Enforcement, Litigation, and Compliance Conference

For the Drug, Device, Food, and Tobacco Industries

Wednesday, December 6

8:00–8:40 AM **Registration and Continental Breakfast** *Presidential Foyer*

8:40–8:50 AM **Welcome and Opening Remarks** *Presidential Ballroom*
Amy Comstock Rick, President & CEO, Food and Drug Law Institute
Cathy Burgess, Partner, Alston & Bird LLP and Chair, Enforcement, Litigation, and Compliance Conference

8:50–9:20 AM **Keynote Address** *Presidential Ballroom*
Rebecca K. Wood, Chief Counsel, FDA

9:20–10:20 AM **Compliance Central with FDA Center Compliance Directors: Part I** *Presidential Ballroom*
This two-part session will address FDA's top compliance issues, enforcement priorities, and goals for 2018. Hear directly from each FDA Center Compliance Director, learn how industry should focus their compliance efforts and what really happens when you don't follow FDA regulations.

Donald Ashley, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA
Sean Boyd, Deputy Director for Regulatory Affairs, Office of Compliance, Center for Devices and Radiological Health, FDA
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA
Mary Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, FDA
Moderated by **Cathy Burgess**, Partner, Alston & Bird LLP and Chair, Enforcement, Litigation, and Compliance Conference

10:20–10:40 AM **Coffee and Networking Break** *Presidential Foyer*

10:40–11:40 AM **Compliance Central with FDA Center Compliance Directors: Part II** *Presidential Ballroom*

Daniel McChesney, Director, Office of Surveillance and Compliance, Center for Veterinary Medicine, FDA
William Correll, Director, Office of Compliance, Center for Food Safety and Nutrition, FDA
Ann Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, FDA
Jennifer Thomas, Acting Director, Office of Enforcement and Import Operations, ORA, FDA
Moderated by **Miriam Guggenheim**, Partner, Covington & Burling LLP and Member, FDLI Board of Directors

11:45–12:45 PM **Concurrent Breakout Sessions:**

How FDA's Program Alignment Affects Your Industry
Why is the Program Alignment good for industry, and what are the challenges? What will be the impact on inspections, both domestic and foreign? During these breakout sessions, you will learn about the implications of FDA's recent Program Alignment. Speakers will discuss what the new offices are, how program alignment will affect changes on the ground, and whether there have been any gaps or unintended consequences.

I. **Medical Products** *Federal A*
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA
Ginette Michaud, Director, Office of Biological Products Operations, ORA, FDA
Moderated by **Deborah M. Autor**, SVP/Head of Strategic Global Quality & Regulatory Policy, Mylan Pharmaceuticals, Inc.

II. **Food and Dietary Supplements** *Federal B*
Rend Al-Mondhiry, Associate General Counsel, Council for Responsible Nutrition
John F. Johnson, Senior Associate Attorney, FDAImports.com, LLC and Benjamin L. England & Associates, LLC
Jennifer Thomas, Acting Director, Office of Enforcement and Import Operations, ORA, FDA

III. **Tobacco: CTP Enforcement Challenges and Opportunities for Reform** *Statler AB*
What are the weaknesses and vulnerabilities in FDA's implementation and enforcement of current and future legal requirements for tobacco products? How can FDA ensure a level playing field for industry? How can FDA's reform its regulation of tobacco products to be proportionate and thereby provide appropriate incentives for compliance rather than black market sales? Are there lessons to be learned from the experience in other countries?

James Solyst, Vice President, Federal Regulatory Affairs, Swedish Match North America
Jeffrey Weiss, General Counsel and EVP of Gov. Affairs, NJOY, Inc
Moderated by **Stacy L. Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP and Member, FDLI Board of Directors

12:45–1:45 PM **Networking Luncheon**

1:45–2:45 PM **Concurrent Breakout Sessions in Your Industry**

I. **Drug/Device: BIMO** *Federal A*
Each year, FDA publishes its BioResearch Monitoring (BIMO) inspection metrics that cover all the medical product centers at FDA. Violations included failure to have or follow investigational plans or continuing reviews, deviation from protocol, and inadequate records. These types of violations can easily be avoided with a strong Human Research Protection

Program (HRPP). A good HRPP must be designed to support all those involved in the research endeavor through proper staffing and procedures, training and education, and monitoring and oversight. We will explore the regulatory requirements generally, what the common regulatory pitfalls are in this space, and how to design and manage an HRPP to avoid a problematic BIMO inspection.

