

Keller and Heckman E-Vapor and Tobacco Law Symposium

Staying in Compliance and Staying in Business in the Face of Regulatory Uncertainty

Day 1 – Tuesday, February 11, 2020

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| 7:30 a.m. – 8:30 a.m. | Registration and Breakfast |
| 8:30 a.m. – 8:35 a.m. | Welcome and Introduction to Keller and Heckman |
| 8:35 a.m. – 9:45 a.m. | FDA Update: Where We Go From Here
Azim Chowdhury, Partner, Keller and Heckman <ul style="list-style-type: none">- Tobacco Control Act and Deeming Rule Requirements- Update on FDA Compliance Policy and Deadlines: Flavor Bans and What the New Guidance Means- Premarket Pathways & Overview of PMTA Proposed Rule and Guidance- Recent PMTA and MRTP Authorizations- Using Tobacco Product Master Files- FDA Warning Letter and Enforcement Update- Protecting Youth and Harm Reduction – How to Achieve Both- Harmful and Potentially Harmful Constituents- Nicotine Salts vs. Flavors- Online Sales: Age Restriction and Verification- Strategies for Small Businesses: Retailer Compliance- and more! |
| 9:45 a.m. – 10:30 a.m. | Litigation Update: Status of Appeal and New Lawsuits
Eric Gotting and Azim Chowdhury, Partners, Keller and Heckman <ul style="list-style-type: none">- Industry PMTA Deadline Appeal: <i>American Academy of Pediatrics v. FDA</i>- <i>Vapor Technology Association v. FDA</i>- Other Challenges to Deeming Rule and FDA- State Actions Against Vapor Companies |
| 10:30 a.m. – 10:45 a.m. | Vape Break |
| 10:45 a.m. – 11:30 a.m. | The Other Premarket Pathways: SE Reports and SE Exemptions
Kathryn Skaggs, Associate, Keller and Heckman <ul style="list-style-type: none">- Establishing Grandfathered Status for Deemed Products- Overview of SE and SE Exemption Pathways- SE Report Proposed Rule- Recreating Products, Surrogates, and Testing Requirements |

11:30 a.m. – 12:15 p.m.

The Next Frontier: Are China and UAE Opening the Door to E-Cigarettes?

David Ettinger, Partner, Keller and Heckman Shanghai Office

- The China Pathway
 - o Governing Authorities and Regulations
 - o New Proposed E-Cigarette Standard
- The UAE Pathway
 - o New Regulation on Electronic Nicotine Products
 - o Regional Considerations, e.g., Dubai, Abu Dhabi
- Opportunities and Challenges

12:15 p.m. – 1:30 p.m.

Lunch, provided by Keller and Heckman

Getting Trump to Get Vaping: How We Stopped Prohibition (For Now) One Century After Its First Failure

Keynote Speaker: Paul Blair, Director of Strategic Initiatives, Americans for Tax Reform

1:30 p.m. – 2:15 p.m.

Consumer Product Safety Commission - Big Year for CNPPA Enforcement

Boaz Green, Counsel, Keller and Heckman

- Child Nicotine Poisoning Prevention Act (CNPPA)
 - o Child-Resistant Packaging
 - o Flow Restricted Packaging
 - o General Certificates of Conformity
- Handling CPSC Enforcement Actions
- FDA Guidance on Packaging and Battery Safety

2:15 p.m. – 3:15 p.m.

Premarket Tobacco Applications for E-Liquids and ENDS

Guest Speaker: Amy Madl, Ph.D., DABT, Senior Principal Health Scientist, Cardio ChemRisk

- Non-Clinical and Clinical Studies
- Bridging Strategies and Leveraging the Published Literature
- Risk Assessment to Inform on the Appropriateness for Public Health (APPH)

3:15 p.m. – 3:30 p.m.

Vape Break

3:30 p.m. – 4:15 p.m.

Hazardous Waste Management and Environmental Concerns for Vapor Manufacturers

James Votaw, Partner, Keller and Heckman

- Overview of Hazardous Waste Regulations Governing E-Liquid Manufacturers and Distributors
- Considerations for Minimizing Regulatory Exposure
- EPA and State Inspections

4:15 p.m. – 5:00 p.m.

