

Keller and Heckman E-Vapor and Tobacco Law Symposium

Day 1 – Tuesday, February 6, 2018

- 8:00 a.m. – 8:30 a.m. **Registration and Continental Breakfast**
- 8:30 a.m. – 8:35 a.m. **Welcome and Introduction to Keller and Heckman LLP**
Azim Chowdhury, Partner, Keller and Heckman
- 8:35 a.m. – 10:00 a.m. **Tobacco Control Act and the Deeming Rule: *How We Got Here and What Happens Next***
Azim Chowdhury, Partner, Keller and Heckman
- Deeming Regulation History: How We Got Here
 - Registration and Product Listing, Health Documents, HPHC Testing and Other Tobacco Control Act Requirements
 - Premarket Review and New Compliance Deadlines
 - Substantial Equivalence (SE) Reports
 - Label and Warning Requirements
 - Modified Risk Tobacco Products and Health Claims
 - Tobacco Product Standards – Flavors and Devices
 - Using Tobacco Product Master Files
 - Retailer Compliance, Sample Bans & Do's and Don'ts
 - Status of Nicotine Salts and Tobacco-Free Nicotine (TFN)
 - Gottlieb's New FDA and Impact on the Vapor Industry
- 10:00 a.m. – 10:45 a.m. **Good Manufacturing Practices and FDA Inspections**
Dean Cirotta, President and Chief Operating Officer, EAS Consulting Group
- Quality and the FDA
 - Current FDA cGMP Regulations and Potential Impact on Tobacco GMP Regulations
 - FDA Inspections and Enforcement
 - Managing FDA Inspections
- 10:45 a.m. – 11:00 a.m. **Networking and Vape Break**
- 11:00 a.m. – 11:45 a.m. **Hazardous Waste Management Pitfalls of Nicotine-Containing Products**
JC Walker, Partner, Keller and Heckman
- Handling E-Liquid and Hazardous Waste
 - How to Prepare for State EPA Inspections

- 11:45 a.m. – 12:45 p.m. **UL 8139 – Safety Standard for Electrical Systems of Electronic Cigarettes and Vaping Devices**
Michael Sakamoto, BD Manager, UL Consumer Technology Division
Flore Chiang, Principal Engineer, UL Taiwan Co., Ltd.
- Battery Safety Concerns
 - Overview of UL 8139 Safety Standard
 - Certification Process
- 12:45 p.m. – 2:15 p.m. **Lunch, provided by Keller and Heckman**
Special Presentation: CBD and Cannabis – What are the Risks?
Chris Van Gundy, Partner, Keller and Heckman
- Legal Status of CBD and Cannabis – DEA, Controlled Substances Act & State Laws
 - FDA Regulation of CBD in E-Liquids
 - California Emergency Cannabis Regulations
- 2:15 p.m. – 3:15 p.m. **FDA Premarket Tobacco Product Application (PMTA)**
Amy Madl, PhD, DABT, Senior Principal Health Scientist, Cardno ChemRisk
Autumn Bernal, PhD, Supervising Health Scientist, Cardno ChemRisk
- PMTA Data Requirements
 - Assessing the Public Health Impact of a Product
 - A Look at the PMI iQOS Application
 - A Consortium Approach: How Vapor Companies Can Work Together
- 3:15 p.m. – 3:30 p.m. **Networking and Vape Break**
- 3:30 p.m. – 4:15 p.m. **U.S. Consumer Product Safety Commission (CPSC) Requirements**
Nathan Cardon, Associate, Keller and Heckman
- Overview of CPSC
 - Children's Nicotine Poisoning Prevention Act (CNPPA) Requirements
 - Requirements for General Certificate of Conformity (GCC)
 - General Product Safety Considerations
 - Managing Battery Safety
- 4:15 p.m. – 5:15 p.m. **Business, IP, and Advertising Issues – How to Stay in Compliance**
Bob Niemann and Tracy Marshall, Partners, Keller and Heckman
- Drafting and Negotiating Vendor, Manufacturing, and Distribution Agreements
 - Insurance Policies for Vapor Companies
 - Website Terms and Conditions and Privacy Policies
 - Protecting your Trademarks, Copyrights, and Trade Secrets and Avoiding Infringing the Intellectual Property Rights of Others
 - Using Social Media to Promote your Business
 - Conducting Contests, Sweepstakes, and Other Promotions
 - Laws Governing Commercial E-mail Messages and Text Messaging
- 5:15 p.m. – 5:30 p.m. **Final Questions**
- 5:30 p.m. – 6:30 p.m. **Networking Reception, hosted by Keller and Heckman**

