

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, January 29, 2019

- 7:45 a.m. – 8:15 a.m. **Registration and Continental Breakfast**
- 8:15 a.m. – 9:35 a.m. **FDA Overview and Compliance; State Law Update**
Azim Chowdhury, Partner, Keller and Heckman
- Deeming Rule Background
 - FDA Policy Update: Overview of New Announcements, Guidance and Rules
 - Product Compliance Overview: Vapor, Cigars, Hookah
 - Flavors and Product Standards
 - Documenting August 8, 2016 Status
 - Reporting on Harmful and Potentially Harmful Constituents (HPHCs)
 - Premarket Review for Deemed Tobacco Products
 - PMTAs, SE Reports and Using Master Files
 - Status of Proposed Rulemakings
 - Modified Risk Tobacco Products
 - Online Sales, Age-Verification and Retailer Compliance
 - Responding to Warning Letters
 - State Licensing and Age-Restriction Update
 -and much more!
- 9:35 a.m. – 10:20 a.m. **Litigation Update: Status of Appeal and New Lawsuits**
Eric Gotting, Partner, Keller and Heckman
- Deeming Rule Appeal: Nicopure and Right to be Smoke-Free Coalition v. FDA
 - American Academy of Pediatrics v. FDA
 - Potential Upcoming Litigation (e.g., Flavor Bans and State Challenges)
- 10:20 a.m. – 10:35 a.m. **State & Local Flavor Ban Update**
Guest Speaker: Greg Conley, President, American Vaping Association
- Update on State and Local Flavor Bans
 - California, New York and others
- 10:35 a.m. – 10:45 a.m. **Using Geographical Information Systems Analysis to Address Regulatory Concerns**
Guest Speaker: Johnny Chaklader, Director and Practice Lead, BDO USA, LLP
- Geographical Information Systems: Functional Overview
 - Business Analyst Module
 - Case Study
- 10:45 a.m. – 11:00 a.m. **Networking and Vape Break**

- 11:00 a.m. – 11:45 a.m. **Advertising and Marketing: Implications for Global Public Policy and the Role of Self-Regulation**
Sheila Millar, Partner, Keller and Heckman
- Marketing Practices: Impact on Public Perception, Regulations, Enforcement and Litigation
 - Expanding Global Concerns About Child-Appealing Marketing
 - Creating and Implementing Effective Advertising Self-Regulation
- 11:45 a.m. – 12:15 p.m. **State Law and Tax Update**
Guest Speaker: Paul Blair, Americans for Tax Reform
- Overview of State Vapor and Tobacco Taxes
 - State Taxation Trends for 2019
- 12:15 p.m. – 1:30 p.m. **Lunch, provided by Keller and Heckman**
Going International: Preparing Your Business for Global Compliance
David Ettinger, Partner, Keller and Heckman Shanghai Office
- Current Regulatory Status of E-Cigarettes in Asia and Middle East
 - China
 - New Zealand
 - Australia
 - Russia, India, Middle East
- 1:30 p.m. – 2:30 p.m. **Harmful and Potentially Harmful Constituent (HPHC) Overview and Scientific Panel**
Guest Panelists:
- **Chris Allen, Broughton Nicotine Services**
 - **Dr. Gene Gillman, Enthalpy Analytical**
 - **Kimberly Hesse, Global Laboratory Services**
 - **Dr. Amy K. Madl, Cardno ChemRisk**
- Moderator: Azim Chowdhury, Partner, Keller and Heckman**
- Scientific Insights and What You Need to Know About HPHCs
 - Analyzing Short-Term vs. Long-Term; Developing a Cost Effective HPHC Strategy
 - Laboratory Considerations: Understanding What to Look For
 - Testing Strategies: E-Liquid vs. Vapor/Aerosol
 - FDA Guidance: What Do We Know?
- 2:30 p.m. – 3:00 p.m. **Compliance and Testing Requirements for Deemed Combustibles: Cigars, Hookah and Pipe Tobacco**
Guest Speaker: Gene Gillman, Ph.D., Enthalpy Analytical
- Section 904 Reporting with the Abbreviated HPHC 20 List and Testing Requirements for Substantial Equivalence (SE) Applications
 - Mass Market Machine Made Cigars (MMCs)
 - Machine Smoking Conditions, HPHCs, and Expected Variability in Cigar Testing
 - SE Process and What Product Changes Might Trigger Additional Product Testing
- 3:00 p.m. – 3:30 p.m. **Networking and Vape Break**

3:30 p.m. – 4:15 p.m.

Regulatory Compliance, Product Stewardship and Beyond

Guest Speaker: Amy K. Madl, Ph.D., DABT, Cardno ChemRisk

- Consumer Product Safety – Effects on Human Health and the Environment
- Regulatory Compliance and Product Stewardship
- Performance-Driven, Science-Based, Stewardship Programs – Products that Improve the Lives of People, Minimize Impacts on Our Planet, and Foster Sustainable Innovation
- Concepts of a Product Stewardship Program and Implications for the Vapor Industry

4:15 p.m. – 5:00 p.m.

