AGENDA

Keller and Heckman E-Vapor and Tobacco Law Symposium

All designated session times are in the Pacific Time (PT) Zone.

Day 1 – Monday, January 27, 2025

8:00 a.m. – 8:30 a.m.	**Registration and Breakfast**
8:30 a.m. – 9:15 a.m.	**Updates from FDA's Center for Tobacco Products** **Keynote Speaker: Brian King, Ph.D., MPH, Director, Center for Tobacco Products (CTP) U.S. Food & Drug Administration (FDA)** – Overview of Tobacco Use in the U.S. – CTP's Role in Tobacco Product Regulation – Updates on CTP's Key Programmatic Areas – Progress on the Center's Strategic Goals and Priorities
9:15 a.m. – 10:00 a.m.	***Expert Reactor Panel*** **Moderated by Azim Chowdhury, Partner, Keller and Heckman** Expert Panelists: - Cliff Douglas, President and Chief Executive Officer of Global Action to End Smoking - Lillian Ortega, Former Director, FDA CTP Division of Enforcement and Manufacturing; Regulatory Consultant, Chemular
10:00 a.m. – 10:15 a.m.	**Networking Break**
10:15 a.m. – 11:00 a.m.	***FDA Compliance & Enforcement Update: What's Next*** **Azim Chowdhury, Partner, Keller and Heckman** – What Happened in 2024 and Beyond: Post-Election Expectations – PMTA & MRTP Authorization Update: What Does FDA Consider APPH? – Tobacco Flavor Benchmark and the Fatal Flaw Analysis: Will FDA Ever Authorize a Non-Tobacco Flavored ENDS Product? – Regulation of Nicotine Pouches and other MONPs – Federal Enforcement Joint Task Force – How to Prepare – Update on FDA Enforcement Actions and Strategies for Compliance: Warning Letters, Import Alerts and Civil Money Penalties – Challenging PMTA Denials and Refusals – Nicotine Alternatives/Analogs – Legal Considerations – NYTS Latest Results and Potential Policy Impact – Upcoming Product Standards and FDA Proposed Rules

11:00 a.m. – 11:40 a.m.	***Litigation Update: Status of Appeals, Flavor Bans, and New Challenges*** **Eric Gotting, Partner, Keller and Heckman** – Update on Supreme Court PMTA MDO Cases: *Wages & RJ Reynolds* – Impact of S. Ct Decision in *Loper* to Overturn *Chevron* Deference – State Enforcement – New York Subpoena to Vapor Companies – Challenging FDA Civil Money Penalties: Impact of *SEC v. Jarkesy* S. Ct Decision
11:40 a.m. – 12:15 p.m.	***Substantial Equivalence Reports and SE Exemptions*** **Kathryn Skaggs, Partner, Keller and Heckman** – Overview of Substantial Equivalence (SE) and SE Exemption (EX REQ) Pathways – FDA's SE Report Final Rule & Authorization Update – SE Exemptions – New Pathway for Flavors – Considerations for Hookah, Pipe, and RYO Tobacco Products
12:15 p.m. – 1:30 p.m.	**Lunch,** *provided by Keller and Heckman*
1:30 p.m. – 2:15 p.m.	***Update on Cigars and Cigarettes*** **Daniel McGee, Counsel, Keller and Heckman** – FDA Status of Premium Cigars – Litigation Update – Update on Menthol Cigarette and Flavored Cigar Ban – Cigarette Graphic Warning Litigation
2:15 p.m. – 3:00 p.m.	***Prevent All Cigarette Trafficking (PACT) Act Update*** **Guest Speaker: Dov Seewald, Principal, Tobacco Vapor Cannabis Group** – Best Practices for Implementing a PACT Compliant Program – Review of Core Compliance Obligations o Registration & Monthly Reporting o Delivery Seller Obligations o Licensing & Excise Tax Obligations – USPS/Shipping Restrictions – Third-Party Compliance Vendors – Applicability to New/Innovative Products – Enforcement Update: What to Expect – NYC, California and ITC PACT Act Litigation Against ENDS Companies
3:00 p.m. – 3:10 p.m.	**Networking Break**
3:10 p.m. – 4:10 p.m.	***State Law Update: ENDS and Nicotine Products*** **Taylor Johnson, Associate, Keller and Heckman** **Guest Speaker: Chris Roy, Excise Tax Subject Matter Expert, IGEN** – Update on State and Local Flavor Bans, Synthetic Nicotine Bans, and Other Restrictions – PMTA Directory Law Update – State Regulation of Oral Nicotine Products – State Licensing & Excise Tax Requirements

4:10 p.m. – 4:55 p.m.	***California Update*** **Rohit Sabnis, Partner, Keller and Heckman San Francisco Office** – Flavor Ban Update: Retailers and Online Sellers – New Legislation – Update on State and Local Enforcement – State Litigation on ENDS and Oral Nicotine Products
4:55 p.m. – 5:30 p.m.	***Extended Producer Responsibility (EPR) Requirements for Tobacco and Nicotine Products*** **Kathryn Skaggs, Partner, Keller and Heckman** – What is EPR? – Overview of Enacted Legislation – Who's Responsible in the Tobacco and Nicotine Industries
5:30 p.m. – 7:00 p.m.	**Networking Happy Hour**
7:00 p.m.	**Symposium Adjourns for the Day**

[See Next Page for Day 2 Agenda]