Environmental Assessments for Vapor and Tobacco Product Applications

Peter Coneski, Ph.D., Scientist, Keller and Heckman

- Background on NEPA and FDA Environmental Assessments
- EA Requirements for PMTAs and SE Reports

- 5:00 p.m. – 5:30 p.m. **Final Q&A/Discussion**
- 5:30 p.m. – 6:30 p.m. **Happy Hour, hosted by Keller and Heckman**

Day 2 – Wednesday, February 12, 2020

- 8:30 a.m. – 9:15 a.m. **How to Sell Your Products in the EU (Without Getting into Problems): TPD and Beyond**
Marcus Navin-Jones, Partner, Keller and Heckman Brussels Office
- Refresher on TPD Requirements
 - EU Requirements which Apply in Addition to the TPD
 - EU Law vs. National Law: Areas Where EU Countries are Allowed to Have their Own Rules
 - Recalls, Withdrawals, and Legal Crisis Management
 - How Brexit is Affecting the Vapor Industry
- 9:15 a.m. – 10:00 a.m. **OSHA's Hazard Communication Standard and Considerations for the E-Liquid Industry**
Manesh Rath, Partner, Keller and Heckman
- Overview of OSHA's Hazard Communication Standard (HCS)
 - Scope of Standard and Exemptions
 - Safety Data Sheets (SDSs)
 - Labeling
 - Employee Training
 - Future Challenges for the E-liquid Industry
- 10:00 a.m. – 10:45 a.m. **State Law Update**
Azim Chowdhury, Partner, Keller and Heckman
- State Law Update: New Flavor Bans and State Taxes
 - California Proposition 56 Update
- 10:45 a.m. – 11:00 a.m. **Vape Break**
- 11:00 a.m. – 11:45 a.m. **Product Liability: Protecting Your Vapor Business**
Bob Niemann, Partner, Keller and Heckman
- Negligence vs. Strict Liability
 - Best Practices for Vape Shop Owners & What to Do If You Get Sued
 - Overheating and Exploding Devices – Are You Protecting Your Company?
 - Current Trends in Vapor Class Actions and Personal Injury Lawsuits
 - Juul Multi-District Litigation Update

- 11:45 a.m. – 12:30 p.m. **UL 8139: Safety Standard for Electrical Systems of E-Cigarettes and Vaping Devices**
Guest Speaker: Michael Sakamoto, Sr. Business Development Manager, UL Consumer Technology Division
Guest Speaker: Art Creidler, Business Development Specialist, UL Consumer Technology Division
- Overview of UL 8139 Safety Standard
 - UL 8139 Reference to FDA November 2019 Guidance
 - Certification Process
- 12:30 p.m. – 1:45 p.m. **Lunch, provided by Keller and Heckman**
The Politics of Tobacco and Vapor Control
Keynote Speaker: Stefanie Miller, Co-founder, Sandhill Strategy
- The Trump Administration, 2020 Presidential Elections & What to Expect in 2021
 - U.S. Congress: Prospects for New Tobacco Control Legislation (including S. 1253)
 - Public Health Stakeholders: Who to Watch
 - State Action: Which States to Watch in 2020
- 1:45 p.m. – 2:30 p.m. **Do E-liquid Flavors Affect the Production of HPHCs: Potential Impacts for Bridging Studies**
Guest Speaker: Gene Gillman, Ph.D., Enthalpy Analytical
- Review of Published Literature on E-Liquid Flavors and HPHC Compounds
 - Changes in Aldehydes and Glycidol Yields in Flavored E-Liquids
 - Effect of Flavors on the Production of Primary Constituents and Aerosol Mass
- 2:30 p.m. – 3:15 p.m. **Preparing Your Facility for GMPs and PMTAs**
Guest Speaker: Kevin Burd, CEO, Chemular
- GMP Definitions and Recent Guidance: Methods, Facilities, and Controls to Conform QMS Systems Risk
 - Hazard Analysis: Manufacturing, Packaging, and Storage
 - Documentation and Records Management
 - Testing and Methods
 - Stability
 - Handling Complaints
- 3:15 p.m. – 3:30 p.m. **Vape Break**

3:30 p.m. – 4:15 p.m.

Update on FDA Regulation of Cannabis and CBD

Rick Stearns, Partner, Keller and Heckman

- Current legal status of cannabis and cannabis-based compounds in FDA regulated products, including:
 - o Current status as controlled substances under the Federal Controlled Substances Act
 - o Impact of the Agricultural Improvement Act of 2018 (the Farm Bill)
 - o Legal basis for FDA's position (stated in December 2018) that it is unlawful to introduce food containing added CBD into interstate commerce or to market CBD products as, or in, food and dietary supplements
- Practical tips for companies to navigate this space in light of the legal and regulatory uncertainties that exist

4:15 p.m. – 5:00 p.m.

CBD in a Post-EVALI World: The Rise of CBD as a Key Product Category for the Cannabis Sector and the Impact of the US Vaping Crisis on its Growth

Guest Speaker: Tim Phillips; ECigIntelligence and CBD-Intel

- Growth of CBD globally, the challenges it faces from a regulatory perspective, and the part it plays in the global cannabis sector
- How the US THC vaping crisis has affected consumer perceptions about CBD and vaped cannabis products more generally
- Future growth prospects for CBD and challenges the category faces which might affect growth

5:00 p.m.

Seminar Adjourns