

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

- 8:00 a.m. – 8:30 a.m. **Registration and Continental Breakfast**
- 8:30 a.m. – 10:00 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
 - ...and much more!
- 10:00 a.m. – 10:45 a.m. **Litigation Update and Flavor Bans**
Azim Chowdhury and Eric Gotting, Partners, 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)
- 10:45 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
- World Health Organization (WHO) Concerns

1:30 p.m. – 2:30 p.m.

Harmful and Potentially Harmful Constituent (HPHC) Overview and Scientific Panel

Guest Panelists:

- **Chris Allen, Broughton Labs**
- **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. – 5:15 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

5:15 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

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| 8:00 a.m. – 8:30 a.m. | Continental Breakfast |
| 8:30 a.m. – 9:15 a.m. | <p>How to Sell Your Products in the EU (Without Getting into Problems): TPD and Beyond
 Marcus Navin-Jones, Partner, Keller and Heckman</p> <ul style="list-style-type: none"> - 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. | <p>Environmental Issues Affecting Nicotine-Containing Products
 JC Walker, Partner, Keller and Heckman</p> <ul style="list-style-type: none"> - Overview of Hazardous Waste Regulations Governing E-Liquid Manufacturers and Distributors - Considerations for Minimizing Regulatory Exposure |
| 10:00 a.m. – 10:45 a.m. | <p>OSHA’s Hazard Communication Standard and Considerations for the E-Liquid Industry
 Manesh Rath, Partner, Keller and Heckman</p> <ul style="list-style-type: none"> - 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 |
| 10:45 a.m. – 11:00 a.m. | Networking and Vape Break |

- 11:00 a.m. – 11:45 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)
- 11:45 a.m. – 12:15 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
- 12:15 p.m. – 1:30 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
- 1:30 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.*