Day 2 – Tuesday, January 28, 2025

7:30 a.m. – 8:30 a.m.	**Breakfast**
8:30 a.m. – 9:30 a.m.	***Cannabis, Hemp, and THC Panel: 2024 and Beyond*** **Moderated by Azim Chowdhury, Partner, Keller and Heckman** Expert Panelists: - Daniel McGee, Counsel, Keller and Heckman - Roxana Weil, Ph.D., DABT, Advisor, McKinney Regulatory Science Advisors, LLC - Tami Wahl, Government Affairs & Public Policy, Modern Advocates
9:30 a.m. – 10:15 a.m.	***European Union and Tobacco Products Directive (TPD) Update*** **David Ettinger, Partner, Keller and Heckman Shanghai Office** **Ales Bartl, Partner, Keller and Heckman Brussels Office** – Pre-Market Obligations Before Placing E-Vapor, Oral Pouches, and Tobacco Products on the EU Market – Upcoming Challenges including Bans of Flavors and Disposables – Update on UK Regulations
10:15 a.m. – 10:50 a.m.	***Tobacco Product Manufacturing Practice (TPMP) Proposed Rule*** **Neelam Gill, Counsel, Keller and Heckman** – Overview of TPMP Rule and Current Status – Impact on PMTAs – FDA Inspections of Manufacturing Establishments & Remote Regulatory Assessments (RRAs) During PMTA Review – What You Will Need to Comply – Tips for Preparation and Compliance – Challenges and the Road Ahead
10:50 a.m. – 11:00 a.m.	**Networking Break**
11:00 a.m. – 11:45 a.m.	***Tobacco and Vapor Litigation Before the U.S. International Trade Commission*** **Guest Speaker: Matthew Duescher, Foster, Murphy, Altman & Nickel, PC** – Introduction to the U.S. International Trade Commission – Why Companies Sue at the ITC – Discussion of Injunctive Remedies Available at the ITC – Overview of Recent Tobacco and Vapor Litigation at the ITC
11:45 a.m. – 12:15 p.m.	***Innovations in Age-Verification Technology*** **Guest Speaker: Martin Steinbauer, Sky X Group** – Point of Sale Technologies: Technologies for Retailers to Verify Age and Prevent Underage Sales – Social Sharing Prevention Technologies: Technologies for Manufacturers to Limit Youth Exposure and Sharing of Nicotine Products – Track and Trace Technologies: Technologies for Governments to Ensure Youth Access Prevention, Counterfeiting Prevention, and Taxation Compliance

12:15 p.m. – 1:30 p.m.	**Lunch,** *provided by Keller and Heckman*
1:30 p.m. – 2:10 p.m.	***U.S. Customs and Border Protection (CBP) Import Requirements for E-Cigarette and Related Products*** **Guest Speaker: Peter Quinter, U.S. Customs and International Trade Attorney, Gunster** – Declaration and Entry Process to CBP – Tariff Classification of Vape Products and Parts – Examination and Detention Process by CBP – Relationship Between FDA and CBP Import Requirements o Misbranding by FDA o Premarket Authorization by FDA for ENDS Products – Seizure and Petition Process by CBP – What is "Drug Paraphernalia" Under Federal Law
2:10 p.m. – 2:50 p.m.	***A Behavioral Research Program Assessing Benefits to Adults to Smoke and Risks to Youth from BREEZE PRO Disposable ENDS in Five Flavor Variants*** **Guest Speaker: Christopher Russell, Ph.D., Director, Russell Burnett Research & Consultancy Ltd.** – Evidence from Five Studies of U.S. Legal Age Adults and Youth – Comparative Efficacy of Four Non-tobacco Flavor Variants Versus One Tobacco Flavor Variant for Cigarette Abstinence, Reduction, and Product Switching Over Time Within a Randomized Trial – Behavioral Intentions and Risk Perceptions of BREEZE PRO Flavor Variants Among U.S. Legal Age Adults – Label Comprehension and Product Usability – Nicotine Uptake, Subjective Effects, and Puff Topography – Prevalence of Youth Use in 2024
2:50 p.m. – 3:00 p.m.	**Networking Break**
3:00 p.m. – 3:45 p.m.	***PMTA Considerations for Oral Nicotine Pouches*** **Guest Speaker: Jessica Zdinak, Ph.D., Applied Research and Analysis Company LLC** – PMTA ABC's: Key **A**nalytical, **B**ehavioral and **C**linical Study Requirements – Importance of Establishing Global and U.S.-Based Standards in the Novel Oral Nicotine Space – Critical Youth-Access Prevention Measures to Avoid a Future Youth "Epidemic"
3:45 p.m. – 4:30 p.m.	***Nicotine Analogs: Due Diligence Considerations*** **Guest Speaker: Willie J. McKinney, Ph.D., DABT, McKinney Regulatory Science Advisors, LLC** – Relevance, Mechanism and Implications of Nicotine Analogs – What are "Nicotine Analogs"? – Safety and Side Effects – Therapeutic Applications – Ethical and Regulatory Considerations

4:30 p.m. – 5:30 p.m.

China, Canada, and Global Regulation Update

Eric Gu, Senior Regulatory Counselor, Keller and Heckman Shanghai Office

LieAnn Van-Tull, Associate, Keller and Heckman

- Requirements Under Tobacco Vaping Products Act and Quebec Tobacco Control Act
- Health Canada Ingredient Submission Reporting Process
- Regulation of Oral Nicotine Products in Canada
- E-Cigarette Regulations in China
  - Management Rules and GB Standard on E-Cigarettes
  - Overview of Licensing, Registration, and Testing Requirements
  - Requirements for Export-Only vs. Domestic Products
- Updates on Other Regions
  - Middle East
  - East Asia (Japan, South Korea, Taiwan)
  - ASEAN countries
  - Australia & New Zealand

5:30 p.m.

Symposium Adjourns