Tobacco and Nicotine Products Regulation and Policy Conference

October 25-26, 2018
The National Press Club | 529 14th Street NW | Washington, DC 20045

Join a diverse number of stakeholders—public health advocates, researchers, manufacturers, lawyers, consumer interest groups, entrepreneurs, governmental agencies and others—for this two-day conference on effectively regulating the broad spectrum of tobacco and nicotine products in the U.S. and globally. Hear from FDA's Center for Tobacco Products Director, Mitch Zeller, to learn about the latest updates on regulations, guidance documents, and other initiatives. The conference will also include a number of timely tobacco and nicotine issues that will allow for interactive dialogues between the panelists and audience.

Thursday, October 25

8:15–8:55 AM	**Registration and Continental Breakfast**
8:55–9:00 AM	**FDLI Welcome and Opening Remarks** **Amy Comstock Rick**, President & CEO, Food and Drug Law Institute
9:00–9:45 AM	**Keynote Address** **Mitchell R. Zeller**, Director, Center for Tobacco Products (CTP), Office of Medical Products and Tobacco, FDA
9:45–10:45 AM	**Reactor Panel** Panelists will respond to Director Zeller's comments regarding effective dialogue among stakeholders, updates on the Advanced Notice of Proposed Rulemakings, and other current policy initiatives. **Brittani Cushman**, Senior Vice President, External Affairs, Turning Point Brands, Inc. **Dennis Henigan**, Vice President, Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids **Jose Luis Murillo**, Vice President, Regulatory Affairs, Altria Client Services LLC **Mitchell R. Zeller**, Director, Center for Tobacco Products (CTP), Office of Medical Products and Tobacco, FDA *Moderated by* **Barry Schaevitz**, Partner, Fox Rothschild LLP
10:45–11:00 AM	**Networking and Coffee Break**
11:00 AM–12:00 PM	**Ensuring an Effective Tobacco and Nicotine Regulatory Framework** As information evolves, should the regulatory framework for how tobacco and nicotine products are regulated be updated? How do you strike a balance between regulation and innovation and balance competing interests? Panelists will discuss the current FDA regulatory landscape and desired characteristics for a modernized approach. **Katherine Ciambrone**, Senior Vice President and Chief Compliance Officer, ITG Brands

Stacey Gagosian, Managing Director of Public Policy, Truth Initiative
David Sweanor, Adjunct Professor of Law, Centre for Health Law, Policy and Ethics, University of Ottawa
Moderated by **Scott Ballin**, Tobacco and Health Policy Consultant

12:00–12:15 PM **Transition**

12:15–1:15 PM **Networking Lunch**

1:15–2:15 PM **The Latest on Product Standards and Other Potential Regulatory Action**
In March 2018, FDA released three Advanced Notices of Proposed Rule Making (ANPRM) seeking comments on a potential product standard for nicotine levels in cigarette products, the role of flavors in tobacco products, and the regulation of premium cigar products. In this session, panelists will discuss those ANPRMs and the next set of issues on which FDA has said it will focus, including product pathways, Tobacco Product Manufacturing Practices, and product standards for batteries and liquids in e-vapor products.

Tony Abboud, Executive Director, Vapor Technology Association
Mitchell A. Neuhauser, Vice President and Assistant General Counsel – Regulatory, RAI Services Company (RAISC)
James Vail, Director of Communications, 22nd Century Group, Inc.
Moderated by **Dean R. Cirotta**, President & Chief Operating Officer, EAS Consulting Group, LLC

2:15–3:15 PM **Premarket Applications and the Element of Uncertainty**
Commissioner Gottlieb and Director Zeller have said FDA will propose foundational rules about what is expected in premarket applications, including SE, PMTAs, and MRTPs. In this session, panelists will address how manufacturers and FDA have been making decisions in this complex and changing regulatory environment, and what they think should be included in these foundational rules.

Carole B. Folmar, Director, Regulatory and Scientific Affairs, ITG Brands
Raymond Niaura, Professor, Department of Social and Behavioral Science, New York University College of Global Public Health
James M. Solyst, Vice President, Federal Regulatory Affairs, Swedish Match North America
Moderated by **Bryan Haynes**, Partner, Troutman Sanders LLP

3:15–3:45 PM **Networking and Coffee Break**

3:45–5:00 PM **Protecting Youth: Targeting Appropriate E-Cigarette Users**
In May 2018, FDA, in conjunction with FTC, initiated enforcement actions aimed at addressing youth use of nicotine, and e-vapor products in particular, including issuing warning letters to companies for selling e-liquids resembling juice boxes and to retailers for selling popular nicotine products to underage youth. In this session, panelists will discuss these enforcement actions, the role of FDA and industry to address the use of tobacco products by kids, and the threat youth uptake poses to the role these products could play in tobacco harm reduction.

