Keller and Heckman E-Vapor and Tobacco Law Symposium

Day 1 – Tuesday, February 6, 2018

8:00 a.m. – 8:30 a.m.  Registration and Continental Breakfast

8:30 a.m. – 8:35 a.m.  Welcome and Introduction to Keller and Heckman LLP
   Azim Chowdhury, Partner, Keller and Heckman

8:35 a.m. – 10:00 a.m.  Tobacco Control Act and the Deeming Rule: How We Got Here and What Happens Next
   Azim Chowdhury, Partner, Keller and Heckman
   − Deeming Regulation History: How We Got Here
   − Registration and Product Listing, Health Documents, HPHC Testing and Other Tobacco Control Act Requirements
   − Premarket Review and New Compliance Deadlines
   − Substantial Equivalence (SE) Reports
   − Label and Warning Requirements
   − Modified Risk Tobacco Products and Health Claims
   − Tobacco Product Standards – Flavors and Devices
   − Using Tobacco Product Master Files
   − Retailer Compliance, Sample Bans & Do’s and Don’ts
   − Status of Nicotine Salts and Tobacco-Free Nicotine (TFN)
   − Gottlieb’s New FDA and Impact on the Vapor Industry

10:00 a.m. – 10:45 a.m.  Good Manufacturing Practices and FDA Inspections
   Dean Cirotta, President and Chief Operating Officer, EAS Consulting Group
   − Quality and the FDA
   − Current FDA cGMP Regulations and Potential Impact on Tobacco GMP Regulations
   − FDA Inspections and Enforcement
   − Managing FDA Inspections

10:45 a.m. – 11:00 a.m.  Networking and Vape Break

11:00 a.m. – 11:45 a.m.  Hazardous Waste Management Pitfalls of Nicotine-Containing Products
   JC Walker, Partner, Keller and Heckman
   − Handling E-Liquid and Hazardous Waste
   − How to Prepare for State EPA Inspections
11:45 a.m. – 12:45 p.m.  
UL 8139 – Safety Standard for Electrical Systems of Electronic Cigarettes and Vaping Devices  
Michael Sakamoto, BD Manager, UL Consumer Technology Division  
Flore Chiang, Principal Engineer, UL Taiwan Co., Ltd.  
- Battery Safety Concerns  
- Overview of UL 8139 Safety Standard  
- Certification Process

12:45 p.m. – 2:15 p.m.  
Lunch, provided by Keller and Heckman  
Special Presentation: CBD and Cannabis – What are the Risks?  
Chris Van Gundy, Partner, Keller and Heckman  
- Legal Status of CBD and Cannabis – DEA, Controlled Substances Act & State Laws  
- FDA Regulation of CBD in E-Liquids  
- California Emergency Cannabis Regulations

2:15 p.m. – 3:15 p.m.  
FDA Premarket Tobacco Product Application (PMTA)  
Amy Madl, PhD, DABT, Senior Principal Health Scientist, Cardno ChemRisk  
Autumn Bernal, PhD, Supervising Health Scientist, Cardno ChemRisk  
- PMTA Data Requirements  
- Assessing the Public Health Impact of a Product  
- A Look at the PMI IQOS Application  
- A Consortium Approach: How Vapor Companies Can Work Together

3:15 p.m. – 3:30 p.m.  
Networking and Vape Break

3:30 p.m. – 4:15 p.m.  
U.S. Consumer Product Safety Commission (CPSC) Requirements  
Nathan Cardon, Associate, Keller and Heckman  
- Overview of CPSC  
- Children’s Nicotine Poisoning Prevention Act (CNPPA) Requirements  
- Requirements for General Certificate of Conformity (GCC)  
- General Product Safety Considerations  
- Managing Battery Safety

4:15 p.m. – 5:15 p.m.  
Business, IP, and Advertising Issues – How to Stay in Compliance  
Bob Niemann and Tracy Marshall, Partners, Keller and Heckman  
- Drafting and Negotiating Vendor, Manufacturing, and Distribution Agreements  
- Insurance Policies for Vapor Companies  
- Website Terms and Conditions and Privacy Policies  
- Protecting your Trademarks, Copyrights, and Trade Secrets and Avoiding Infringing the Intellectual Property Rights of Others  
- Using Social Media to Promote your Business  
- Conducting Contests, Sweepstakes, and Other Promotions  
- Laws Governing Commercial E-mail Messages and Text Messaging

5:15 p.m. – 5:30 p.m.  
Final Questions

5:30 p.m. – 6:30 p.m.  
Networking Reception, hosted by Keller and Heckman
Keller and Heckman E-Vapor and Tobacco Law Symposium