David Burrow, Acting Director, Office of Scientific Investigations, CDER, FDA
Chrissy J. Cochran, Director, Office of Bioresearch Monitoring Operations, ORA, FDA
Moderated by **Heidi F. Gertner**, Partner, Hogan Lovells US LLP

II. FSMA Enforcement: The First Year *Federal B*

Now that the first compliance dates for FSMA regulations have passed, the focus has shifted from preparation to implementation. What should you expect, and how can you prepare? What are both companies and inspectors seeing thus far? This session will feature first-hand accounts from attorneys on the FSMA "front lines," and will include lessons learned from FDA enforcement.

Steve Armstrong, Independent Consultant, EAS Consulting Group, LLC and Member, FDLI Board of Directors
Mark C. Levy, Member, Eckert Seamans Cherin & Mellott, LLC
Scott MacIntire, Director, Division of Enforcement, ORA, FDA

III. Tobacco: ENDS *Statler AB*

How FDA is enforcing against current active regulatory requirements (such as age restrictions) for websites, social media platforms, and other marketplaces? During this session, we will delve into FDA's current enforcement and strategy around this area and understand how other companies within the space are combating these types of sales.

Owen Chaput, Associate, Keller and Heckman LLP
Patricia I. Kovacevic, General Counsel and Chief Compliance Officer, Nicopure Labs LLC
Moderated by **Bryan M. Haynes**, Partner, Troutman Sanders LLP

2:45–3:00 PM **Networking Break** *Presidential Foyer*

3:00–3:55 PM **Concurrent Breakout Sessions**

I. Drugs: Quality Systems Approach to Data Integrity *Federal A*

This panel will delve into data integrity issues, including how to address data integrity problems and what the agency expects. Speakers will also analyze FDA's "new" data integrity warning letter language and the expectations it creates for manufacturers, including how to respond.

Bob Buhlmann, Director, Corporate Quality Assurance, Amgen, Inc.
Jamie Colgin, Principal Consultant, Validant
Michael A. Swit, Partner, Law Offices of Michael A. Swit

Moderated by **Jack Garvey**, Founder and CEO, Compliance Architects LLC

II. Medical Devices: Do I need to Open a CAPA? *Federal B*
There is widespread disagreement in industry about when to open a Corrective and Preventive Action (CAPA). When is it appropriate to open a CAPA, and what are the implications of doing so, or choosing not to? What are agency expectations – should everything go into a CAPA? If not, how are non-CAPA activities managed, and where are they documented? What will FDA expect to see during an inspection? What role have CAPAs played in medical device litigation?

Adrienne Franco Busby, Partner, Faegre Baker Daniels LLP
Anne Miller, Principal Regulatory Counsel, Medtronic
Marta L. Villarraga, Principal, Exponent, Inc.
Moderated by **Dennis Gucciardo**, Senior Associate, Hogan Lovells US LLP

III. FDA Regulation, Competitor Actions, and Private Litigation *Statler AB*
In the food industry, labels and label claims have garnered enforcement actions from FDA, other government agencies, competitors, and private litigants. A company could find itself in the midst of all of the above, based on a single claim on one product. What are key techniques to prevent or minimize risk of an enforcement action by a government agency – FDA or otherwise – and subsequent action by a private actor? What can other industries learn from what has happened in the food industry?

Leslie Krasny, Partner, Keller and Heckman LLP
Yvonne M. McKenzie, Partner, Pepper Hamilton LLP
Moderated by **Deborah Livornese**, Of Counsel, Arnall Golden Gregory LLP

4:00–5:00 PM **Enforcement Throughout the Supply Chain** *Presidential Ballroom*
As companies continue to shift manufacturing operations and procurement overseas, knowing your supply chain and having comprehensive quality agreements becomes increasingly important. In addition, there are substantive differences between foreign inspections and domestic inspections, in terms of notice and agency responsibility, and more subtle differences, in terms of cultural differences, language barriers, and actions that FDA has viewed as delaying, denying, limiting, or refusing an inspection, which can lead to enforcement actions. This session will discuss how to succeed in foreign inspections, what your responsibilities are, and ensuring your supply chain is secure.

