Keller and Heckman E-Vapor and Tobacco Law Symposium

What can we expect in 2021 and beyond?

All sessions will take place in the Eastern Time Zone.

Day 1 – Tuesday, February 9, 2021

11:00 a.m. – 11:05 a.m.	**Welcome Address**
11:05 a.m. – 12:30 p.m.	**FDA Update: Where We Go from Here** **Azim Chowdhury, Partner, Keller and Heckman** – 2020 Year in Review – FDA's Premarket Review Process: What's Next – PMTA, SE, and MRTP Authorizations – New Guidance and Proposed Rulemakings – Compliance and Enforcement Update: FDA's Priorities – Protecting Youth and Harm Reduction – How to Achieve Both – Online Sales: Age Restriction and Verification – Strategies for Small Businesses – Critical Updates re PMTA List, Flavors, Cigars, Synthetic Nicotine, Youth Use and Disposables, Appeals, and Lawsuits – …. and much more!
12:30 p.m. – 12:45 p.m.	**15-Minute Vape Break**
12:45 p.m. – 1:30 p.m.	**PMTAs – Protecting Your Rights Through Litigation** **Eric P. Gotting, Partner, Keller and Heckman** – Refusals to Accept and Refusals to File – Substantive Review Delays – PMTA Denials – What Are Your Options?
1:30 p.m. – 1:35 p.m.	**5-Minute Transition Break to Next Session**
1:35 p.m. – 2:15 p.m.	**The Other Premarket Pathways: SE Reports and SE Exemptions** **Kathryn C. Skaggs, Partner, Keller and Heckman** – Establishing Grandfathered Status for Deemed Products – Overview of Substantial Equivalence (SE) and SE Exemption Pathways – SE Report Proposed Rule Update – Recreating Products, Surrogates, and Testing Requirements

2:15 p.m. – 2:45 p.m.	**Lunch/Networking Break**
2:45 p.m. – 3:25 p.m.	**U.S. Politics & Tobacco Policy: What We're Watching in 2021** **Guest Speaker: Stefanie Miller, Managing Director, FiscalNote Markets** − State of Politics: Where We Are in February 2021 vs Where We Were in February 2020 − Risks to the E-Vapor Industry Under the Biden Administration, the Newly Seated 117th Congress, and Newly Elected State Regulators, and Legislatures − How Key Administration Officials, Members of Congress, and the Unfolding PMTA Process are Likely to Shape the Politics and Policies Governing E-Vapor − States to Watch that are Likely to Advance New Tobacco Policies in 2021
3:25 p.m. – 3:30 p.m.	**5-Minute Transition Break to Next Session**
3:30 p.m. – 4:15 p.m.	**FDA Enforcement Tools** **Owen Chaput, Associate, Keller and Heckman** − Background on CTP's Office of Compliance and Enforcement − FDA Enforcement Process and Toolbox − 2021 Enforcement Outlook for Vapor and Tobacco CTP's Office of Enforcement
4:15 p.m. – 4:20 p.m.	**5-Minute Transition Break to Next Session**
4:20 p.m. – 5:00 p.m.	**Vaping Science and News: Keeping Up with the Evidence & Countering Misinformation** **Guest Speaker: Amelia Ruby Howard** − COVID-19, Vaping and Tobacco Use - What We Know − Cochrane Review on Vaping and Smoking Cessation − Youth Vaping Update: 2020 National Youth Tobacco Survey and the Monitoring the Future Survey
5:00 p.m. – 6:00 p.m.	**Networking Happy Hour Q&A Session** Join us for a Q&A session in the Networking Lounge.
6:00 p.m.	**Symposium Adjourns for the Day**

Day 2 – Wednesday, February 10, 2021

11:00 a.m. – 11:45 a.m.	**Tobacco Product GMPs and FDA Inspections** **Neelam Gill, Associate, Keller and Heckman** – Setting the Foundation: The 3 C's of cGMPs – Building Quality into the Manufacturing Process – Tracking and Traceability – Contract Manufacturing Arrangements – FDA Inspections – Product Returns, Complaints, and Recalls – Avoiding Pitfalls: Common Mistakes
11:45 a.m. – 11:50 a.m.	**5-Minute Transition Break to Next Session**
11:50 a.m. – 12:15 p.m.	**FDA's New Registration System: TRLM NG** **LieAnn Van-Tull, Associate, Keller and Heckman** – Registration and Product Listing for U.S. Manufacturing Establishments – Overview of FDA's Tobacco Registration and Listing Module – Next Generation – CTP Portal Accounts
12:15 p.m. – 12:30 p.m.	**15-Minute Vape Break**
12:30 p.m. – 1:15 p.m.	**PMTA ENDS Testing: Analytical Chemistry and In-Vitro Toxicology Testing in a Compliance Environment** **Guest Speaker: Andrew Mooney, VP of Business Development, Labstat International, Inc.** – Phase I: HPHCs and In-Vitro Toxicology Testing for Submission – Phase II: FDA Follow-Up Letters – Phase III: Post Market Testing
1:15 p.m. – 1:20 p.m.	**5-Minute Transition Break to Next Session**
1:20 p.m. – 1:55 p.m.	**PMTAs: Considerations of Product Development and Stewardship in the Post-Market** **Guest Speaker: Amy Madl, Ph.D., DABT, Senior Principal Health Scientist, Cardno ChemRisk** – Non-Clinical and Clinical Studies for the PMTA – Considerations for Device and E-Liquid Testing – Integration of Testing and Health Risk Assessment for Product Stewardship
1:55 p.m. – 2:25 p.m.	**Lunch/Networking Break**

