Tobacco and Nicotine Products Regulation and Policy Conference

The Westin DC Downtown | 999 9th Street Northwest | Washington, DC 20001
October 28–29, 2025

Agenda

Subject to Change (All Times Are Eastern Standard Time)

Tuesday, October 28, 2025

8:15–9:00 AM ***Registration and Breakfast***

9:00–9:50 AM **FDLI Welcome and Keynote Address**

FDLI Welcome
Christine M. Simmon, President & CEO, FDLI

Keynote Address
Bret Koplow, Acting Director, Center for Tobacco Products (CTP), U.S. Food & Drug Administration (FDA)

10:00–11:00 AM **The Future of Tobacco Policy: Aligning CTP's Present with MAHA's Vision**

Ten months into the current administration, what has changed—and what hasn't? Panelists will discuss the evolving APPH standard and how the MAHA movement may influence enforcement, consumer education, and product authorization. As FDA realigns its workforce and priorities, panelists will consider what a modern, effective tobacco strategy could look like in 2026 and beyond.

Robyn Gougelet, Vice President, US Regulatory Affairs, JUUL Labs
Cheryl K. Olson, Independent Health Behavior Consultant, Cheryl K. Olson Sc.D., LLC
Jeff Weiss, Chief Engagement Officer, DF Medical Ventures
Jeffrey Willett, Founder, Network for Principled Nicotine Policy
Moderated by **Beth Oliva**, Partner, Fox Rothschild LLP and Member, FDLI Board of Directors

11:00–11:15 AM ***Networking Break***

11:15 AM–12:15 PM **PMTAs and MRTPs: Rethinking Product Review**

How does the product review process impact innovation? This panel will explore potential reforms to FDA's PMTA and MRTP pathways with a focus on speed, transparency, and statutory fidelity. Can FDA's AI initiative, Elsa, be incorporated into product review

reform? And if so, how might it be used to improve the pathways and what would integration look like in practice? The panel will discuss concrete proposals, including creating a faster authorization process for reduced-risk products, implementing a default approval, providing clear review criteria, and improving transparency through standardized guidance documents.

Matthew R. Holman, Chief Scientific & Regulatory Strategy Officer US, Philip Morris International
Sarah Marking, Chief Strategy Officer, Sanova
Brian Miller, Associate Professor of Medicine, Johns Hopkins University
Cristi Stark, Associate Director, Office of Science, CTP, FDA
Moderated by **Stacy L. Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP

12:15–1:30 PM ***Lunch Break***

1:30–2:30 PM **Product Standards: Building a Clearer Pathway for Non-Combustibles**

Could product standards help FDA and stakeholders evaluate e-cigarettes, nicotine pouches, and other smoke-free products more consistently and efficiently? This panel will explore potential FDA-enforced product standards, the impact of state and local restrictions, and how such standards could simplify PMTA requirements and product reviews. Panelists will also examine the possibility of legal challenges to product standards and ways to balance stakeholder interests. Potential alternatives, such as monographs or voluntary consensus standards, will also be discussed.

Amy K. Madl, Founder, Sr. Principal Health Scientist, Valeo Sciences
John Patterson, President, IKE Tech
Rachael Schmidt, Regulatory Compliance Consultant, ALINC Consulting LLC
Moderated by **Joe G. Gitchell**, CEO, Pinney Associates, Inc.

2:40–3:40 PM **Communicating Harm Reduction: Clinical Conversations, Public Perception, and FDA's Role**

How should health care providers talk to their patients about smoke-free products? Drawing lessons from FDA's public health communication efforts, European policy interventions, effective and ineffective media messaging, and recent data on pouches and e-cigarettes, this panel examines opportunities for clinical care guidelines and effective public communication around harm reduction. As the administration advances the MAHA initiative, how does FDA's communication to the public and clinicians about harm reduction align with Commissioner Makary's call for "gold standard science and common sense"?

Georges Benjamin, Executive Director, American Public Health Association
Cliff Douglas, Adjunct Professor, University of Michigan School of Public Health
Mohamadi Sarkar, Fellow, Regulatory Science, Altria Client Services LLC

David Utley, CEO, Pivot
Moderated by **Lauren Gardner**, Reporter, Politico

3:40–4:00 PM ***Networking Break***

4:00–5:00 PM **Consumer Behavior: What People Are Doing and Why it Matters**

How are regulations, market dynamics, public health campaigns, and social trends affecting consumer behavior? This panel will explore patterns in product use, switching, quitting, and uptake across product categories, generational cohorts, location, and time. Speakers will examine how adult and youth nicotine users react to changes in the real world, based on FDA's interpretation of the TCA and adaptive definitions of APPH responding to a changing nicotine user landscape.

