PRELIMINARY CONFERENCE SCHEDULE

(subject to change)

Thursday, May 3

7:30–8:30 AM **Registration and Continental Breakfast**

8:30–8:45 AM **Welcome**
Amy Comstock Rick, President & CEO, FDLI

8:45–9:15 AM **FDA Keynote Address**
Scott Gottlieb, Commissioner of Food and Drugs, FDA *(Invited)*
Introduced by Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara, PC, and Chair, FDLI Board of Directors

9:15–10:15 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

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

10:45–11:30 AM **Breakout Sessions**

- **Evolving Regulatory Pathways for Medical Devices**
- **Regulatory Implications and Practical Challenges of Real World Evidence and Real World Data**
- **Regulation of Cell-Based Meat and Other Modified Foods**
- **Key Trends and Questions in FSMA Inspections and Compliance of Animal Food**
- **Effects of FDA Enforcement on the Tobacco Industry and Consumers**

11:30–11:45 AM **Transition**

11:45 AM–12:30 PM **Breakout Sessions**

- **The Evolving Regulatory Landscape for Orphan Drugs**
- **Biosimilars: New Developments and Updates**
- **Medical Device Innovations: Welcome to the Future**
- **FSMA Inspections and Compliance for Human Food: Key Trends and Questions**
- **Trends in Animal Food Litigation**
- **A Smoke-Free World: Evolving Technologies and Policies**

12:30–1:30 PM **Networking Luncheon**

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

2:00–2:15 PM **Transition**

2:15–3:30 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

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 *(Invited)*

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

4:00–4:45 PM **Breakout Sessions**

- **Generic Drug Initiatives: FDARA, GDUFA II, and Administrative Proposals**
- **Regenerative Medicine and the Changing Regulatory Landscape**
- **Digital Health Developments and Changing Regulatory Approaches**
- **Current Nutrition Facts Labeling Challenges**
- **Risk-Based Approval of Tobacco Products**

4:45–5:00 PM **Transition**

5:00–5:30 PM *Speaker:* **Rebecca K. Wood**, Chief Counsel, FDA

5:30–7:00 PM **Networking Reception**

Friday, May 4

7:30–8:15 AM **Breakfast**

8:30–9:00 AM **FDLI Welcome**

9:00–10:00 AM **International Harmonization Efforts**
As manufacturing, sales and product development become more global in nature, there is a growing impact of increasing government agency coordination and cooperation. This session will focus on international cooperation efforts, including FDA's inspection recognition agreements as well as coordinated actions on imported products.

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

10:30–11:15 AM **Breakout Sessions**

- **OTC Drug Monograph Reform**
- **From Approval to Coverage – FDA and CMS Jurisdictional Lines**
- **EU Medical Device Regulation: Implementation and Compliance**
- **Cannabis: FDA's Role in Regulation**
- **Advertising and Marketing in a Mobile World**
- **Comprehensive Approach to Nicotine: Misperceptions, Regulations, and Science**

11:15–11:30 AM **Transition**

11:30 AM–12:15 PM **Breakout Sessions**

- **FDA's New Approach to Drug and Device Inspections**
- **Emerging Issues for Drug Compounders**
- **Food and Dietary Supplement Hot Topics**
- **Tobacco Prohibition v. Active Harm Reduction Policies**

12:15–12:30 PM	**Transition**
12:30–1:15 PM	**Luncheon**
	Facilitated Table Topic Discussions Led by a FDLI-member expert, 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.
1:15–1:30 PM	**Transition**
1:30–2:30 PM	**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.
2:30–3:45 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*.
3:45 PM	**Conference Adjournment**