

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. **Tobacco Control Act and the Deeming Rule:
How We Got Here and What Might Happen Next
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 Government Flavor Bans
Guest Speaker: Gregory 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 (GIS) Analysis to Address
Regulatory Concerns
Guest Speaker: Johny 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. **Tobacco and Vapor Product Taxation**
Guest Speaker: Paul Blair, Strategic Initiatives Director, 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**
Current Regulatory Status of E-Cigarettes in Asia and Middle East
David Ettinger, Partner, Keller and Heckman Shanghai Office
- 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**
 - **Gene Gillman, Ph.D. Enthalpy Analytical, LLC**
 - **Kimberly Hesse, Global Laboratory Services**
 - **Amy Madl, Ph.D., 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., VP, Enthalpy Analytical, LLC
- 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 Madl, Ph.D., DABT, Senior Principal Health Scientist, 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. **Integration of Nonclinical and Clinical Research for Public Health Evaluation**
Guest Speaker: Stacey Benson, Ph.D., Supervising Health Scientist, 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**

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Day 2 – Wednesday, January 30, 2019

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| 7:45 a.m. – 8:15 a.m. | <p>Continental Breakfast</p> |
| 8:15 a.m. – 9:00 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 |
| 9:00 a.m. – 9:45 a.m. | <p>CBD: Beyond Nicotine for the Vapor Industry?
 Navigating this Complex High-Growth Cannabis Space Globally
 Guest Speaker: Tim Phillips, Managing Director, ECigIntelligence and CBD-Intel</p> <ul style="list-style-type: none"> - Why is CBD of interest to the vaping/tobacco sectors? - Why is it a controversial product, and what regulatory landscape affects its sale? - Who are the consumers of CBD, and where to they buy? - What is the future of the CBD sector, and why should you be interested? |
| 9:45 a.m. – 10:30 a.m. | <p>Hazardous Waste Management for the E-Liquid Industry
 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 |
| 10:30 a.m. – 10:45 a.m. | <p>Networking and Vape Break</p> |
| 10:45 a.m. – 11:30 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 |

- 11:30 a.m. – 12:15 p.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)
- 12:15 p.m. – 1:30 p.m. **Lunch, provided by Keller and Heckman**
Special Presentation: Canada's New Regulatory Framework for Vapor Products
Vape Regulation – A Love Story
Guest Speaker: Marc Kealey, Chief Advocate, Kealey and Associates, Inc.
- 1:30 p.m. – 2:00 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
- 2:00 p.m. – 2:15 p.m. **Fighting Excess Taxation and Regulation Through Communications**
Guest Speaker: Dan Blum, Strategist, Vapers United
- Impact of Media on Vapor Tax and Regulatory Landscape
 - Working with Media: Who Should Tell Your Story & Top Talking Points and Resources
- 2:15 p.m. – 3:15 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
- 3:15 p.m. – 3:30 p.m. **Networking and Vape Break**
- 3:30 p.m. – 4:00 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

4:00 p.m. – 4:45 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

4:45 p.m. – 5:15 p.m.

Indiana’s CBD Law

Guest Speaker: Amy Netherton, President, 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

5:15 p.m.

Symposium Adjourns