AGENDA

Keller and Heckman E-Vapor and Tobacco Law Symposium

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

Day 1 – Wednesday, February 15, 2023

9:00 a.m. – 9:05 a.m.	**Welcome Address**
9:05 a.m. – 10:35 a.m.	**FDA CTP State of Affairs:** **New Leaders, PMTA Denials and Enforcement** **Azim Chowdhury, Partner, Keller and Heckman** – What Happened in 2022 – CTP State of Affairs – PMTA Marketing Denial Order Update and Juul Appeal – Synthetic Tobacco-Free Nicotine – FDA Response to PMTAs – New PMTA Authorizations – What We Can Learn – Tobacco Flavor Benchmark and the Fatal Flaw Analysis – FDA Warning Letters and Enforcement Update – FDA Prohibited Acts and Penalties Under the FDCA – PMTA Deficiency Letters and Strategies for Responding to FDA – Menthol Cigarette and Cigar Flavor Ban Update – FDA 2023 and Beyond – What Happens Next for the Vaping Industry?
10:35 a.m. – 11:20 a.m.	**Litigation Update: Status of Appeals, Flavor Bans and New Challenges** **Eric Gotting, Partner, Keller and Heckman** – Update on Lawsuits Challenging MDOs for Flavored ENDS – California and State Flavor Ban Appeals – Supreme Court Challenge – FDA/DOJ Lawsuits Against Vape Companies and Consent Decrees
11:20 a.m. – 11:35 a.m.	**Break**
11:35 a.m. – 12:15 p.m.	**Substantial Equivalence Reports and SE Exemptions** **Kathryn C. Skaggs, Partner, Keller and Heckman** – Overview of Substantial Equivalence (SE) and SE Exemption Pathways – SE Report Final Rule Update – Strategies to Consider – New SE and SE Exemption Authorizations – New Pathway for Flavors? – Considerations for Hookah, Pipe and RYO Tobacco Products
12:15 p.m. – 1:45 p.m.	**Lunch, provided by Keller and Heckman + Keynote Address** **The World Health Organization, FCTC and Tobacco Harm Reduction** **Guest Speaker: Derek Yach, Global Health Advocate, Former WHO Lead for Development of the FCTC and Former President of the Foundation for a Smoke-Free World**

1:45 p.m. – 2:30 p.m.	**Flavored Tobacco Products: Public Health and Regulatory Challenges** **Guest Speaker: Willie J. McKinney, Ph.D., DABT, McKinney Regulatory Science Advisors, LLC** – Flavored Tobacco Products – Science & Regulatory Update – FDA CTP's Position on Flavored Tobacco Products – Is Authorization Possible? – The Importance of Alternative Tobacco Product Variety and Consumer Choice for Harm Reduction – Call to Action
2:30 p.m. – 3:15 pm	**State Law Update: ENDS and Nicotine Products** **Daniel McGee, Counsel, Keller and Heckman** **Taylor Johnson, Associate, Keller and Heckman** – Update on State and Local Flavor Bans and Other Restrictions – State Licensing and Tax Requirements – State and PACT Act Enforcement Actions – Synthetic Nicotine Bans and Requirements
3:15 p.m. – 3:30 p.m.	**Break**
3:30 p.m. – 4:15 p.m.	**FDA Inspections, PMTA Remote Assessments and Tobacco Product Manufacturing Standards/cGMP Update** **Neelam Gill, Counsel, Keller and Heckman** – cGMP/TPMP Update – 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 – What You Will Need to Comply
4:15 pm – 5:15 p.m.	**Protecting Your Brand, Products & Consumers: Age-Gating & Supply Chain Security** **Guest Speakers:** **Jessica Zdinak, Ph.D., CEO, Applied Research and Analysis, LLC** **Eric Hawk, Illicit Trade Independent Consultant** **Dave DeJean, Head of Sales and Business Development, Systech International** – How Gray Market Issues Impact Your Business – Brand Protection for ENDS: Technology and Process – Options for Age-Gating Adult-Only Products – How to Combat Counterfeit Products – Addressing Illicit Trade Issues, China New E-Cigarette Standards and Regulations
5:15 p.m. – 6:45 p.m.	**Networking Happy Hour**
6:45 p.m.	**Symposium Adjourns for the Day**

Day 2 – Thursday, February 16, 2023

9:00 a.m. – 9:05 a.m.	**Welcome Remarks**

9:05 a.m. – 10:00 a.m.	**Global Regulatory Update: China and the European Union**
	David Ettinger, Partner and Chief Representative, Keller and Heckman Shanghai Office
	Elisa Giusto, Associate, Keller and Heckman Brussels Office
	- European Union TPD Update and Notification Process
	  - Labeling and Other Requirements
	  - Flavor Bans
	  - Member State Case Study: Poland
	- China New E-Cigarette Standards and Regulations
	  - Tobacco Monopoly Act and New GB Standards
	  - Overview of Licensing, Registration and Testing Requirements
	  - Requirements for Export-Only vs. Domestic Products

10:00 a.m. – 10:45 a.m.	**Licensed E-Cigarettes on Prescription: The Greatest Unmet Need in Smoking Cessation and Tobacco Control** **Guest Speaker: Ian Fearon, Ph.D., Director, whatIF? Consulting Ltd** - Brief History of Licensing E-Cigarettes as Medicines - Overview of Global Routes to Market: How to Navigate Regulatory Pathways - Permissive and Pragmatic vs. Restrictive Regulatory Regimes - Pros and Cons of ENDS Licensing – Consumers and Manufacturers
10:45 a.m. – 11:00 a.m.	**Break**
11:00 a.m. – 12:00 p.m.	**Demonstrating Benefits to Adult Smokers through an ENDS Actual Use Study** **Guest Speaker: Christopher Russell, Ph.D., Russell Burnett Research & Consultancy Ltd** - FDA Requirements for Reliable and Robust Observational and Behavioral Evidence on Switching or Cigarette Reduction Over Time - Designing and Conducting an ENDS Actual Use Study (AUS) to Demonstrate the Switching and Cigarette Reduction Effects for Adult Smokers
12:00 p.m. – 1:15 p.m.	**Lunch/Networking Break, provided by Keller and Heckman**
1:15 p.m. – 2:00 p.m.	**Cigar Update: Litigation, State Laws and Flavor Bans** **Daniel McGee, Counsel, Keller and Heckman** - Premium Cigar Litigation Overview and Update - Key Considerations for Compliance and Importation - FDA Proposed Flavor Ban - State Excise Tax (SET) Considerations

2:00 p.m. – 2:30 p.m.	**Flavors, Taxes, PMTAs, Preemption & More: 2023 State Legislative Update** **Guest Speaker: Gregory Conley, Director of Legislative & External Affairs, American Vapor Manufacturers** − 2023 State Legislative Update
2:30 p.m. – 3:00 p.m.	**Break**

3:00 p.m. – 3:45 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:
	  ○ Current Status as Controlled Substances Under the Federal Controlled Substances Act (Including Delta-8 THC) and Recent Federal Court Decisions
	  ○ Impact of the Agricultural Improvement Act of 2018 (the Farm Bill)
	  ○ 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

3:45 p.m. – 4:30 p.m.	**Update on State Regulation of Cannabinoid Products** **Daniel McGee, Counsel, Keller and Heckman** − Update on State Regulations of Cannabinoid Products, including CBD, Delta-8 and other THC and Cannabinoid Products
4:30 p.m.	**Symposium Adjourns**