Kathleen Crosby, Director, Office of Health Communication and Education, FDA - CTP
Mark Greenwold, Senior Consultant, Campaign for Tobacco-Free Kids
Carrie Wade, Director of Harm Reduction Policy and Senior Fellow, R Street Institute
Moderated by **J. Benneville (Ben) Haas**, Partner, Latham and Watkins LLP

5:00 PM **Adjournment**

5:00–6:30 PM **Networking Reception**

Friday, October 26

8:15–8:55 AM **Registration and Continental Breakfast**

8:55–9:00 AM **FDLI Welcome and Announcements**
Paige Samson, Assistant Director, Educational Programs, Food and Drug Law Institute

9:00–10:15 AM **Risk Communications: Educating the Public About Harm Reduction**
As part of its comprehensive approach to regulating tobacco and nicotine products, FDA placed nicotine as the keystone of their efforts, including promoting innovation across noncombustible tobacco and nicotine products and consideration of a maximum nicotine standard in combustible products. A potential barrier to the success of this integrated approach is the public's belief that nicotine itself is the cause of smoking-related diseases, while science indicates that it is the byproducts of combustion that are responsible for the majority of harm. This session will consider the array of opportunities and barriers to success for overcoming risk communication challenges.

Clive Bates, Director, Counterfactual Consulting Limited
Cliff Douglas, Vice President for Tobacco Control and Director, Center for Tobacco Control, American Cancer Society
Michiel Reerink, Vice President, Global Regulatory Strategy, Japan Tobacco International
Moderated by **Stacy Ehrlich**, Partner, Kleinfeld, Kaplan, & Becker, LLP and Member, FDLI Board of Directors

10:15–10:45 AM **Networking and Coffee Break**

10:45 AM–12:00 PM **How to Identify and Interpret Quality Science**
Scientific studies form the basis of many tobacco and nicotine laws and regulations. What are the important criteria to consider when analyzing science to ensure it is sound? This session will focus on how to identify good science from bad science and how FDA and the tobacco industry can utilize data to drive science and public communications.

David B. Abrams, Professor, Department of Social and Behavioral Sciences, New York University College of Global Public Health
Michael Fisher, Senior Principal Scientist, Scientific Strategy & Analysis, Altria Client Services, LLC
Robert Guzman, Regulatory Counsel, Thompson Hine LLP

Moderated by **Eric N. Lindblom**, Director, Tobacco Control and Food & Drug Law, O'Neill Institute for National and Global Health Law, Georgetown University Law Center

12:00–12:15 PM **Transition**

12:15–1:15 PM **Networking Lunch**

1:15–2:30 PM **The Future of Nicotine Products and FDA's Nicotine Steering Committee**
FDA established the Nicotine Steering Committee to analyze opportunities for nicotine-containing tobacco products, like e-vapor products, to be approved as drug products. In August, FDA issued draft guidance with the promise of additional guidance to be issued this fall. Panelists will discuss this guidance, the latest developments with the Nicotine Steering Committee, and what it could all mean for pathways for orally inhaled nicotine containing products at CTP and CDER.

Marc S. Firestone, President, External Affairs and General Counsel, Philip Morris International
Joseph Gitchell, President, Pinney Associates, Inc.
Dorothy Hatsukami, Associate Director, Cancer Prevention and Control, Masonic Cancer Center and Professor, Department of Psychiatry, University of Minnesota
Grail Sipes, Deputy Center Director, Regulatory Policy, FDA - CDER
Moderated by **Mark Vaders**, Counsel, Womble Bond Dickinson (US) LLP

2:30–3:30 PM **Illicit Trade of Tobacco and Nicotine Products**
What impact will a product standard on nicotine levels in cigarettes and flavors have on the illicit trade of tobacco and nicotine products? FDA issued a draft concept paper on this topic and asked for public comment. Panelists will discuss illicit trade issues that could result from product standards on nicotine and flavors.

Alex Clark, Chief Executive Officer, Consumer Advocates for Smoke Free Alternatives Association (CASAA)
Christopher (C.J.) Griffiths, Policy Counsel, FDA - CTP
Eric Heyer, Partner, Thompson Hine LLP
Clarissa Manning, Director of Business Operations, BOTEC Analysis
Moderated by **Seth A. Mailhot**, Partner, Michael Best & Friedrich LLP

3:30 PM **Conference Adjournment**