

Keller and Heckman E-Vapor and Tobacco Law Symposium

Day 1 – Tuesday, February 6, 2018

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| 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– Handling E-Liquid and Hazardous Waste– How to Prepare for State EPA Inspections |

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| 11:45 a.m. – 12:45 p.m. | UL 8139 – Safety Standard for Electrical Systems of Electronic Cigarettes and Vaping Devices
Michael Sakamoto, UL Consumer Technology Division <ul style="list-style-type: none">– Battery Safety Concerns– Overview of UL 8139– 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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

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| 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– 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, General Counsel, New York 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**