2:25 p.m. – 3:10 p.m.	**The FDA TPPI Studies DRAFT Guidance: A Human Health Risk Assessment Perspective** **Guest Speaker: Autumn Bernal, Ph.D., ToxCreative, LLC** – Key Considerations from FDA's Latest Guidance on Tobacco Product Perception and Intention (TPPI) Studies – Incorporating TPPI Study Findings into the Human Health Risk Assessment Process and the Evaluation of APPH – Opportunities for Alignment of TPPI Studies with the Risk Assessment Process
3:10 p.m. – 3:15 p.m.	**5-Minute Transition Break to Next Session**
3:15 p.m. – 3:45 p.m.	**SFATA's Responsible Industry Network (RIN) Program** **Guest Speaker: Mark Anton, Executive Director, Smoke-Free Alternatives Trade Association (SFATA)** – Marketing of Open-System Vapor Products through a Responsible Retailer and Distributor Network – Overview of RIN Program: Responsible Network, Robust Age Verification, Product Tracking, Monitoring and Data Collection, Enhanced Enforcement, Post Market Surveillance
3:45 p.m. – 3:50 p.m.	**5-Minute Transition Break to Next Session**
3:50 p.m. – 4:30 p.m.	**Product Liability Considerations** **Robert S. Niemann, Partner, Keller and Heckman** – Exploding Battery Claims and Battery Safety Standards – Retailer Protection Considerations – Insurance Coverage Issues – JUUL Multi-District Litigation
4:30 p.m. – 5:00 p.m.	**Q&A** Join us for a Q&A session in the Networking Lounge.
5:00 p.m.	**Symposium Adjourns for the Day**

Day 3 – Thursday, February 11, 2021

11:00 a.m. – 11:45 a.m.	**Environmental Assessments for Vapor and Tobacco Product Applications** **Steven J. Manning, Ph.D., Scientist, Keller and Heckman** – Background on NEPA and FDA Environmental Assessments – EA Requirements for PMTAs and SE Reports – Update on EA Related Deficiencies
11:45 a.m. – 11:50 a.m.	**5-Minute Transition Break to Next Session**
11:50 a.m. – 12:30 p.m.	**Hazardous Waste Management and Environmental Concerns for Vapor Manufacturers** **James G. Votaw, Partner, and Alexa M. Pecht, Associate, Keller and Heckman** – Overview of Hazardous Waste Regulations Governing E-Liquid Manufacturers and Distributors – Considerations for Minimizing Regulatory Exposure – EPA and State Inspections
12:30 p.m. – 12:35 p.m.	**5-Minute Transition Break to Next Session**
12:35 p.m. – 1:20 p.m.	**State Law Update** **Taylor D. Johnson, Associate, Keller and Heckman** – Update on State and Local Flavor Bans and Other Restrictions – State Licensing Requirements – State Enforcement Actions against Vapor Companies
1:20 p.m. – 1:50 p.m.	**Lunch/Networking Break**
1:50 p.m. – 2:20 p.m.	**State Legislative Round Up** **Guest Speaker: Gregory Conley, President, American Vaping Association** – 2021 State Legislative Update
2:20 p.m. – 2:25 p.m.	**5-Minute Transition Break to Next Session**
2:25 p.m. – 3:05 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
3:05 p.m. – 3:20 p.m.	**15-Minute Vape Break**

3:20 p.m. – 4:00 p.m. **How to Sell Your Products in the EU: TPD and Beyond**
Ales Bartl, Associate, Keller and Heckman Brussels Office
- Update on Tobacco Products Directive (TPD)
- EU Requirements Beyond 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

4:00 p.m. – 4:05 p.m. **5-Minute Transition Break to Next Session**

4:05 p.m. – 4:45 p.m. **The Next Frontier: Regulation of E-Cigarettes in Asia**
David Ettinger, Partner, and Eric Gu, Associate, Keller and Heckman Shanghai Office
- The China Pathway
  - Governing Authorities and Regulations
  - New Proposed E-Cigarette Standard
- The UAE Pathway
  - Development in the Regulation of Electronic Nicotine Products
  - Regional Considerations, *e.g.,* Dubai, Abu Dhabi
- Other countries (*e.g.*, Australia, South Korea, and more)
- Opportunities and Challenges

4:45 p.m. – 4:50 p.m. **5-Minute Transition Break to Next Session**

4:50 p.m. – 5:30 p.m. **Update on FDA Regulation of Cannabis and CBD**
Frederick A. Stearns, Partner, Keller and Heckman
- Current Legal Status of Cannabis and Cannabis-Based Compounds in FDA Regulated Products, Including:
  - Current Status as Controlled Substances Under the Federal Controlled Substances Act (including Delta-8 THC)
  - Impact of the Agricultural Improvement Act of 2018 (the Farm Bill)
  - Legal Basis for FDA's Position (stated in December 2018) 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

5:30 p.m. – 6:00 p.m. **Q&A and Closing Remarks**

6:00 p.m. **Symposium Adjourns for 2021**

**Please note, the agenda is subject to change between now and the start of the program.*