

# 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
  - State Licensing and Age-Restriction Update
  - .....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**

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### Day 2 – Wednesday, January 30, 2019

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|-------------------------|--|
| 8:00 a.m. – 8:30 a.m.   | <b>Continental Breakfast</b>   |
| 8:30 a.m. – 9:15 a.m.   | <p><b>How to Sell Your Products in the EU (Without Getting into Problems): TPD and Beyond</b><br/> <b>Marcus Navin-Jones, Partner, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>- Refresher on TPD Requirements</li> <li>- EU Requirements which Apply in Addition to the TPD</li> <li>- EU Law vs. National Law: Areas Where EU Countries are Allowed to Have their Own Rules</li> <li>- Recalls, Withdrawals and Legal Crisis Management</li> <li>- How Brexit is Affecting the Vapor Industry</li> </ul> |
| 9:15 a.m. – 10:00 a.m.  | <p><b>Environmental Issues Affecting Nicotine-Containing Products</b><br/> <b>JC Walker, Partner, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>- Overview of Hazardous Waste Regulations Governing E-Liquid Manufacturers and Distributors</li> <li>- Considerations for Minimizing Regulatory Exposure</li> </ul>  |
| 10:00 a.m. – 10:45 a.m. | <p><b>OSHA’s Hazard Communication Standard and Considerations for the E-Liquid Industry</b><br/> <b>Manesh Rath, Partner, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>- Overview of OSHA’s Hazard Communication Standard (HCS)</li> <li>- Scope of Standard and Exemptions</li> <li>- Safety Data Sheets (SDSs)</li> <li>- Labeling</li> <li>- Employee Training</li> <li>- Future Challenges for E-liquid Industry</li> </ul>   |
| 10:45 a.m. – 11:00 a.m. | <b>Networking and Vape Break</b>   |

- 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.*