutrition: Real People, Real Choices and has published numerous book chapters, articles in peer- reviewed journals on dietary supplements, CBD, cannabis, pharmacokinetics, and nutrition. Throughout her career, she has served on several scientific and advisory boards in academia and industry. She recently completed a graduate certificate in cannabis science from The University of Vermont College of Medicine. Dr. Hewlings is Founder and Director of The ARF Shack 501c3 non-profit animal rescue.

BRYAN HITCHCOCK is Senior Director of Food Chain and Executive Director at the Food Traceability Center in the Institute of Food Technologists (IFT). Mr. Hitchcock brings extensive product and process development expertise in the food and beverage industry. This includes experience with emerging and mature brands across the supply chain spanning new product and technology innovation, ingredients, food processing, quality and food safety, and manufacturing. Mr. Hitchcock spent much of his career at PepsiCo in roles including Principal Engineer R&D, Director, R&D (Global Beverages Discover & Applications), and most recently as the Senior Director, North America Nutrition R&D (Fruits & Vegetables). Prior to PepsiCo he was a product developer with Procter and Gamble. He possesses a Bachelor of Science in Chemical Engineering from Cornell University.

GREGORY JAFFE is the Biotechnology Project Director for the Center for Science in the Public Interest, a consumer organization located in the US. Mr. Jaffe came to CSPI in 2001 after a distinguished career in government service as a Trial Attorney at the US Department of Justice and as Senior Counsel with the US EPA. He is a recognized international expert on biotechnology and biosafety and has worked on biosafety issues in numerous countries in Asia and Africa. Gregory Jaffe earned his BA with High Honors from Wesleyan University in Biology and Government and a law degree from Harvard Law School.

JOHN F. JOHNSON is counsel at Shook, Hardy & Bacon LLP where he works with companies to develop and implement solutions for complying with the laws administered by Food and Drug Administration (FDA), US Department of Agriculture (USDA), Customs and Border Protection (CBP) and other federal and state agencies. He works with manufacturers, distributors, brand owners, importers and retailers of food, drugs, medical devices, cosmetics, and animal products to satisfy their regulatory obligations. John represents companies before FDA and other government agencies subject to inspections or compliance activities, including a judicial action, Warning Letter, Untitled Letter, regulatory meeting, administrative detention, import detention and import alert, and FDA Form 483. Additionally, he helps companies evaluate complaints to determine if a recall is necessary, and if so, he works with clients to manage the product recall to remove the product from market. John counsels clients throughout the product life cycle, including product development and specifications, marketing and labeling, and manufacturing, importation, distribution, and sales. This includes determining the possible registrations, permits, licenses and pre-market submissions. Also, he works with clients to create, implement, and maintain internal programs to help foster smooth compliance.

KARIL L. KOCHENDERFER advises clients in the fast-moving food, consumer products and retail sectors through LINKAGES, her global trade, industry, and government affairs firm. For 30 years, she has had the privilege of representing the food, beverage and retail sector before Congress, FDA, Wall Street, and the media nationally as well as before the European Commission, the UN, WHO, WTO, Codex and over three dozen foreign governments internationally. During this time, she has worked on some of the most critical issues facing the industry ranging from biotechnology and blockchain, to food safety, CBD, sustainability, regulatory trade barriers and now digital trade. Prior to establishing her consultancy, Kochenderfer worked at the Grocery Manufacturers of America and PhRMA. Today, she is privileged today to include the Global Food Safety Initiative (GFSI), GS1 Global Supply-chain Standards, Mars, Anheuser-Busch, Procter & Gamble and Estee Lauder among her many clients.

Kochenderfer has served on four US Government advisory committees – for trade, supply-chain efficiency, regulatory trade barriers and biotechnology -- and is a graduate of The University of Michigan.

