Tobacco Products Regulation and Policy Conference

October 26-27, 2017
W Hotel Washington, DC | 515 15th Street, NW | Washington, DC

Agenda

Thursday, October 26

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

9:00–9:05 AM **FDLI Welcome**
Amy Comstock Rick, President & CEO, FDLI

9:05–9:45 AM **Keynote Address**
Mitchell R. Zeller, Director, CTP, Office of Medical Products and Tobacco, FDA

9:45–10:30 AM **Reactor Panel**
Panelists will respond to Director Zeller's comments regarding FDA's July 28th announcement of FDA's new plan for tobacco and nicotine regulation, public health challenges related to tobacco use, in particular cigarettes, and limitations under the current Tobacco Control Act.

Brittani Cushman, Vice President, External Affairs, Turning Point Brands, Inc.
James E. Dillard, Senior Vice President, Research, Development and Sciences, Chief Innovation Officer, Altria Group, Inc.
David Dobbins, COO, Government Affairs, Truth Initiative
Mitchell R. Zeller, Director, CTP, Office of Medical Products and Tobacco, FDA
Moderated by **Scott Ballin**, Tobacco and Health Policy Consultant

10:30–11:00 AM **Coffee and Networking Break**

11:00 AM–12:00 PM **Pros and Cons of Very Low Nicotine Cigarettes as a Public Health Strategy**
On July 28th, FDA announced that it will "begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards." Panelists will discuss the pros and cons of such a strategy and whether there may be ways to mitigate any unintended consequences, such as by encouraging innovation and simultaneously making more science-based reduced risk products available to smokers.

Clive Bates, Director, Counterfactual Consulting Limited

Eric C. Donny, Professor, Departments of Physiology & Pharmacology and Social Science and Health Policy and Director, Tobacco Control Center of Excellence, Wake Forest Comprehensive Cancer Center
Henry Sicignano, President, CEO & Director, 22nd Century Group, Inc.
Moderated by **Raymond Niaura**, Professor, Social and Behavioral Sciences, NYU College of Global Public Health, New York University

12:00–1:15 PM **Luncheon Address**
Derek Yach, Founder and President-Designate of the Foundation for a Smoke-Free World

1:15–1:30 PM **Transition**

1:30–2:15 PM **PMTA/MRTP Processes, Product Standards, and Other Options**
Speakers will discuss how best to regulate tobacco, nicotine, and alternative products using the concept of the continuum of risk. Do these processes stifle or promote innovation and competition and what are the implications for small businesses? Can these processes be streamlined to better serve both public health needs and the needs of manufacturers?

Bryan Haynes, Partner, Troutman Sanders LLP
Michael Hufford, Vice President, Regulatory Affairs, Behavioral Science, and Innovation, Pinney Associates, Inc.
Patricia Kovacevic, General Counsel and Chief Compliance Officer, Nicopure Labs LLC and Member of the Vapor Technology Association Board
Moderated by **James M. Solyst**, Vice President, Federal Regulatory Affairs, Swedish Match North America

2:15–3:00 PM **Risk Communications: Getting Truthful Information to the Public, Consumers, and Other Stakeholders**
During this session, speakers will discuss how truthful, accurate, and non-misleading information about the risks and relative risks of tobacco, nicotine, and alternative products is transmitted to consumers. What is the role of FDA, other governmental agencies, public health community, and manufacturers?

John Hughes, Professor of Psychiatry, Psychological Science and Family Medicine, University of Vermont
Lynn T. Kozlowski, Professor of Community Health and Health Behavior, University at Buffalo School of Public Health and Health Professions
Donna Vallone, Chief Research Officer, Truth Initiative
Moderated by **David Sweanor**, Adjunct Professor of Law, University of Ottawa

3:00–3:30 PM **Coffee and Networking Break**

3:30–4:15 PM **Developing a Transparent Multi-Stakeholder Scientific Research Effort**
How can communications, collaboration, priority setting, and peer review involving a spectrum of stakeholders, which includes trade associations;

manufacturers; academic institutions; and FDA and other governmental agencies such as the National Institute of Drug Abuse (NIDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and US Department of Agriculture (USDA) with a goal of better science to benefit all, be improved?