Day 2 – Wednesday, February 7, 2018

8:00 a.m. – 8:30 a.m.  Continental Breakfast

8:30 a.m. – 9:15 a.m.  FDA Ingredient Listing Process
Azim Chowdhury, Partner, Keller and Heckman
Ben Wolf, Associate, Keller and Heckman
- Overview of Ingredient Listing Requirement
- Step-by-Step Instructions and Demonstration of FDA eSubmitter and CTP Portal

9:15 a.m. – 10:15 a.m.  Deeming Lawsuit Update
Eric Gotting, Partner, Keller and Heckman
- Nicopure and Right to be Smoke-Free Coalition Appeal Update
- How You Can Help

Current Trends in E-Cig and Vapor Class Actions
Bob Niemann, Partner, Keller and Heckman
- Class Action Lawsuits and How to Protect Yourself

10:15 a.m. – 10:30 a.m.  Networking and Vape Break

10:30 a.m. – 11:15 a.m.  Requirements Under the EU Tobacco Products Directive (TPD)
Marcus Navin-Jones, Partner, Keller and Heckman
- Overview of TPD Requirements
- Product Standards
- New Product Notifications
- Labeling Requirements under TPD and CLP
- Other EU Regulations Applicable to Vapor Products
- Certain Member State Requirements

11:15 a.m. – 12:00 p.m.  Navigating the UK and the Medicines and Healthcare Products Regulatory Agency (MHRA)
Chris Allen, Co-Founder & Managing Director, Broughton Laboratories
- History of TPD and Marketing Authorisation Application (MAA) – Evolution with the MHRA
- TPD vs MAA – Two Ends of the Spectrum
- Current Issues within the UK – Shortfills, Quality Control, Lack of Enforcement, etc.
- Impact of TPD on Public Perception of Vapor Products
AGENDA

12:00 p.m. – 1:15 p.m.  
**Lunch, provided by Keller and Heckman**  
**Special Presentation: Market Reaction to Regulation**  
*Tim Phillips, Managing Director, ECigintelligence*  
- Impact of TPD and Other Regulations on European E-Vapor Market  
- Growth of Pods Systems in the US: Will They Work in Europe?  
- Prospects for Tax in the US in 2018: Global Market Reactions  
- Heated Tobacco and Alternatives: Market Reaction Compared to E-Vapor  
- Predictions for 2018 and Beyond

1:15 p.m. – 2:15 p.m.  
**Current Regulatory Status of E-Cigarettes in Asia and Middle East**  
*David Ettinger, Partner, Keller and Heckman Shanghai Office*  
- World Health Organization (WHO)  
- China and Asia  
- New Zealand  
- Australia  
- Russia, India, Middle East, and More!

2:15 p.m. – 3:00 p.m.  
**Electronic Cigarette and Vapor Product Taxation**  
*Paul Blair, Strategic Initiatives Director, Americans for Tax Reform*  
- Overview of State Vapor and Tobacco Taxes  
- State Taxation Trends for 2018

3:00 p.m. – 3:30 p.m.  
**California Tax and License Requirements**  
*Robert Zivkovich, CA Department of Tax and Fee Administration (CDTFA)*  
- Overview of Prop 56 Tax for E-Vapor and Other Tobacco Products  
- Cigarette & Tobacco Products Licensing Act Requirements

3:30 p.m. – 4:15 p.m.  
**Networking and Vape Break**

3:45 p.m. – 4:15 p.m.  
**STAKE Act and California Proposition 65**  
*Mitzi Clark and Azim Chowdhury, Partners, Keller and Heckman*  
- CA STAKE Act Requirements for Age Verification  
- Prop 65 Background and Enforcement Actions Against Vapor Companies  
- New Prop 65 Warning Requirements

4:15 p.m. – 4:45 p.m.  
**Flavor Ban Update**  
*Stefan Didak, Founder & President, Not Blowing Smoke*  
- Update on San Francisco and Other CA Flavor Bans

4:45 p.m. – 6:30 p.m.  
**Update on State Laws: Licensing Requirements**  
- Indiana – *Amy Netherton, President, Indiana Smoke-Free Alliance*  
- New York – *Mary Bielaska, Founder and CEO, Zanicorn International Ltd.*  
- Texas & Beating Tobacco 21 – *Schell Hammel, President, The Vapor Bar*  
- Arkansas, Utah, Iowa, and more - *Azim Chowdhury, Partner, K&H*

6:30 p.m.  
**Final Questions and Seminar Adjourns**