vCONFERENCE

prop 65 clearinghouse

Annual Conference

Monday, September 21, 2020

Breakout Session
4:00 to 5:00

New Prop. 65 Hurdles Facing The Marijuana And Alcohol Industry

Moderator: **Joel Cohen**, Senior Toxiologist, Gradient
Panel: **Cynthia Bryant**, Chief Business Officer, Demetrix
Anne Marie Ellis, Senior Counsel, Buchalter
Natalie Rainer, Counsel, Keller & Heckman
Will Wagner, Associate, Greenberg Traurig

Bios

Joel Cohen

Senior Toxiologist, Gradient

Dr. Cohen is a senior toxicologist with specialties in computational toxicology and human health risk assessment. At Gradient, his primary responsibilities include chemical hazard and risk assessment, consumer product safety evaluation, particulate matter inhalation exposure assessment and dose modeling, and non-clinical safety assessments of medical device and pharmaceutical components.

Before joining Gradient, Dr. Cohen earned his doctoral degree at the Harvard School of Public Health, applying in vitro cellular models to study the fate, transport and toxicity of nanoparticles in the lung. He has authored several peer-reviewed articles and one patent, and presented his work to academic and general audiences. Dr. Cohen holds a Visiting Scientist appointment at the Harvard T. H. Chan School of Public Health where he researches the applications and human health implications of nanomaterials across the life cycle of nano-enabled products.

Representative Projects

Evaluation and Literature Review of Printing Technology Emissions: Conducted a literature review evaluating the physico-chemical properties and toxicological hazard profiles of particulate emissions from printers and copy machines. Special attention was paid to characterizing exposure composition and concentrations of nanoparticles emitted during the printing process. Findings were summarized in a high level fact sheet for distribution internally and to consumers.

Evaluation of Lead Releases from Consumer Products: Developed and applied adult blood lead model to predict blood lead levels from discontinuous exposures to lead released from a consumer product.

Evaluation and Comment on Alternatives Analysis Regulatory Guidance: Assisted in developing comments on the California Department of Toxic Substances Control's (DTSCs) Draft Alternatives Analysis Guide (AA Guide). Reviewed the draft guidance in the context of other available AA frameworks, provided comments about the suitability of various tools and methods suggested by DTSC for carrying out an AA, and offered possible solutions for ways to improve the draft guidance as written.

Evaluation of Residue Accumulation on Wearable Electronic Devices: Designed and managed a clinical study to evaluate the accumulation of chemical and biological residue on the surface of a wearable electronic device. Evaluated the effect of following recommended product care and cleaning procedures, as well as the effect of a proposed antimicrobial additive. Summarized the results in a series of presentations and documented findings in a final report.

Evaluation and Comment on Sunscreen Regulatory Guidance: Reviewed the United States Food and Drug Administration's (FDAs) Over the Counter Sunscreens draft guidance. Considered the proposed methods in the context of Toxicology in the 21st century (Tox21) principles, and efforts towards adopting alternative testing methods for chemical hazard and risk assessment. Comments were provided to FDA as part of the public comment period.

Cynthia Bryant

Chief Business Officer, Demetrix

Cynthia leads all aspects of the commercial business at Demetrix. She has over 15 years of experience building new biotechnology businesses and forging partnerships with some of the world's largest companies. Her experience spans from fuels and chemicals to personal and household care to pharmaceuticals. Cynthia's expertise in building global businesses is essential in helping Demetrix navigate the regulatory landscape and relationships across the globe.

Cynthia earned her MBA from the University of California, Berkeley.

Anne Marie Ellis

Senior Counsel, Buchalter

Anne Marie Ellis' practice focuses on product liability, commercial litigation, regulatory compliance and client counseling. She has litigated high-exposure cases involving allegedly defective products, food, toxic substances, motor vehicle collisions, large-scale wildland fires, construction defects, e-commerce, and consumer class actions.

She has significant experience with motor vehicles, motorcycles, food and cosmetics, off-road vehicles, sporting goods equipment, power tools, exercise equipment, restaurants, trash and recycling haulers and amusement park venues. Ms. Ellis regularly helps her clients navigate complex regulatory schemes such as the FDA and California's Proposition 65, and has been recognized as a thought leader in this subject matter. Ms. Ellis also consults with clients on warranty issues arising under state and federal statutes. Ms. Ellis consults and litigates cases involving concussions, head injuries and return to play laws throughout the country. Ms. Ellis also provides consultation regarding Title III of the Americans with Disability Act, and corresponding California statutes including the Unruh Civil Rights Act for brick and mortar stores and websites.

With extensive experience in complex litigation, Ms. Ellis has successfully defended cases of all sizes including catastrophic personal injury and wrongful death lawsuits. She also advises clients on a wide-range of discovery issues and procedures including e-discovery and trade secrets.

Outside of work, Ms. Ellis has served as a Board Member and Vice-Chair to the Board of Directors of WHW (formerly known as Women Helping Women). Currently, Ms. Ellis is a Member of the Founders Guild of Casa Teresa, where she is an active fundraiser and dedicates significant volunteer time at Holy Family Cathedral School in Orange. She was also recently recognized by JD Supra as a Top Author in the area of products liability for the 2019 Readers' Choice Awards, which acknowledges top authors and firms for their thought leadership in key topics.

Natalie Rainer

Counsel, Keller & Heckman

Natalie Rainer practices in the area of food and drug law. She advises clients on regulatory requirements for foods, dietary supplements, cosmetics, and food and drug packaging in jurisdictions around the world, including North America, Latin America, Europe, Asia, and the Middle East.

Ms. Rainer's practice includes evaluating the regulatory status of food-contact materials, food additives, and color additives; advising companies on advertising and labeling requirements (including claim substantiation, nutrition labeling, menu labeling and environmental/green claims); and counseling clients on the Food Safety Modernization Act and its regulations. She also advises clients on compliance with U.S. Department of Agriculture regulations, including the Bioengineered Labeling rules, organic rules, and regulations related to additives in meat and poultry products. Additionally, Ms. Rainer advises clients on the practical application of Proposition 65 and assists in defending against Proposition 65 enforcement actions.

Will Wagner

Associate, Greenberg Traurig

Will Wagner focuses his practice in the areas of consumer product defense and regulatory enforcement litigation, including California's unique Proposition 65, California regulatory actions pertaining to labeling and emissions of Volatile Organic Compounds (VOC) from consumer products, and actions under the Consumer Legal Remedies Act (CLRA) and Unfair Competition Law (UCL). Will also handles writ actions related to administrative decisions and procedures, along with commercial disputes and accessibility cases under the Americans With Disabilities Act.

In addition to litigation, Will counsels clients on a variety of compliance issues including:

- Proposition 65 matters involving California's Office of Environmental Health Hazard Assessment (OEHHA);
- VOC emission and labeling matters involving the California Air Resources Board (CARB) and the South Coast Air Quality Management District (SCAQMD);
- CARB and Environmental Protection Agency (EPA) regulations pertaining to formaldehyde in composite wood products; and various other consumer product regulations.

He is admitted to practice in California, Arizona, and Nevada, handling matters before administrative agencies, trial courts, and appellate matters before state supreme courts and the Ninth Circuit Court of Appeals.w