

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. **Overview of Tobacco Control Act and the FDA Deeming Regulation**
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
 - Update on Cole/Bishop
- 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 p.m. **Environmental Concerns for Vapor Companies**
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. – 2:00 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
- 2:00 p.m. – 3:00 p.m. **A Practical Approach to Premarket Tobacco Product Applications (PMTAs)**
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
- 3:00 p.m. – 3:15 p.m. **Networking and Vape Break**
- 3:15 p.m. – 4:00 p.m. **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)
- 4:00 p.m. – 5:00 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, Distribution, and Nondisclosure 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
- 5:00 p.m. – 5:15 p.m. **Final Questions**
- 5:15 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 and Class Action Litigation**
Eric Gotting and Bob Niemann, Partners, Keller and Heckman
- Nicopure and Right to be Smoke-Free Appeal Update
 - How You Can Help
 - Class Action Lawsuits and How to Protect Yourself
- 10:15 a.m. – 10:30 a.m. **Networking and Vape Break**
- 10:30 a.m. – 11:30 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
- 11:30 a.m. – 12:15 p.m. **Market Reaction to Regulation: EU Market Impact from TPD; Future Regulatory Impact on U.S. and Other Markets**
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

- 12:15 p.m. – 1:30 p.m. **Lunch**, *provided by Keller and Heckman*
Special Presentation: 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
- 1:30 p.m. – 2:30 p.m. **Global Requirements for Vapor and Other Tobacco Products**
David Ettinger, Partner, Keller and Heckman Shanghai Office
– World Health Organization (WHO)
– China and Asia
– Canada
– Russia
– India, Middle East, and More!
- 2:30 p.m. – 3:15 p.m. **U.S. State Vapor Tax Overview**
Paul Blair, Strategic Initiatives Director, Americans for Tax Reform
– Overview of State Vapor and Tobacco Taxes
– State Taxation Trends for 2018
- 3:15 p.m. – 3:30 p.m. **Networking and Vape Break**
- 3:30 p.m. – 4:15 p.m. **California Propositions 56 & 65 and STAKE Act**
Mitzi Clark and Azim Chowdhury, Partners, Keller and Heckman
– Prop 65 Background and Enforcement Actions Against Vapor Companies
– New Prop 65 Warnings Requirements
– Prop 56 Tax and Cigarette & Tobacco Products Licensing Act Requirements
– CA STAKE Act Requirements for Age Verification
- 4:15 p.m. – 4:35 p.m. **Flavor Ban Update**
Stefan Didak, Founder & President, Not Blowing Smoke
– Update on San Francisco and Other CA Flavor Bans
- 4:35 p.m. – 6:00 p.m. **Other State Vapor Laws**
– Indiana – **Amy Lane, President, Indiana Smoke-Free Association**
– New York State & NYC – **Mary Bielaska, GC, NY State Vapor Association**
– Texas & Beating Tobacco 21 – **Schell Hammel, President, The Vapor Bar**
– Arkansas, Utah, Iowa, Delaware and More - **Azim Chowdhury, Partner, K&H**
- 6:00 p.m. **Final Questions and Seminar Adjourns**