KELLY G. LAUDON is an attorney in the Minneapolis office of Jones Day and is a trusted advisor and skilled litigator representing clients in the food and beverage industry. Kelly has over 12 years of litigation experience in complex commercial and consumer disputes, including claims for food product mislabeling, unfair trade practices, false advertising, food contamination, breach of contract, breach of warranty, and indemnification in federal and state court and arbitration. She also counsels companies on risk mitigation and compliance with state food and beverage labeling and product safety requirements. Kelly is President of the Minnesota Chapter of the Federal Bar Association; a leader of the Food, Drug, and Device Law Section of the Minnesota State Bar Association; and a member of the Board of Directors of the Twin Cities German Immersion School. She has been recognized as a "Super Lawyer" in Minneapolis since 2018 and was listed as a "Rising Star" from 2013 to 2017. Prior to entering private practice, she clerked for the Honorable James M. Rosenbaum, then-Chief Judge of the United States District Court for the District of Minnesota. She earned her JD magna cum laude from the University of Minnesota Law School in 2006, where she was editor-in-chief of the Minnesota Journal of International Law, and her BA magna cum laude from Rhodes College in 1999.

WILLIAM (BILL) MARLER is an accomplished attorney and national expert in food safety. He has become the most prominent foodborne illness lawyer in America and a major force in food policy in the US and around the world. Marler Clark, The Food Safety Law Firm, has represented thousands of individuals in claims against food companies whose contaminated products have caused life altering injury and even death. Bill began litigating foodborne illness cases in 1993, when he represented Brianne Kiner, the most seriously injured survivor of the historic Jack in the Box E. coli O157:H7 outbreak, in her landmark $15.6 million settlement with the company. The 2011 book, Poisoned: The True Story of the Deadly E. coli Outbreak that Changed the Way Americans Eat, by best-selling author Jeff Benedict, chronicles the Jack in the Box outbreak and the rise of Bill Marler as a food safety attorney.

SHARON LINDAN MAYL has been with FDA for more than 25 years and currently serves as Senior Advisor for Policy in the Office of Food Policy and Response. In this position, she oversees and manages significant policy initiatives in the foods area. Among other issues, Ms. Mayl is the implementation lead for FDA's New Era of Smarter Food Safety initiative, which seeks to develop a new approach to food safety that leverages technology and other modern tools to create a safer and more digital, traceable food system. Previously, she co-led the team that developed and implemented the import provisions of FSMA, including those related to the Foreign Supplier Verification Program, Voluntary Qualified Import Program, and Accredited Third-Party Certification Program. Ms. Mayl also serves as the lead for the foods program on issues related to cannabis. She is a graduate of Cornell University and Harvard Law School.

JENNIFER McENTIRE is Senior Vice President of Food Safety at United Fresh Produce Association. A food microbiologist by background, she has worked in the Washington, DC area for 20 years, bringing the scientific perspective to food safety regulatory issues. She was previously Vice President of Science Operations at the Grocery Manufacturers Association. She has also had roles as VP and Chief Science Officer at The Acheson Group and as the Senior Staff Scientist and Director of Science & Technology Projects at the Institute of Food Technologists. McEntire earned a PhD from Rutgers University as a USDA National Needs Fellow in Food Safety and received a Bachelor of Science with Distinction, magna cum laude, in food science from the University of Delaware. She serves as an advisory board member of the Global Food Traceability Center, on the technical committee of the Center for Produce Safety, and was the 2020 recipient of the NSF International Food Safety Leadership Award.

DANIEL McGEE is an experienced in-house lawyer and keen strategic business advisor. He navigates murky state and federal regulatory waters and provides clients with sound and actionable legal advice. Mr. McGee built and managed in-house legal departments and government affairs programs as General Counsel for companies in the cannabis, vape and tobacco sectors: Solari Hemp; Fontem Ventures; Scandinavian Tobacco Group; and Swedish Match. He is a successful advocate and lobbyist for highly regulated industries at US local, state, and federal levels and abroad.