PMTA – Integration of Nonclinical and Clinical Research for Informing Protection of Public Health; How the Vapor Industry Can Work Together

Guest Speaker: Autumn Bernal, Ph.D., Cardno ChemRisk

- Pre-Market Approval of Tobacco Products by FDA – Demonstrate through PMTA that Product is Protective of Public Health
- Nonclinical and Clinical Research Supporting a PMTA Application
- Ways in which Product Testing, Toxicity Assays, and Human Clinical Studies can/should be Integrated to Characterize Impacts of Vapor Products on Human Health

5:00 p.m. – 5:15 p.m.

Industry Initiatives to Prevent Minor Access to Vapor Products

Guest Speaker: Schell Hammel, President, The Vapor Bar

- Youth Education, Protection & Prevention (YEPP)
- We ID and We Care Product Stewardship Programs and Implications for the Vapor Industry

5:15 p.m. – 6:30 p.m.

Networking Reception, hosted by Keller and Heckman

6:30 p.m.

End Day 1

Keller and Heckman E-Vapor and Tobacco Law Symposium

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

Day 2 – Wednesday, January 30, 2019

- 7:45 a.m. – 8:15 a.m. **Continental Breakfast**
- 8:15 a.m. – 9:00 a.m. **How to Sell Your Products in the EU (Without Getting into Problems): TPD and Beyond**
Marcus Navin-Jones, Partner, Keller and Heckman
- 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
- 9:00 a.m. – 9:45 a.m. **Hazardous Waste Management for the E-Liquid Industry**
JC Walker, Partner, Keller and Heckman
- Overview of Hazardous Waste Regulations Governing E-Liquid Manufacturers and Distributors
 - Considerations for Minimizing Regulatory Exposure
- 9:45 a.m. – 10:30 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 E-liquid Industry
- 10:30 a.m. – 10:45 a.m. **Networking and Vape Break**
- 10:45 a.m. – 11:30 a.m. **FDA Inspections: Are You Prepared?**
Azim Chowdhury, Partner, Keller and Heckman
Daniel Rubenstein, Associate, Keller and Heckman
- Overview of FDA Inspection Authority
 - Update on Tobacco Product Manufacturing Practices
 - The FDA Inspection: Before, During and After
 - Enforcement and Penalties
 - Keller and Heckman’s Audit and Inspection Program (AIP)

- 11:30 a.m. – 12:00 p.m. **CPSC: Jurisdiction and Enforcement Updates**
Boaz Green, Counsel, Keller and Heckman
- Requirements for Child-Resistant Packaging for Liquid Nicotine
 - Overview of Certificates of Compliance
 - CPSC Enforcement Updates
 - Battery Safety – Key Government and Private Initiatives Relevant to Manufacturers, Retailers, and Vapers
- 12:00 p.m. – 1:15 p.m. **Lunch, provided by Keller and Heckman**
Special Presentation: Canada’s New Regulatory Framework for Vapor Products
Guest Speaker: Marc Kealey, Canadian Vaping Association
- 1:15 p.m. – 1:30 p.m. **Fighting Excess Taxation and Regulation Through Communications**
Guest Speaker: Dan Blum, Vapors United
- Impact of Media on Vapor Tax and Regulatory Landscape
 - Working with Media: Who Should Tell Your Story & Top Talking Points and Resources
- 1:30 p.m. – 2:30 p.m. **Business, IP, and Advertising Issues – How to Stay in Compliance**
Tracy Marshall and Bob Niemann, Partners, Keller and Heckman
- Drafting and Negotiating Vendor, Manufacturing, and Distribution Agreements
 - Insurance Policies for Vapor Companies
 - Protecting Trademarks, Copyrights, and Trade Secrets and Avoiding IP Infringement
 - Privacy and Data Security
 - Using Digital Marketing to Promote Your Business
 - Conducting Contests, Sweepstakes, and Other Promotions
- 2:30 p.m. – 3:00 p.m. **Product Liability: Protecting Your Vapor Business**
Bob Niemann, Partner, Keller and Heckman
- Overheating and Exploding Devices – Are You Protecting Your Company?
 - Negligence vs. Strict Liability
 - Best Practices for Vape Shop Owners
 - What to Do If You Get Sued
- 3:00 p.m. – 3:15 p.m. **Networking and Vape Break**
- 3:15 p.m. – 4:00 p.m. **CBD – Legal Overview and Practical Tips for Businesses**
Chris Van Gundy, Partner, Keller and Heckman
- Learn the Latest on Federal and State Developments
 - Legal Issues in Sourcing
 - Tinctures, E-liquids, Edibles and “Medibles”
 - Risk Mitigation Checklist
 - FDA Considerations

4:00 p.m. – 4:30 p.m.

Indiana’s CBD Law

Guest Speaker: Amy Netherton, Indiana Smoke Free Alliance

- CBD Enforcement in Indiana
- Lesson Learned in Defining Low-THC Hemp Extract
- Distribution and Sales of Low THC Hemp Extract
- Penalties Under the Current Law
- Practical Applications of SEA-52

4:30 p.m. – 5:15 p.m.

CBD: Beyond Nicotine for the Vapor Industry?

Navigating this Complex High-Growth Cannabis Space Globally

Guest Speaker: Tim Phillips; ECigIntelligence and CBD-Intel

5:15 p.m.

Symposium Adjourns

**Please note, this is a draft agenda and is subject to change between now and the start of the program.*