

ANNUAL CONFERENCE

prop.65clearinghouse

MONDAY, SEPTEMBER 23, 2024

JULIA MORGAN BALLROOM

11:15 to 12:15 Beech-Nut Lives On: Calculating Exposure in Food

Round Table: **Dennis Raglin**, Partner, Steptoe
Carolyn Scrafford, Principal Scientist, Exponent
Margaret Whittaker, Managing Director and Chief Toxicologist, ToxServices

Beech-Nut Lives On

Bios

Dennis Raglin Partner, Steptoe

Dennis Raglin has over 25 years of experience counseling and defending clients in California's Proposition 65 right-to-know chemical warnings law and is co-chair of Steptoe's Prop 65 group. He is a tenacious litigator who has represented clients in bet-the-company cases. Dennis was trial counsel in one of the few Prop 65 cases to ever be tried to verdict in the law's 37-year history – representing a national food manufacturer. He was also part of the team achieving victory at the California Court of Appeals establishing federal law preempts Prop 65 warnings for generic over-the-counter medication. He has also secured favorable settlements for national clients in high-profile Prop 65 suits brought by the state Attorney General. His practice includes knowledge of, and counseling on, a broad range of other state and federal chemical laws and regulations, including those related to foods and the FDA, PFAS, personal and children's products, TSCA and CPSIA, packaging and recycling, and green chemistry initiatives.

Dennis works with companies large and small to understand these laws and fashion the most effective outcome, whether it be a strengthened compliance program, resolution and settlement, or through litigation - always with an eye toward what works and what gets the best results. Dennis partners with his clients to understand their business and then works together to achieve their goals.

Dennis also defends clients in products liability matters, with a focus on medical devices and

pharmaceuticals. He is currently California counsel for a national medical device manufacturer. His diverse experience has encompassed defending products such as implantable and prescription medical devices, prescription and over-the-counter pharmaceuticals, biologics, baby and toddler formula and nutritional supplements.

Dennis has been both a speaker and an author of numerous articles in his fields of practice. He has spoken to various companies and trade groups on best practices for compliance with Prop 65 and regulations in California and other states related to green chemistry, PFAS chemicals, and consumer product chemical reporting obligations, all issues of increasing importance with states across the country enacting more regulations in these areas. He has also written numerous articles on the constitutionality of Prop 65, including on the issue of federal preemption. In the area of medical and pharmaceutical products, he has presented and written on topics related to FDA regulation of nutritional supplements, best practices in complying with FDA guidance governing device and pharmaceutical companies' social media policies, and scientific information exchange.

Carolyn Scrafford

Principal Scientist, Exponent

Dr. Scrafford has over 20 years of multi-disciplinary experience in epidemiological methods, applied statistics, and risk assessment to evaluate the human health effects of food contaminants and additives, nutrients, and environmental compounds in the U.S. as well as Europe and other international settings. She has designed, conducted, and analyzed data from national, market basket, customized surveys on food consumption patterns and has experience in using that data to conduct dietary risk assessments for food ingredients, nutrients, heavy metals, and contaminants.

Dr. Scrafford provides technical and expert support related to dietary exposure to food toxins and contaminants including lead, cadmium, inorganic arsenic, and acrylamide. Dr. Scrafford has expertise in designing sampling protocols with the objective to determine levels of components and contaminants in food products currently in the marketplace. Dr. Scrafford is responsible for analyzing the survey results to estimate the concentration of the contaminants in the food that is combined with consumption data to estimate consumer exposure to these compounds through the diet. As part of this work, Dr. Scrafford has presented and testified on topics related to statistics, dietary consumption patterns, dietary exposure, and risk assessment.

Dr. Scrafford has developed GRAS notifications, Food Additive Petitions (FAPs), and Color Additive Petitions (CAPs) in support of pre-market approval submissions to the U.S. FDA as well as regulatory submissions to other international authoritative bodies by providing evaluations of the human safety data and conducting dietary exposure assessments. The exposure assessments are based on a variety of large databases from the US and other countries including NHANES (National Health and Nutrition Examination Survey), the United Kingdom's National Diet and Nutrition Survey (NDNS), EFSA's Comprehensive European Food Consumption Database, and USAID's Demographic and Health Surveys (DHS). As part of these submissions, Dr. Scrafford communicates complex scientific information directly with federal regulators and other key stakeholders.

Dr. Scrafford has expertise in the synthesis of epidemiological evidence to both quantitatively and qualitatively evaluate causal associations between dietary and environmental exposures and health outcomes. With a background in epidemiological methods and analysis, Dr. Scrafford has expertise in the synthesis of epidemiological evidence to both quantitatively and qualitatively evaluate causal associations between dietary and environmental exposures and health outcomes. Scrafford has evaluated study protocols for clients conducting clinical trials designed to measure the association between novel food and dietary supplement products on specific health outcomes including weight loss and gastrointestinal health in support of safety and efficacy evaluations. She has also collaborated with academic institutions to investigate the association between dietary patterns and health outcomes using data from ongoing prospective cohort studies.

Dr. Scrafford has an undergraduate degree in Biology from Colgate University. Concurrent to her work at Exponent, she earned her MPH (Masters of Public Health) in environmental health, MHS (Masters of Health Science) in Biostatistics, and a Ph.D. and post-doctoral fellowship in epidemiology at Johns Hopkins University Bloomberg School of Public Health. While at Hopkins, Dr. Scrafford was awarded a training grant from 2008-2010 by the National Institutes of Health to conduct research related to maternal and child

nutrition and health in international settings. Dr. Scrafford is a Professorial Lecturer at George Washington University's Milken Institute School of Public Health where she teaches a course on global child health. She is a member of the American College of Epidemiology, the International Epidemiological Association, and the American Society for Nutrition. She has co-authored many peer-reviewed published scientific manuscripts relating to the work she has done both at Exponent and in collaboration with colleagues at Johns Hopkins University and in Nepal.

Margaret Whittaker

Managing Director and Chief Toxicologist, ToxServices

Dr. Margaret "Meg" Whittaker is the Managing Director and Chief Toxicologist of ToxServices LLC. She is an accomplished human health risk assessor, chemical hazards assessor, and alternatives assessor. Dr. Whittaker performs quantitative exposure and risk assessments for projects including California Proposition 65 safe harbor assessments, medical device extractables and leachables assessments, consumer product safety assessments, and cosmetics/personal care product assessments, among others.

Dr. Whittaker is a Diplomate of the American Board of Toxicology who earned a Ph.D. in Toxicology from The University of Maryland, Baltimore and an M.P.H. in Environmental Health from The University of Michigan. Dr. Whittaker is a U.K./EuroTox Registered Toxicologist, as well as a Chartered Biologist and Fellow of the U.K. Royal Society of Biology. Meg has served as an officer on multiple SOT Specialty Section and Regional Chapters, including the Metals Specialty Section, Mixtures Specialty Section, Sustainable Chemicals for Contemporary Toxicology (SCCT) Specialty Section, and the National Capital Area Chapter of SOT. She served as a member of the SOT Nominating Committee from 2021-2023, and has served as an SOT Roving Reporter since 2014.