JESSICA P. O'CONNELL is a partner in Covington & Burling's Food and Drug practice group in Washington, DC. She advises companies and trade associations on complying with US regulatory requirements enforced by FDA, USDA, FTC, and state regulators for the manufacture and sale of foods, dietary supplements, cosmetics, OTC drugs, and animal products, and the import and export of all FDA and USDA-regulated products. Before joining Covington, she was an Associate Chief Counsel in FDA's Office of Chief Counsel. While at FDA, Jessica counseled various components of FDA and HHS on legal issues primarily related to cosmetics, foods, and dietary supplements. Jessica received a bachelor's degree in biology and physics from the University of Virginia, an MPH from Johns Hopkins, and a JD from Georgetown University Law Center.

MEGAN L. OLSEN is Vice President and Assistant General Counsel for the Council for Responsible Nutrition (CRN) in Washington, DC. At CRN, she provides legal counsel and advice to CRN's staff and members in the areas of legislation, regulatory compliance and advocacy, and international policy development with respect to dietary supplements and nutrition issues. Prior to joining CRN, Ms. Olsen was in-house counsel for Walgreen Co., where she provided legal advice about Food and Drug Administration, Federal Trade Commission, and other consumer protection regulatory requirements for a wide variety of consumer products, including conventional food, dietary supplements, OTCs, and cosmetics. Ms. Olsen began her career at Kelley Drye and Warren LLP working on a variety of consumer protection, regulatory, and advertising law issues.

EVANGELIA PELONIS is a partner at Keller & Heckman LLP where she assists clients on US Food and Drug Administration (FDA) and US Department of Agriculture (USDA) matters relating to human food, animal feed, food additives and ingredients, and dietary supplements. She helps clients achieve their marketing goals within the relevant legal frameworks and counsels them in all aspects of food development and marketing, from product formulation and manufacturing considerations to food labeling and advertising. Eve helps her clients with issues regarding food labeling and promotional materials, product identity statements, ingredient declarations, nutrient content claims, structure function claims, health claims, and allergen, nutrition, bioengineered and organic labeling. Clients seek her advice regarding obtaining appropriate regulatory status for food ingredients including preparing self-determined Generally Recognized as Safe (GRAS) positions or submitting GRAS Notices, New Dietary Ingredient Notifications (NDINs), food additive petitions (FAPs) or color additive petitions (CAPs) to FDA. Eve guides clients through product recalls and reports to the Reportable Food Registry. She helps clients navigate complex import and export issues regulated by FDA and USDA and assists companies in gaining the release of detained products. She regularly presents on food law matters for various trade associations and food conferences including Keller and Heckman's Practical Food Law Seminar.

JUDITH M. PRAITIS is a partner at Faegre Drinker where she counsels clients on environmental transactional issues and on air, water and waste management permitting, compliance, release reporting and enforcement issues under California and federal law. With decades of experience in environmental law, Judith is a trusted source of legal and business guidance for clients working to develop and implement environmental management systems, audit compliance protocols, and anticipate and adapt to emerging regulatory environments. Judith has experience managing complex environmental matters for distressed entities, or those with material legacy environmental liabilities, to orchestrate a controlled resolution of such obligations. She is particularly adept at crafting novel settlements with governmental regulators and prosecutors. Judith advises clients on compliance with and, if necessary, litigation of, Proposition 65 matters, particularly those involving the food and supplement industries and other consumer products. She assists clients with compliance under many of California's product- and chemical-specific regulatory regimes, including the Green Chemistry Initiative.

ANITA ROACH is Vice President of Health Innovation Strategies & Corporate Ventures at Food Allergy Research & Education (FARE). She has nine years of experience in developing and managing patient-centered research and programs. In her previous roles at the National Sleep Foundation and Lupus Foundation of America, she partnered with patients to identify outcomes that mattered most and to develop data-driven solutions. Anita is skilled at communicating complex and technical information to patient and professional communities and has several publications in the Journal of Arthritis & Rheumatology and Sleep Health. She has a master's degree from Georgetown University in Biochemistry.

