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
  Lisa Rachlin, Associate Director & Corporate Counsel, Vertex Pharmaceuticals
  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
  Zachary Rothstein, Associate Vice President, Technology & Regulatory Affairs, AdvaMed

- **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
Peter Pitts, President, Center for Medicine in the Public Interest
Frances Zipp, President, Lachman Consultants
Moderated by **Carla Cartwright**, Director, Federal Affairs, Johnson & Johnson

Center for Biologics Evaluation and Research (CBER)
Peter W. Marks, Director, Center for Biologics Evaluation and Research, Office of Medical Products and Tobacco, FDA
Margo Heath-Chiozzi, Senior Vice President of Regulatory Affairs, Celldex Therapeutics, Inc.
Christopher Mikson, Partner, Mayer Brown LLP

John Murphy, Deputy General Counsel for Healthcare, Biotechnology Innovation Organization
Moderated by **Neil DiSpirito**, Of Counsel, Ballard Spahr LLP

Center for Devices and Radiological Health (CDRH)
Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, Office of Medical Products and Tobacco, FDA
Moderated by **Paul Gadiock**, Senior Attorney, Arent Fox LLP

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
Moderated by **Martin Hahn**, Partner, Hogan Lovells LLP

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
  Maryll Toufanian, Acting Director, Office of Generic Drug Policy, CDER, FDA
  Elizabeth Jex, Attorney Advisor, Office of Policy Planning, Federal Trade Commission
  Moderated by **William B. Schultz**, Partner, Zuckerman Spaeder LLP

- **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
  Jennifer Thomas, Interim Director for FSMA Operations, FDA

- **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**
  Michael S. Blume, Partner, Venable LLP
  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
  Lori F. Hirsch, VP of Regulatory Compliance and External Engagement, Bristol-Myers Squibb Company
  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
  Amy Norris, Chief Counsel, Clif Bar & Co.
  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**
  Dale A. Cooke, President, PhillyCooke Consulting
  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**
  Jonette Foy, Associate Director for Policy, CDRH, FDA
  Judith O'Grady, Partner, Pepper Hamilton LLP
  Rachel Turow, Executive Counsel – Regulatory Law, TEVA Pharmaceuticals, Inc.
  Moderated by **Cassie Scherer**, Principal Legal Counsel, Corporate Legal Regulatory, Medtronic

- **From Approval to Coverage – FDA and CMS Jurisdictional Lines**
  Rochelle Fink, Senior Health Science Project Specialist, CDRH, FDA
  Moderated by **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**