



2018 FDLI Annual Conference

Exploring Advanced Topics in Food and Drug Law

May 3-4 | Washington, DC

PRELIMINARY CONFERENCE SCHEDULE

(subject to change)

Thursday, May 3

- 8:00–9:15 AM** **Registration and Continental Breakfast**
- 9:15–9:30 AM** **Welcome**
Amy Comstock Rick, President & CEO, FDLI
- 9:30–10:00 AM** **FDA Keynote Address**
Scott Gottlieb, Commissioner of Food and Drugs, FDA
Introduced by Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara, PC, and
Chair, FDLI Board of Directors
- 10:00–11:00 AM** **Update on Implementation of FDA Initiatives and Legislation**
During this session, speakers will provide an analysis of and update on activities
implementing key regulatory initiatives that have come out of FDA, as well as
discuss prominent legislation affecting FDA regulation.

Moderated by Amy Comstock Rick, President and CEO, FDLI
- 11:00–11:30 AM** **Coffee and Networking Break**
- 11:30–12:20 PM** **Breakout Sessions**
- **Regulatory Implications and Practical Challenges of Real World
Evidence and Real World Data**
John Manthei, Partner, Latham & Watkins LLP
Moderated by Meaghan Bailey, Executive Director, NSF Health
Sciences
 - **Regenerative Medicine and the Changing Regulatory Landscape**
Barbara Binzak Blumenfeld, Partner, Buchanan Ingersoll &
Rooney PC
Anne Marie Polak, Senior Director, Leavitt Partners

Michael Werner, Partner, Holland & Knight

- **Medical Device Innovations: Welcome to the Future**
Sonali Gunawardhana, Of Counsel, Wiley Rein LLP
Vernessa Pollard, Partner, McDermott Will & Emery LLP
- **Regulation of Cell-Based Meat and Other Modified Foods**
Gregory Jaffe, Biotechnology Project Director, CSPI
Nicole Negowetti, Clinical Instructor, Harvard Food Law and Policy Clinic
Moderated by **Stuart M. Pape**, Shareholder, Polsinelli PC
- **Key Trends and Questions in FSMA Inspections and Compliance of Animal Food**
- **Effects of FDA Enforcement on the Tobacco Industry and Consumers**

12:20–1:30 PM **Networking Luncheon and FDCA Anniversary Presentation**

1:30–2:00 PM *Speaker:* **Anna Abram**, Deputy Commissioner for Policy, Planning, Legislation and Analysis, FDA

2:00–2:10 PM **Transition**

2:10–3:25 PM **Breakout Sessions: FDA Center Directors**

Center for Drug Evaluation and Research (CDER)

Janet Woodcock, Director, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, FDA

Daniel A. Kracov, Partner, Arnold & Porter LLP, and Member, FDLI Board of Directors

Center for Biologics Evaluation and Research (CBER)

Peter W. Marks, Director, Center for Biologics Evaluation and Research, Office of Medical Products and Tobacco, FDA

Center for Devices and Radiological Health (CDRH)

Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, Office of Medical Products and Tobacco, FDA

Center for Food Safety and Applied Nutrition (CFSAN)

Susan T. Mayne, Director, Center for Food Safety and Applied Nutrition, Office of Foods and Veterinary Medicine, FDA

Center for Tobacco Products (CTP)

Mitchell R. Zeller, Director, Center for Tobacco Products, Office of Medical Products and Tobacco, FDA

Center for Veterinary Medicine (CVM)

Steven M. Solomon, Director, Center for Veterinary Medicine, Office of Foods and Veterinary Medicine, FDA

3:25–3:50 PM

Coffee and Networking Break

3:50–4:50 PM

Breakout Sessions

- **Generic Drug Initiatives: FDARA, GDUFA II, and Administrative Proposals**
Jeffrey Francer, Senior Vice President & General Counsel, Association for Accessible Medicine (AAM), and Member, FDLI Board of Directors
- **Biosimilars: New Developments and Updates**
Chad A. Landmon, Partner, Axinn, Veltrop & Harkrider LLP
Daniel Orr, Partner, Womble Bond Dickinson (US) LLP
- **Digital Health Developments and Changing Regulatory Approaches**
Bakul Patel, Associate Director for Digital Health, CDRH, FDA
Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara, PC, and Chair, FDLI Board of Directors
Moderated by Nancy Stade, Partner, Sidley Austin LLP
- **FSMA Inspections and Compliance for Human Food: Key Trends and Questions**
Marc C. Sanchez, Regulatory Attorney, CIHCC, LLC
- **Trends in Animal Food Litigation**
Jeannie Perron, Partner, Covington & Burling LLP
- **Risk-Based Approval of Tobacco Products**

4:50–5:00 PM

Transition

5:00–5:30 PM

Speaker: Rebecca K. Wood, Chief Counsel, FDA

5:30–7:00 PM

Networking Reception

Friday, May 4

8:00–8:30 AM

Breakfast

8:30–9:00 AM

FDLI Welcome and FDAAA Awards

9:00–10:00 AM

International Harmonization Efforts

As manufacturing, sales, and product development become more global in nature, government agency coordination and cooperation are increasingly relevant. This session will focus on international cooperation efforts, including FDA's inspection recognition agreements as well as coordinated actions on imported products.