Kenneth Michael Cummings, Professor, Department of Psychiatry and Behavioral Sciences, College of Medicine, Medical University of South Carolina
Marina Murphy, Senior Director, Scientific Affairs, Haypp Group
Skip Murray, Consumer Advocate, Minnesota Smoke Free Association
Moderated by **Jessica Zdinak**, Chief Research Officer, CEO, Applied Research and Analysis Company LLC

5:00–6:00 PM ***Reception (In-Person Only)***
Sponsored by OWNiT powered by HAYPP Group

Wednesday, October 29, 2025

9:00–9:30 AM ***Registration and Breakfast***

9:30–10:40 AM **FDLI Welcome and Science that Drives Policy Session**

FDLI Welcome
Paige Samson, Director, Education, FDLI

Science that Drives Policy: What Research Do We *Really* Need?

What questions should be answered for future regulation—and where do we already know enough to act? Leading researchers and policy experts will discuss which science gaps should be filled next and which topics may warrant immediate rulemaking and authorization decisions. Panelists will discuss the state of research on toxicology,

epidemiology, public health communications, and behavioral science—including specific examples such as the NYTS—and ways to help scientific findings better guide regulatory decisions.

Michael Fisher, Senior Director, Regulatory Strategy, JUUL Labs
Andrew Joyce, CEO, Sanova
Robin J. Mermelstein, Professor and Director, University of Illinois-Chicago
Moderated by **LieAnn T. Van-Tull**, Counsel, Keller & Heckman LLP

10:40–11:00 AM ***Networking Break***

11:00 AM–12:00 PM **Strategies for Addressing Unauthorized Nicotine Products**

Unauthorized nicotine products, including ENDS, pouches, and nicotine analogue products, present regulatory and public health challenges. Experts will discuss actionable solutions to the unauthorized nicotine market and consider concrete policy proposals, from disposable vape bans to expedited review pathways, and more.

Brian King, Executive Vice President, U.S. Programs, Campaign for Tobacco-Free Kids
David Spross, Executive Director, National Association of Tobacco Products (NATO)
John Verbeten, Director, Office of Compliance and Enforcement, CTP, FDA
Brian Weinhaus, Director, Illicit Trade Prevention, Philip Morris International
Moderated by **Lillian Ortega**, Owner and Chief Regulatory Compliance Strategist, WOW Solutions LLC

12:00–1:15 PM ***Lunch Break***

1:15–2:15 PM **Taxed, Tracked, and Transformed: State-Level Strategies for Nicotine Control**

States are transforming the nicotine landscape through taxation, product registries, and shifting enforcement priorities. As budget pressures increase and certain nicotine products remain untaxed, states face challenges in balancing regulation with revenue and public health objectives. This panel will examine the economic factors influencing state-level decisions, their effects on supply chains and consumer behavior, and insights from states that have taken action already.

Kellsi Booth, Chief Legal Officer, Black Buffalo Inc.
Peter Brennan, Executive Director, New England Convenience Store & Energy Marketers Association, Inc. (NECSEMA)
Jacob James Rich, Director of Consumer Freedom, Reason Foundation
Moderated by **Bryan Haynes**, Partner, Troutman Pepper Locke

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2:15–2:30 PM	***Networking Break***
2:30–3:30 PM	**Tobacco on Trial: Key Legal Cases Influencing FDA's Authority** This panel will examine how recent court decisions are reshaping the environment for challenging FDA actions, including marketing denial orders, product standards, and delays on menthol and nicotine regulations. Panelists will discuss emerging risks and opportunities for both industry and public health groups and evaluate potential legal challenges FDA may encounter in the future. **Eric N. Heyer**, Partner, Thompson Hine **Andrew Tardiff**, Senior Staff Attorney, Campaign for Tobacco-Free Kids **Ryan J. Watson**, Partner, Jones Day *Moderated by* **Eric Lindblom**, Senior Scholar, O'Neill Institute for National and Global Health Law, Georgetown Law
3:30 PM	***Conference Adjournment***