LARISA RUDENKO holds a Research Affiliate position in the Program on Emerging Technologies at the Massachusetts Institute of Technology, and she is the Co-Founder of BioPolicy Solutions LLC, a boutique consultancy providing regulatory and due diligence assistance to the private and public sectors. In her academic work, Dr. Rudenko studies emerging biotechnologies to characterize the different components of distributed governance throughout the life cycle of these products and technologies from the active and tacit involvements and motivations of groups and the forces they exert to the impacts those polities have on the success (or lack thereof) of these products and the bioeconomy of the United States. She serves on US and international public sector advisory boards; US and international grant review committees involved in policy directions for emerging biotechnologies; and as a peer-reviewer for publications involved in public health. At BioPolicy Solutions, she works with the private (start-ups through established food and biomedical companies) and public sectors to develop strategies for cost-effective product development using emerging

biotechnologies. Dr. Rudenko previously worked at the US FDA developing a successful science-based regulatory strategy for products of genetic engineering, genome editing, and gene therapy; developing a new interdisciplinary team to oversee several first-in-kind regulatory approvals; and working with agency attorneys and interagency groups to develop US policy. She represented the US government in international venues from consensus documents on safety to trade policies.

ALLEN SAYLER is the Senior Director for Food Consulting Services at EAS Consulting Group LLC., part of the Certified Laboratory family of companies. EAS is headquarter in the Alexandria, Virginia (across the Potomac from Washington, DC). His food-based career spans thirty-eight years, sixteen years as a state, FDA, and USDA food regulator, with the last twenty-two years as a food processing industry regulatory advisor, specializing in evaluation, assessments and the trouble shooting of food plant processing operations and their food safety and quality programs, having attained ISO 22000, BRC auditor certifications. He is an FDA-recognized "Lead Instructor" for the US FDA FSMA regulations on Preventive Controls for Human Foods (PCHF) and the Foreign Supplier Verification Program (FSVP) and is familiar with the SQF, BRC, IFS, FSSC22000 and various ISO food safety standards. At EAS, he leads the food consulting services provided by almost 170 Independent Consultants, each with 20 or more years of experience in their area of expertise. Mr. Sayler has been active in the International Dairy Federation (IDF) since 1996 and has served in various leadership roles, including being elected to the IDF Scientific Program Coordination Committee (SPCC) in October. He has a working knowledge of USDA, FDA, EPA, and US Customs & Border Protection requirements as they apply to foods imported into the US. He received Group Excellence Awards from both the US FDA and the US Department of Agriculture, the Harold Barnum and the Lifetime Membership Award from IAFP and the IDF Leadership and Prize of Excellence Award from IDF in 2020.

JACK WENIK is a Member of Epstein Becker & Green in the Health Care and Life Sciences and Litigation practices and serves on the firm's National Health Care and Life Sciences Steering Committee. He is a graduate of Yale Law School and previously served as an Assistant US Attorney in the Eastern District of New York and the Eastern District of Pennsylvania. Mr. Wenik represents dietary supplement companies in FTC and FDA litigation and proceedings. He also represents numerous healthcare clients in various regulatory compliance matters and litigation, including state and federal investigations.