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Day 2 – Wednesday, February 7, 2018

- 8:00 a.m. – 8:30 a.m. **Continental Breakfast**
- 8:30 a.m. – 9:15 a.m. **FDA Ingredient Listing Process**
Azim Chowdhury, Partner, Keller and Heckman
Ben Wolf, Associate, Keller and Heckman
- Overview of Ingredient Listing Requirement
 - Step-by-Step Instructions and Demonstration of FDA eSubmitter and CTP Portal
- 9:15 a.m. – 10:15 a.m. **Deeming Lawsuit Update**
Eric Gotting, Partner, Keller and Heckman
- Nicopure and Right to be Smoke-Free Coalition Appeal Update
 - How You Can Help
- Current Trends in E-Cig and Vapor Class Actions**
Bob Niemann, Partner, Keller and Heckman
- Class Action Lawsuits and How to Protect Yourself
- 10:15 a.m. – 10:30 a.m. **Networking and Vape Break**
- 10:30 a.m. – 11:15 a.m. **Requirements Under the EU Tobacco Products Directive (TPD)**
Marcus Navin-Jones, Partner, Keller and Heckman
- Overview of TPD Requirements
 - Product Standards
 - New Product Notifications
 - Labeling Requirements under TPD and CLP
 - Other EU Regulations Applicable to Vapor Products
 - Certain Member State Requirements
- 11:15 a.m. – 12:00 p.m. **Navigating the UK and the Medicines and Healthcare Products Regulatory Agency (MHRA)**
Chris Allen, Co-Founder & Managing Director, Broughton Laboratories
- History of TPD and Marketing Authorisation Application (MAA) – Evolution with the MHRA
 - TPD vs MAA – Two Ends of the Spectrum
 - Current Issues within the UK – Shortfills, Quality Control, Lack of Enforcement, etc.
 - Impact of TPD on Public Perception of Vapor Products

- 12:00 p.m. – 1:15 p.m. **Lunch, provided by Keller and Heckman**
Special Presentation: Market Reaction to Regulation
Tim Phillips, Managing Director, ECigIntelligence
- Impact of TPD and Other Regulations on European E-Vapor Market
 - Growth of Pods Systems in the US: Will They Work in Europe?
 - Prospects for Tax in the US in 2018: Global Market Reactions
 - Heated Tobacco and Alternatives: Market Reaction Compared to E-Vapor
 - Predictions for 2018 and Beyond
- 1:15 p.m. – 2:15 p.m. **Current Regulatory Status of E-Cigarettes in Asia and Middle East**
David Ettinger, Partner, Keller and Heckman Shanghai Office
- World Health Organization (WHO)
 - China and Asia
 - New Zealand
 - Australia
 - Russia, India, Middle East, and More!
- 2:15 p.m. – 3:00 p.m. **Electronic Cigarette and Vapor Product Taxation**
Paul Blair, Strategic Initiatives Director, Americans for Tax Reform
- Overview of State Vapor and Tobacco Taxes
 - State Taxation Trends for 2018
- 3:00 p.m. – 3:30 p.m. **California Tax and License Requirements**
Robert Zivkovich, CA Department of Tax and Fee Administration (CDTFA)
- Overview of Prop 56 Tax for E-Vapor and Other Tobacco Products
 - Cigarette & Tobacco Products Licensing Act Requirements
- 3:30 p.m. – 3:45 p.m. **Networking and Vape Break**
- 3:45 p.m. – 4:15 p.m. **STAKE Act and California Proposition 65**
Mitzi Clark and Azim Chowdhury, Partners, Keller and Heckman
- CA STAKE Act Requirements for Age Verification
 - Prop 65 Background and Enforcement Actions Against Vapor Companies
 - New Prop 65 Warning Requirements
- 4:15 p.m. – 4:45 p.m. **Flavor Ban Update**
Stefan Didak, Founder & President, Not Blowing Smoke
- Update on San Francisco and Other CA Flavor Bans
- 4:45 p.m. – 6:30 p.m. **Update on State Laws: Licensing Requirements**
- Indiana – **Amy Netherton, President, Indiana Smoke-Free Alliance**
 - New York – **Mary Bielaska, Founder and CEO, Zanicorn International Ltd.**
 - Texas & Beating Tobacco 21 – **Schell Hammel, President, The Vapor Bar**
 - Arkansas, Utah, Iowa, and more - **Azim Chowdhury, Partner, K&H**
- 6:30 p.m. **Final Questions and Seminar Adjourns**