

Keller and Heckman E-Vapor and Tobacco Law Symposium

All designated session times are in the Eastern Time (ET) Zone.

Day 1 – Wednesday, February 2, 2022

10:30 a.m. – 10:35 a.m.

Welcome Address

10:35 a.m. – 12:05 p.m.

FDA CTP State of Affairs: Post-PMTA Aftermath & Where We Go From Here **Azim Chowdhury, Partner, Keller and Heckman**

- What Happened in 2021 – and Why?
- PMTA Marketing Denial Order Update
- PMTA and Substantial Equivalence Report New Final Rule
- PMTA Authorizations – What We Can Learn
- Administrative Appeals
- Menthol Cigarette and Cigar Flavor Ban Update
- Synthetic Tobacco-Free Nicotine – Promises and Pitfalls
- FDA Warning Letter and Enforcement Update
- FDA 2022 and Beyond – What Happens Next for the Vaping Industry?

12:05 p.m. – 12:10 p.m.

Transition Break

12:10 p.m. – 1:00 p.m.

Litigation Update: Status of Appeals and New Cases **Eric Gotting, Partner, Keller and Heckman**

- Update on Lawsuits Challenging FDA's Marketing Denial Orders for Flavored ENDS
- Basis for Lawsuits/Legal Arguments

1:00 p.m. – 2:00 p.m.

Lunch/Networking Break

2:00 p.m. – 2:45 p.m.

Demonstrating an “Added Benefit” of Flavored ENDS for Adult Smokers **Guest Speaker: Christopher Russell, Ph.D., Russell Burnett Research & Consultancy Ltd**

- What Can a Randomized Controlled Trial (RCT) and/or a Longitudinal Cohort Study (LCS) Tell You About Your Products That Other Study Designs Cannot?
- Designing Studies to Compare Switching and Cigarette Reduction Rates Associated with Adult Smokers' Use of Specific Non-Tobacco-Flavored ENDS vs. Tobacco-Flavored ENDS

2:45 p.m. – 2:50 p.m.

Transition Break

2:50 p.m. – 3:30 p.m.

PMTA Deficiency Letter Preparation and Response Strategy

Guest Speaker: Willie J. McKinney, Ph.D., McKinney Regulatory Science Advisors LLC

- Deficiency Letters
- Types of PMTA Deficiencies
- Strategies for Responding to FDA

3:30 p.m. – 3:45 p.m.

Break

3:45 p.m. – 4:40 p.m.

Preparing for Tobacco Product Manufacturing Standards and cGMPs

Neelam Gill, Counsel, Keller and Heckman

- Setting the Foundation: The Three C's of Current Good Manufacturing Practices
- Building Quality into the Manufacturing Process – Impact on PMTA Authorization
- PMTA Deficiencies Related to Manufacturing and Quality Control
- FDA Inspections of Manufacturing Establishments
- Remote Regulatory Assessments (RRAs) During PMTA Review

4:40 p.m. – 4:45 p.m.

Transition Break

4:45 p.m. – 5:15 p.m.

State Law Update

Taylor Johnson, Associate, Keller and Heckman

- Update on State and Local Flavor Bans and Other Restrictions
- State Licensing Requirements
- State Enforcement Actions Against Vapor Companies
- Synthetic Nicotine Bans and Requirements

5:15 p.m. – 6:30 p.m.

Q&A Happy Hour

Join us in the Networking Lounge for a live Q&A session with speakers.

6:30 p.m.

Symposium Adjourns for the Day

Day 2 – Thursday, February 3, 2022

- 10:30 a.m. – 10:35 a.m. **Welcome Remarks**
- 10:35 a.m. – 11:30 a.m. **E-Cigarette Regulation in China: The Tobacco Monopoly Act**
David Ettinger, Managing Partner, Keller and Heckman Shanghai Office
Eric Gu, Senior Regulatory Counselor, Keller and Heckman Shanghai Office
- Impact of ENDS Coming Under the Tobacco Monopoly Act and the State Tobacco Monopoly Administration
 - Governing Authorities and Regulations
 - National E-Cigarette Standard
 - Overview of Licensing, Registration and Testing Requirements
- 11:30 a.m. – 11:35 a.m. **Transition Break**
- 11:35 a.m. – 12:15 p.m. **European Union: Regulatory Update for ENDS and Nicotine Products**
Ales Bartl, Counsel, Keller and Heckman Brussels Office
- Regulation of Synthetic Nicotine ENDS and Oral Products in the EU
 - UK MHRA Guidance Update: Medical Product Pathway for ENDS
 - TPD Revision Update (Including Flavor Bans)
- 12:15 p.m. – 1:15 p.m. **Lunch/Networking Break**
- 1:15 p.m. – 2:00 p.m. **Flavors, Taxes, PMTAs, Preemption & More: 2022 State Legislative Update**
Guest Speaker: Gregory Conley, President, American Vaping Association
- 2022 State Legislative Update
- 2:00 p.m. – 2:05 p.m. **Transition Break**
- 2:05 p.m. – 2:45 p.m. **Taxing Nicotine Products**
Guest Speaker: Ulrik Boesen, Senior Policy Analyst, Center for State Tax Policy at The Tax Foundation
- Are Excise Taxes on Vapor Products Justified?
 - Pending Federal Excise Tax Bills
 - Update on State Vapor Taxes
- 2:45 p.m. – 3:00 p.m. **Break**
- 3:00 p.m. – 3:45 p.m. **Prevent All Cigarette Trafficking (PACT) Act: Update & Outlook for ENDS**
Guest Speaker: Dov Seewald, Principal, Tobacco Vapor Cannabis Group
- Update on State PACT Act Reporting Requirements
 - USPS Mail Ban and Delivery Options for ENDS Products
- 3:45 p.m. – 3:50 p.m. **Transition Break**

3:50 p.m. – 4:30 p.m.

Establishing a Responsible Industry Network (RIN)

Guest Speaker: Andrew O’Bright, Responsible Industry Network Compliance Officer, Smoke-Free Alternatives Trade Association (SFATA)

- Marketing of Open-System Vapor Products Through a Controlled Retailer and Distributor Network
- Need for RIN in a Post-PMTA World: Controlled Network, Robust Age Verification, Product Tracking, Monitoring and Data Collection, Enhanced Enforcement, and Postmarket Surveillance

4:30 p.m. – 4:35 p.m.

Transition Break

4:35 p.m. – 5:15 p.m.

Update on FDA Regulation of Cannabis and CBD

Rick Stearns, Partner, Keller and Heckman

- Current Legal Status of Cannabis and Cannabis-Based Compounds in FDA Regulated Products, Including:
 - o Current Status as Controlled Substances Under the Federal Controlled Substances Act (Including Delta-8 THC)
 - o Impact of the Agricultural Improvement Act of 2018 (the Farm Bill)
 - o Legal Basis for FDA's Position That it is Unlawful to Introduce Food Containing Added CBD into Interstate Commerce or to Market CBD Products as, or in, Food and Dietary Supplements
- Practical Tips for Companies to Navigate this Space Considering the Legal and Regulatory Uncertainties that Exist

5:15 p.m. – 6:30 p.m.

Final Q&A/Networking Happy Hour

Join us in the Networking Lounge for a final Q&A session with speakers.

6:30 p.m.

Seminar Adjourns