Food and Dietary Supplement Safety and Regulation Conference

March 24-25, 2021

Attendee List *(current as of 3.23.21)*

First Name	Last Name	Job Title	Company Name	City and State
Claudia	Ahiabor	General Attorney	FDA - OC	Silver Spring, MD
Cheryl	Alesso	Vice President, Business Development	RQA, Inc.	Mahwah, NJ
Steven	Armstrong*	Senior Regulatory Advisor	Haynes and Boone LLP	Washington, DC
Morgan	Barg	Director, Global Regulatory Affairs	Mannatech, Inc.	Dallas, TX
April	Bartosch	Supervisory Regulatory Specialist	FDAImports.com, LLC/ Benjamin L. England & Associates LLC	Fredericksburg, VA
Laurie	Beyranevand	Professor of Law and Director	Vermont Law School	South Royalton, VT
Laura	Braden	Regulatory Counsel	The Good Food Institute	Washington, DC
Mari Beth	Cansanay	Senior Associate, Regulatory Affairs	Mannatech, Inc.	Coppell, TX
Coleen	Carney	Manager, Meetings	Food and Drug Law Institute (FDLI)	Washington, DC
Iris	Case	Student	Johns Hopkins University	Clarksville, MD
Seda	Celik	Senior Associate, Regulatory Affairs	The Hain Celestial Group	Lake Success, NY
Jacqueline	Chan*	Partner	Kleinfeld, Kaplan & Becker, LLP	Washington, DC
Katherine	Collins	Regulatory Counsel	FDA - CVM	Rockville, MD
Tara Lin	Couch	Senior Director of Dietary Supplement and Tobacco Services	EAS Consulting Group	Woodland Park, CO
Walery	Desmond	Regulatory Liaison, Global Consumer Safety	Michigan State University	Pasadena, CA
Sam	Dietle	Senior Associate	Hogan Lovells US LLP	Washington, DC
Andrew	Do	Associate	Covington & Burling LLP	Silver Spring, MD
Jason	Downey	Staff Fellow	FDA - CFSAN	College Park, MD
Robert	Durkin	Of Counsel	Arnall Golden Gregory LLP	Washington, DC
Daniel	Dwyer	Partner	Kleinfeld, Kaplan & Becker, LLP	Washington, DC
Elizabeth	Fawell*	Partner	Hogan Lovells US LLP	Washington, DC
Andrea	Ferrenz*	Food Law Counsel	Campbell Soup Company	Camden, NJ
Neal	Fortin*	Professor and Director	Michigan State University	Okemos, MI
Eileen	Francis	Reporter	Informa PLC	Rockville, MD
Vasilios (Bill)	Frankos	Senior Vice President, Product Compliance and Safety	Herbalife International of America Inc	Torrance, CA
Tess	Garraty	Manager, Member Engagement	Food and Drug Law Institute (FDLI)	Washington, DC
Madeleine	Giaquinto	Manager of Regulatory Affairs at Greenleaf Health	Greenleaf Health, Inc.	Washington, DC
Anastasia	Gilmartin	Director of Regulatory Compliance, Counsel	Bodybuilding.com	Seattle, WA
Kat	Giordano	Student	Stanford University	Palo Alto, CA
Rebecca	Goldberg	Associate Chief Counsel	FDA - OC	Rockville, MD
Jonathan	Havens	Partner | Co-Chair, Cannabis Law | Co-Chair, Food, Beverage & Agribusiness	Saul Ewing Arnstein & Lehr LLP	Baltimore, MD
Susan	Hewlings	Director of Scientific Affairs	Nutrasource Pharmaceutical & Nutraceutical Services	Cudjoe Key, FL
Bryan	Hitchcock	Senior Director, Food Chain and Executive Director, Global Food Traceability Center	Institute of Food Technologists	
Mical	Honigfort	Consumer Safety Officer	FDA - CFSAN	College Park, MD
Gregory	Jaffe	Biotechnology Project Director	Center for Science in the Public Interest	Washington, DC
John	Johnson	Of Counsel	Shook, Hardy & Bacon LLP	Washington, DC
Karil	Kochenderfer	Principal	LINKAGES	Potomac, MD
Laura	Kurpad	Attorney	FDA - OC	Silver Spring, MD
Kelly	Laudon	Of Counsel	Jones Day	Minneapolis, MN
Christine	Lawson	Partner	Womble Bond Dickinson (US) LLP	Atlanta, GA
Anthony	Lee	Supervisory Consumer Safety Officer	FDA - CFSAN	College Park, MD
Steven	Leslie	Assistant Director, Educational Programs	Food and Drug Law Institute (FDLI)	Washington, DC
Jane	Licata	Partner	Licata & Tyrrell P.C.	Marlton, NJ
Bill	Marler	Managing Partner	Marler Clark	Seattle, WA

