Tobacco and Nicotine Products Regulation and Policy Conference

October 24-25, 2019
The National Press Club | 529 14th Street NW | Washington, DC 20045

Join a diverse group 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 US and globally. Hear from FDA's Center for Tobacco Products Director, Mitchell Zeller, to learn about the latest updates on regulations, guidance documents, and other initiatives. The conference will also address a number of timely tobacco and nicotine issues that will allow for productive and interactive dialogues between the panelists and attendees.

Thursday, October 24

8:15–8:50 AM — **Registration and Continental Breakfast**

8:50–9:00 AM — **Welcome and Opening Remarks**
Amy Comstock Rick, President & CEO, Food and Drug Law Institute

9:00–9:45 AM — **Keynote Address: An Update on FDA's Comprehensive Plan for Tobacco and Nicotine Products**
Mitchell Zeller, Director of FDA's Center for Tobacco Products (CTP), will provide updates on key aspects of FDA's comprehensive plan for tobacco and nicotine regulation, including the agency's nicotine policies and science-based review of tobacco products. Director Zeller will also highlight key efforts of the agency's youth tobacco prevention plan, including the latest actions to prevent youth access to tobacco products, curb marketing of tobacco products aimed at youth, and educate teens about the dangers of using any tobacco product (including e-cigarettes).

Mitchell R. Zeller, Director, Center for Tobacco Products (CTP), FDA

9:45–10:45 AM — **Reactor Panel**
In this session, panelists will discuss Director Zeller's comments on FDA's comprehensive plan for tobacco and nicotine reduction, FDA efforts to prevent youth tobacco and nicotine product use, and address other current policy initiatives.

David Dobbins, Chief Operating Officer, Government Affairs, Truth Initiative
Moira Gilchrist, Vice President, Scientific and Public Communications, Philip Morris International
Kathleen Hoke, Director, Legal Resource Center for Public Health and Policy, University of Maryland Carey School of Law
Moderated by **Dean Cirotta,** President and COO, EAS Consulting Group

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

11:15 AM–12:15 PM **Risk Communication to Adults: How Should Relative Risk be Conveyed?**
In this session, panelists with diverse perspectives will take a broad look at how the relative risks of tobacco and nicotine products should be communicated to adults. The discussion will include the roles of government, public health, and industry; ways to communicate beyond public education campaigns; and how to coordinate messaging across all stakeholders. Barriers to communication and the impact on consumers and the public will also be discussed.

Marissa G. Hall, Assistant Professor, Department of Health Behavior, University of North Carolina Gillings School of Global Public Health
Cheryl Healton, Dean, New York University College of Global Public Health
Mitchell A. Neuhauser, Vice President and Assistant General Counsel, RAI Services Company (RAISC)
Moderated by **Stacy L. Ehrlich,** Partner, Kleinfeld, Kaplan & Becker LLP and Member, FDLI Board of Directors

12:15–1:15 PM **Luncheon with Guest Speaker**
Thomas J. Miller, Attorney General, Iowa
Introduced by **Laura Brown,** Director of Educational Programs, FDLI

1:15–1:30 PM **Transition**

1:30–2:30 PM **The Role of Government, Public Health, Industry, and Academia in Combatting Youth Vaping**
We can all agree that youth should not begin using e-cigarettes or other Electronic Nicotine Delivery Systems (ENDS). In this session, panelists will review recent youth vaping statistics and current FDA efforts to combat youth use, then turn to a discussion of what roles public health, industry, retailers, schools, law enforcement, and technological solutions can and should play in such efforts in the future, including the current Administration's proposed ban on all non-tobacco flavors for e-cigarettes.

David Abrams, Professor of Social and Behavioral Sciences, New York University College of Global Public Health
James Baumberger, Senior Director, Federal Advocacy, American Academy of Pediatrics
Parker David Kasmer, Regulatory Counsel, JUUL Labs
Moderated by **J. Benneville (Ben) Haas,** Partner, Latham & Watkins LLP

2:30–3:30 PM **Marketing and Advertising for Modified Risk Tobacco Products**
In this session, panelists will discuss how modified risk tobacco products (MRTPs) both are and should be marketed and advertised to adults, considering both their value as alternative to combustible products and the interest in preventing youth use. Panelists will discuss FDA's perspective on modified risk claims, the potential value of these claims, the information and misinformation

being shared via marketing channels, and offer industry's perspective on how modified risk product claims should be approached.

Aruni Bhatnagar, Chair, School of Medicine, University of Louisville and co-Director, American Heart Association Tobacco Center for Regulatory Science
Cynthia Cabrera, President, The Cating Group
Brittani Cushman, Senior Vice President, External Affairs, Turning Point Brands, Inc.
Moderated by **Bryan M. Haynes,** Partner, Troutman Sanders LLP

3:30–4:00 PM **Networking and Refreshment Break**

4:00–5:00 PM **Reading the Tobacco Leaves: Paths and Challenges for a Nicotine Reduction Rule**
An important part of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation to reduce smoking is limiting nicotine in combustible tobacco products to minimally or non-addictive levels. In this session, panelists will review research on Very Low Nicotine Content (VLNC) products, discuss what an ideal nicotine product standard would like, and predict what legal or other challenges may arise in implementing such a rule.