Ben England, Founder and CEO, Benjamin L. England & Associates, LLC

10:00–10:30 AM

Coffee and Networking Break

10:30–11:20 AM

Breakout Sessions

- **Guidance on Guidance: FDA, DOJ, and Enforcement**
Jennifer L. Bragg, Partner, Skadden, Arps, Slate, Meagher & Flom LLP, and Vice Chair, FDLI Board of Directors
- **FDA's New Approach to Drug and Device Inspections**
Cathy Burgess, Partner, Alston & Bird, LLP
Moderated by Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf Health
- **The Evolving Regulatory Landscape for Orphan Drugs**
Krista Carver, Partner, Covington & Burling LLP
Adora Ndu, Executive Director, Regulatory Policy, Research & Engagement, BioMarin Pharmaceuticals
- **Current Nutrition Facts Labeling Challenges**
Leslie Krasny, Partner, Keller and Heckman LLP
Moderated by Bruce Silverglade, Principal, Olsson Frank Weeda Terman Matz PC
- **A Smoke-Free World: Evolving Technologies and Policies**
Dennis Henigan, Director, Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids
- **Advertising and Marketing in a Mobile World**
Jason Gordon, Counsel, Reed Smith LLP

11:20–11:30 AM

Transition

11:30 AM–12:20 PM

Breakout Sessions

- **OTC Drug Monograph Reform**
Elizabeth Jungman, Director, Public Health Programs, The Pew Charitable Trusts, and Member, FDLI Board of Directors
Moderated by Deborah Livornese, Of Counsel, Arnall Golden Gregory LLP
- **Evolving Regulatory Pathways for Medical Devices**

Judith O’Grady, Partner, Pepper Hamilton LLP
Cassie Scherer, Principal Legal Counsel, Corporate Legal
Regulatory, Medtronic
Rachel Turow, Executive Counsel – Regulatory Law, TEVA
Pharmaceuticals, Inc.

- **From Approval to Coverage – FDA and CMS Jurisdictional Lines**
David R. Zook, Partner, Faegre Baker Daniels LLP
- **Cannabis: FDA’s Role in Regulation**
Jonathan Havens, Associate, Saul Ewing Arnstein & Lehr LLP
- **Comprehensive Approach to Nicotine: Misperceptions, Regulations,
and Science**
Moderated by Joseph Gitchell, President, Pinney Associates, Inc.

12:20–1:30 PM

Luncheon

- **Facilitated Table Topic Discussions**
Led by FDLI-member experts, these informal facilitated discussions provide an ideal way to engage with colleagues, gain new information, and share best practices on a hot topic in food and drug law. Attendees have the option to choose from one of the 30+ topics or enjoy open-seating during lunch.

1:30–1:45 PM

Transition

1:45–2:35 PM

Breakout Sessions

- **Pre-Approval Communications, the First Amendment, and Compelled Speech: To Say or Not to Say, That is the Question**
First Amendment issues continue to be prominent in all areas of FDA-regulated industry, including in scientific exchange, product promotion, and as a defense to lawsuits. This panel will discuss FDA and industry perspectives on First Amendment issues and the regulatory landscape in wake of recent cases and FDA guidance and statements.
Maia Kats, Director of Litigation, Center for Science in the Public Interest
- **EU Medical Device Regulation: Implementation and Compliance**
Christian Fulda, Partner, Jones Day
Jana Grieb, Counsel, McDermott Will & Emery LLP
Sarah H. Stec, Associate, Squire Patton Boggs LLP
- **Emerging Issues for Drug Compounders**
Rachael G. Pontikes, Partner, Reed Smith LLP

Moderated by Joanne Hawana, Of Counsel, Mintz Levin Cohn Ferris Glovsky Popeo PC

- **Food and Dietary Supplement Hot Topics**
Suzanne Trigg, Partner, Haynes and Boone LLP
- **Tobacco Prohibition v. Active Harm Reduction Policies**
Cynthia Cabrera, President, The Cating Group

2:35–2:45 PM

Transition

2:45–4:00 PM

Top Cases in Food and Drug Law

Always informative and entertaining, this perennially popular session promises insight into the most significant litigation from 2017, and a look at cases to keep an eye on in 2018. Annual Conference attendees receive the companion publication, *Top Food and Drug Law Cases 2017, and Cases to Watch, 2018*.

Ralph F. Hall, Professor of Practice, University of Minnesota Law School

William M. Janssen, Professor of Law, Charleston School of Law

Erika F. Lietzan, Associate Professor, University of Missouri-Columbia School of Law

Moderated by August Horvath, Partner, Foley Hoag LLP

4:00 PM

Conference Adjournment