Sharon	Mayl	Senior Advisor for Policy	FDA - OC	Silver Spring, MD
Jennifer	McEntire	Senior Vice President, Food Safety and Technology	United Fresh Produce Association	Washington, DC
Daniel	McGee	Former Chief Legal Officer	Solari Hemp	Longmont, CO
David	McPherson	Regulatory Affairs	The Kroger Company	Boca Raton, FL
Molly	McTaggart	Administrative Coordinator	Food and Drug Law Institute (FDLI)	Washington, DC
Heather	Messick	International Policy Analyst	HHS/PHS Food & Drug Administration	Silver Spring, MD
Joan	Murphy	Reporter	IHS Health Information	Arlington, VA
Louisa	Nickerson	Attorney	FDA - OC	Bethesda, MD
Fernanda	Nogueira	Regulatory Manager	Amway Corporation	Sao Paulo, Brazil
Gray	Norton	Student	University of Arkansas	Fayetteville, AR
Jessica	O'Connell	Partner	Covington & Burling LLP	Washington, DC
Elizabeth	Oestreich	VP Regulatory Compliance	Greenleaf Health, Inc.	Washington, DC
Lynn	O'Grady		Walgreen Company	Northbrook, IL
Janete	Oliveira	FDA - Administrative Assistant	US Department of State	Washington, DC
Megan	Olsen	VP & Associate General Counsel	Council for Responsible Nutrition	Washington, DC
Caitlion	O'Neill	Student	Loyola University- New Orleans	New Orleans, LA
Larisa	Pavlick	VAP Global Regulatory and Compliance	United Natural Products Alliance	Salt Lake City, UT
Jonathan	Pegg		IEG Policy	
Evangelia	Pelonis	Partner	Keller and Heckman LLP	Washington, DC
Paul	Pisano	Senior VP and General Counsel	National Beer Wholesalers Association	Alexandria, VA
Judith	Praitis	Partner	Faegre Drinker Biddle & Reath LLP	Los Angeles, CA
Margarita	Raycheva	Reporter	IEG Policy	Arlington, VA
Amy Comstock	Rick**	President & CEO	Food and Drug Law Institute (FDLI)	Washington, DC
Anita	Roach	Vice President of Health Innovation Strategies & Corporate Ventures	Food Allergy Research & Education (FARE)	Arlington, VA
Siarra	Rogers	Associate Attorney	Winston & Strawn LLP	Washington, DC
Larisa	Rudenko	Research Affiliate, Program of Emerging Technologies	Massachusetts Institute of Technology (MIT)	Cambridge, MA
Allen	Sayler	Senior Director of Food Consulting Services	EAS Consulting Group	Alexandria, VA
Cynthia	Schnedar**	Executive Vice President, Regulatory Compliance	Greenleaf Health, Inc.	Washington, DC
Elizabeth	Sharpe	Food Safety Manager	Red Rabbit, LLC	Jersey City, NJ
John	Sheehan	Food Technologist	FDA	College Park, MD
Mollie	Soloway	Student	University of Maryland Carey School of Law	Baltimore, MD
Ge	Song	Associate Attorney	Faegre Drinker Biddle & Reath LLP	Washington, DC
Baiyun	Song		Mannatech, Inc.	Coppell, TX
Malcolm	Spicer	Consumer Health Care Products Editor	Informa PLC	Washington, DC
Suzie	Trigg	Partner	Haynes and Boone LLP	Dallas, TX
Laura	Tyler		Mannatech, Inc.	Coppell, TX
Kiana	Walker	Web Manager	Food and Drug Law Institute (FDLI)	Washington, DC
Lynn	Walsh	Manager-Legal Services	Bolthouse Farms	Bakersfield, CA
Beth	Wang	Reporter	InSide Washington Publishers	Arlington, VA
Matthew	Watson	Student	Pace University School of Law	White Plains, NY
Jack	Wenik	Member	Epstein Becker & Green, PC	Newark, NJ
Ren	White	Manager, Publications	Food and Drug Law Institute (FDLI)	Washington, DC
Mark	Yacura	Attorney at Law, Partner	Fox Rothschild LLP	Washington, DC
Emily	Yslas	Student	University of Wisconsin	Madision, WI
Janet	Zhang	Food Technologist	FDA - CFSAN	College Park, MD
Daniel	Zinn	Manager, Membership & Communications Analytics	Food and Drug Law Institute (FDLI)	Washington, DC

***Member, Conference Planning Committee**

****Member, FDLI Board of Directors**