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  
- 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
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.  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
- 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.  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

10:30 a.m. – 10:45 a.m.  Networking and Vape Break

10:45 a.m. – 11:30 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
AGENDA

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**