

## 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.               **Overview of Tobacco Control Act and the FDA Deeming Regulation**  
**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
  - Update on Cole/Bishop and Hunter bills
- 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.               **Environmental Concerns for Vapor Companies**  
**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. – 2:00 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
- 2:00 p.m. – 3:00 p.m.      **A Practical Approach to Premarket Tobacco Product Applications (PMTAs)**  
**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
- 3:00 p.m. – 3:15 p.m.      **Networking and Vape Break**
- 3:15 p.m. – 4:00 p.m.      **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)
- 4:00 p.m. – 5:00 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, Distribution, and Nondisclosure 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
- 5:00 p.m. – 5:15 p.m.      **Final Questions**
- 5:15 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

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| 8:00 a.m. – 8:30 a.m.   | <p><b>Continental Breakfast</b></p>   |
| 8:30 a.m. – 9:15 a.m.   | <p><b>FDA Ingredient Listing Process</b><br/> <b>Azim Chowdhury, Partner, Keller and Heckman</b><br/> <b>Ben Wolf, Associate, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>– Overview of Ingredient Listing Requirement</li> <li>– Step-by-Step Instructions and Demonstration of FDA eSubmitter and CTP Portal</li> </ul>   |
| 9:15 a.m. – 10:15 a.m.  | <p><b>Deeming Lawsuit Update</b><br/> <b>Eric Gotting, Partner, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>– Nicopure and Right to be Smoke-Free Coalition Appeal Update</li> <li>– How You Can Help</li> </ul> <p><b>Class Action Litigation</b><br/> <b>Bob Niemann, Partner, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>– Class Action Lawsuits and How to Protect Yourself</li> </ul>   |
| 10:15 a.m. – 10:30 a.m. | <p><b>Networking and Vape Break</b></p>   |
| 10:30 a.m. – 11:15 a.m. | <p><b>Requirements Under the EU Tobacco Products Directive (TPD)</b><br/> <b>Marcus Navin-Jones, Partner, Keller and Heckman</b></p> <ul style="list-style-type: none"> <li>– Overview of TPD Requirements</li> <li>– Product Standards</li> <li>– New Product Notifications</li> <li>– Labeling Requirements under TPD and CLP</li> <li>– Other EU Regulations Applicable to Vapor Products</li> <li>– Certain Member State Requirements</li> </ul>  |
| 11:15 a.m. – 12:00 p.m. | <p><b>Market Reaction to Regulation: EU Market Impact from TPD; Future Regulatory Impact on U.S. and Other Markets</b><br/> <b>Tim Phillips, Managing Director, ECigIntelligence</b></p> <ul style="list-style-type: none"> <li>– Impact of TPD and Other Regulations on European E-Vapor Market</li> <li>– Growth of Pods Systems in the US: Will They Work in Europe?</li> <li>– Prospects for Tax in the US in 2018: Global Market Reactions</li> <li>– Heated Tobacco and Alternatives: Market Reaction Compared to E-Vapor</li> <li>– Predictions for 2018 and Beyond</li> </ul> |

- 12:00 p.m. – 1:15 p.m.      **Lunch, provided by Keller and Heckman**  
**Special Presentation: 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
- 1:15 p.m. – 2:15 p.m.      **Global Requirements for Vapor and Other Tobacco Products**  
**David Ettinger, Partner, Keller and Heckman Shanghai Office**
- World Health Organization (WHO)
  - China and Asia
  - New Zealand
  - Canada
  - Russia, India, Israel, Middle East, Africa and More!
- 2:15 p.m. – 3:00 p.m.      **U.S. State Vapor Tax Overview**  
**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 Proposition 56 and Cigarette & Tobacco Products Licensing Act**  
**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. – 3:45 p.m.      **Networking and Vape Break**
- 3:45 p.m. – 4:15 p.m.      **California Proposition 65 and STAKE Act**  
**Mitzi Clark and Azim Chowdhury, Partners, Keller and Heckman**
- Prop 65 Background and Enforcement Actions Against Vapor Companies
  - New Prop 65 Warning Requirements
  - CA STAKE Act Requirements for Age Verification
- 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.      **Other State Vapor Laws**
- Indiana – **Amy Lane, President, Indiana Smoke-Free Association**
  - New York State & NYC – **Mary Bielaska, GC, NY State Vapor Association**
  - Texas & Beating Tobacco 21 – **Schell Hammel, President, The Vapor Bar**
  - Arkansas, Utah, Iowa, Delaware and more - **Azim Chowdhury, Partner, K&H**
- 6:30 p.m.      **Final Questions and Seminar Adjourns**