Jonathan Foulds, Professor of Public Health Sciences and Psychiatry, Penn State University College of Medicine
Stacey Gagosian, Managing Director, Public Policy, Truth Initiative
John D. Pritchard, Vice President of Regulatory Science, 22nd Century Group
Moderated by **Robyn Gougelet,** Senior Associate, Pinney Associates, Inc.

5:00–6:30 PM **Networking Reception**

Friday, October 25

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

8:55–9:00 AM **Welcome and Announcements**
Steven Leslie, Assistant Director, Educational Programs, FDLI

9:00–9:45 AM **A Conversation with David A. Kessler on the Future of Youth e-Cigarette Use and Regulation**
David A. Kessler, Chairman, Board of Directors, Center for Science in the Public Interest, and former FDA Commissioner
A Discussion with **Amy Comstock Rick**, President & CEO, FDLI

9:45–10:30 AM **Premarket Tobacco Applications Session One: A Review of FDA's ENDS Guidance and the IQOS Marketing Order**
FDA recently finalized its "Premarket Tobacco Product Applications (PMTAs) for Electronic Nicotine Delivery Systems (ENDS)" guidance. FDA also issued a marketing order for a non-combustible tobacco product, IQOS, in accordance

with the guidance. In this session, panelists will engage in a detailed discussion of both the finalized guidance and the marketing order.

Priscilla Callahan-Lyon, Deputy Director, Division of Individual Health Science, CTP, FDA
Mark Greenwold, Senior Consultant, Campaign for Tobacco-Free Kids
Jim Solyst, Vice President, Federal Regulatory Affairs, Swedish Match North America
Moderated by **Scott Ballin,** Tobacco and Health Policy Consultant

10:30–10:45 AM **Networking and Refreshment Break**

10:45–11:30 AM **Premarket Tobacco Applications Session Two: Issues and Challenges for Pending and Future Applications**
Building off the previous session, panelists will discuss the future of PMTAs in light of recent developments. The discussion will focus on the particular challenges faced by ENDS manufacturers as well as the public health perspective on the PMTA process.

Katherine Ciambrone, Executive Vice President, Legal, Regulatory, and External Affairs, Fontem Ventures
Eric N. Lindblom, Director for Tobacco Control and Food and Drug Law, O'Neil Institute for National and Global Health Law, Georgetown Law
Beth G. Oliva, Partner, Fox Rothschild LLP
Moderated by **Scott Ballin,** Tobacco and Health Policy Consultant

11:30 AM–12:15 PM **The TCA's Population Impact Standard for New Products and Health Claims: How does Population Modeling Actually Work?**
The Tobacco Control Act (TCA) establishes a novel population impact standard for reviewing applications for new products and health claims. In this session, panelists will discuss computational modeling of tobacco product impacts on public health, various types of modeling systems used for nicotine products, and what factors should be considered or included when utilizing these models to support an application.

Ryan Black, Associate Fellow, Regulatory Sciences, Altria Client Services LLC
David Levy, Professor, Lombardi Comprehensive Cancer Center, Georgetown University Global Health Initiative
Moderated by **Saul Shiffman,** Professor of Psychology, University of Pittsburgh and Senior Scientific Advisor, Pinney Associates, Inc.

12:15–1:15 PM **Luncheon with Table Topic Discussions**

1:15–1:30 PM **Transition**

1:30–2:00 PM **Substantial Equivalence Update**
The session will feature an overview of the key elements of FDA's proposed rule for substantial equivalence, as well as a question and answer session.

Barry S. Schaevitz, Partner, Fox Rothschild LLP

2:00-3:00 PM

Pathways for Approval for Post-PMTA Product Modifications

Currently, if a tobacco or nicotine product is modified or altered after a PMTA is submitted, a new PMTA would need to be submitted for the altered product. This results in substantial costs to manufacturers and restricts the number of reduced risk products in the marketplace by hindering innovation. In this session, panelists will discuss post-application product modifications in light of FDA's proposed rule for PMTAs, as well as potential alternatives and their respective benefits and drawbacks.

Matt Holman, Director, Office of Science, CTP, FDA
Patricia Miller, Senior Director, Premarket Tobacco Applications, Altria Client Services LLC
Moderated by **Elizabeth Oestreich,** Vice President, Regulatory Compliance, Greenleaf Health

3:00–4:00 PM

A Comprehensive Discussion About Flavors in Tobacco and Nicotine Products

From cigarettes to cigars to chewable tobacco to e-cigarettes, flavored tobacco and nicotine products are widely available...for now. This session will feature a comprehensive discussion of flavors, including why manufacturers use flavors, responsible marketing of flavored products, how flavors fold into public health goals, and FDA guidance on and enforcement discretion of flavored products.

Tony Abboud, Executive Director, Vapor Technology Association
Aruni Bhatnagar, Chair, School of Medicine, University of Louisville and co-Director, American Heart Association Tobacco Center for Regulatory Science
Carole B. Folmar, Senior Director, Product Integrity and Compliance, Associate General Counsel, ITG Brands
Moderated by **Seth A. Mailhot,** Partner, Husch Blackwell LLP

4:00 PM

Conference Adjournment