Charles Garner, Vice President-Scientific Regulatory Affairs, Reynolds American, Inc. Services Company (RAISC)
Scott J. Leischow, Professor, College of Health Solutions, Arizona State University and Editor-in-Chief, Tobacco Regulatory Science
Kathleen Stratton, Scholar, National Academies of Sciences, Engineering, and Medicine
Moderated by **David Abrams**, Professor, Social and Behavioral Sciences, NYU College of Global Public Health, New York University

4:15–5:00 PM **Substantial Equivalence: Is it in Need of a Tune-up or Modification?**
Determining when and if products are substantially equivalent to existing products on the market will be discussed. Are the current requirements excessively burdensome? Does FDA have the resources? Can changes be made that will make the process more workable and flexible without compromising public health goals?

Katherine Ciambrone, Chief Compliance Officer and Senior Vice President, ITG Brands
Desmond Jenson, Staff Attorney, Public Health Law Center, Tobacco Control Legal Consortium
Barry Schaevitz, Partner, Fox Rothschild LLP
Moderated by **Stacy Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP and Member, FDLI Board of Directors

5:00–6:30 PM **Networking Reception**

Friday, October 27

8:30–8:55 AM **Continental Breakfast**

8:55–9:00 AM **FDLI Welcome**
Paige Samson, Assistant Director, Educational Programs, FDLI

9:00–10:00 AM **Where are the Large Domestic and International Tobacco Companies Headed?**
Hear from high-level representatives from the tobacco industry who produce cigarettes and a spectrum of reduced risk or next generation products. They will also share their views and perspectives about the future regulatory landscape in the US and globally.

Marc Firestone, Senior VP and General Counsel, Philip Morris International, Inc.
Ian Jones, Scientific and Regulatory Affairs, Japan Tobacco
Joe Murillo, Vice President, Regulatory Affairs, Altria Client Services LLC
Mitchell A. Neuhauser, Vice President and Assistant General Counsel, RAI Services Company
Fredrik Peyron, Senior VP, Regulatory Affairs and Group Communications, Swedish Match
Moderated by **Toni Clarke**, Correspondent, Thomson Reuters

10:00–10:45 AM **Multi-Stakeholder Panel**
The reactor panel will ask questions, get clarification, and make suggestions about where they believe the industry should be headed, from their perspectives, and what their responsibilities are.

Tony Abboud, Executive Director, Vapor Technology Association
Gregory Conley, President, American Vaping Association
David Levy, Professor, Lombardi Comprehensive Cancer Center, Georgetown University
Matthew Myers, President, Campaign for Tobacco-Free Kids
Moderated by **Toni Clarke**, Correspondent, Thomson Reuters

10:45–11:15 AM **Coffee and Networking Break**

11:15 AM–12:15 PM **The Future of Deeming Regulations: Policy and Litigation**
Panelists will engage in discussions about the future of the Deeming regulations, including issues pertaining to litigation, regulations, legislation, and the pros and cons of extending the implementation dates to 2021 and 2022. Attention will also be given to the appropriate uses of flavorings in both e-cigarettes and cigars and how we can ensure that children and youth are not being encouraged to use such products.

Cynthia Cabrera, President, The Cating Group
David Clissold, Partner, Hyman, Phelps & McNamara, PC

Dennis Henigan, Director, Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids
Kathleen Hoke, Professor & Director, Network for Public Health Policy, University of Maryland Law School
Moderated by **Azim Chowdhury**, Partner, Keller and Heckman LLP

12:15–1:15 PM **Networking Lunch**

1:15–1:30 PM **Transition**

1:30–2:30 PM **Engaging with FDA: Communications and Relationships**
Given the relative newness of FDA's tobacco products authority, often there can be more questions than answers. This panel will explore best practices for engaging with the agency, examine how (if possible) to obtain authoritative guidance from FDA in a timely manner, and how relationships between regulators and industry can be improved.

Jonathan A. Havens, Associate, Saul Ewing Arnstein & Lehr, LLP
Nathan Hurley, CTP Ombudsman, FDA
Marc J. Scheineson, Partner, Alston & Bird LLP
Valerie Briggs Solomon, Managing Counsel, R&D and Regulatory, RAI Services, Inc.
Moderated by **Dean Cirotta**, President & CEO, EAS Consulting Group, LLC

2:30–3:30 PM **How Might Lessons Learned from the US Inform Regulatory Development in Other Countries?**
Given that issues related to tobacco, nicotine, and alternative products regulation are global in scope, panelists will discuss how US policy might serve as a roadmap for both developed and developing countries and benefits and challenges in using the US as a roadmap.

Germana Barba, Vice President, Regulatory Affairs, Philip Morris International, Inc.
Jeannie Cameron, Founder and Managing Director, JCIC International
Nilesh Jain, Founder and MD, iVape.in
Moderated by **Delon Human**, President, Health Diplomats

3:30 PM **Conference Adjournment**