Frederick (Rick) Ball, Partner, Duane Morris LLP and Member, FDLI Board of Directors
Paula R. Katz, Director, Manufacturing Quality Guidance and Policy Staff, CDER, FDA
Anne K. Walsh, Director, Hyman, Phelps & McNamara, PC
Moderated by **Howard R. Sklamberg**, Partner, Akin Gump Strauss Hauer & Feld LLP

5:00–7:00 PM **FDLI 2017 Annual Holiday Reception** *Congressional Room*

Thursday, December 7

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

8:55–9:00 AM **FDLI Welcome and Remarks** *Presidential Ballroom*
Laura Brown, Director, Educational Programs, FDLI

9:00–9:45 AM **Keynote Address** *Presidential Ballroom*
Ethan Davis, Deputy Assistant Attorney General, Consumer Protection Branch, US Department of Justice

9:45–10:45 AM **Recent Trends in Criminal Enforcement** *Presidential Ballroom*
This session will provide an overview of recent criminal cases, and current priorities for OCI and DOJ with respect to criminal prosecutions. In addition, panelists will discuss how to avoid criminal prosecution, and best practices for responding if you or your firm is the target of a criminal investigation.

Jill Furman, Deputy Director, Consumer Protection Branch, US Department of Justice
George M. Karavetsos, Partner, DLA Piper LLP
Peter J. Leininger, Counsel, King & Spalding LLP
Thomas South, Special Agent in Charge of Investigative Operations, Office of Criminal Investigations, FDA
Moderated by **William F. Gould**, Partner, Holland & Knight LLP

10:45–11:00 AM **Coffee and Networking Break** *Presidential Foyer*

11:00–12:00 PM **Management Oversight and Control: How to Ensure Compliance and Limit Liability** *Presidential Ballroom*
FDA expects senior management to exercise appropriate oversight and control of manufacturing operations to ensure product quality and public safety. Panelists will discuss management responsibility and communications related to establishment inspections, recalls, warning letters and government enforcement. The panel will also discuss how communications on these topics have the potential to trigger shareholder derivative suits or product liability, and how to mitigate these risks.

Jennifer Bragg, Partner, Skadden, Arps, Slate, Meagher & Flom LLP and Member, FDLI Board of Directors
Ricki A. Chase, Director, Compliance Practice, Lachman Consultants
John H. Fuson, Partner, Crowell & Moring LLP
Moderated by **Geoffrey M. Levitt**, Senior Vice President & Associate General Counsel, Pfizer, Inc.

12:05–1:00 PM **Concurrent Breakout Sessions**

I. **ORA and CDER: A New Concept of Operations (ConOps)** *Presidential Ballroom*
The Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) have entered into an unprecedented concept of

operations (ConOps) agreement to integrate facility evaluations and inspections for human drugs. The agreement, Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations, outlines the responsibilities and the workflow for Pre-Approval, Post-Approval, Surveillance, and For-Cause Inspections at domestic and international facilities. This panel will discuss the improvements in communications and processes between ORA and CDER, and consider the impacts on industry.

Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA
Allison Fulton, Partner, Sidley Austin LLP
Paula R. Katz, Director, Manufacturing Quality Guidance and Policy Staff, CDER, FDA
Moderated by **John Manthei**, Partner, Latham & Watkins LLP

II. Medical Devices: Cybersecurity, IoT, and FDA *Statler AB*
As medical devices become more integrated into an increasingly digital healthcare infrastructure, they are vulnerable to being exposed to privacy and security threats that could have broad implications for patient health, the manufacturer's reputation, lawsuits, and fines. This session will discuss the infrastructure that has been put in place to protect the medical device ecosystem against cyber threats and risks, and what different segments of industry are proactively doing to keep patients and communities safe.

David J. Bloch, Principal Legal Counsel, Corporate Legal Regulatory, Medtronic
Neil F. O'Flaherty, Partner, Baker & McKenzie
Moderated by **Sonali Gunawardhana**, Of Counsel, Wiley Rein LLP

III. First Amendment Issues in Advertising and Product Packaging *Senate Room*
This session will address First Amendment concerns with regard to advertising and promoting a product, and will be geared toward food and tobacco-related issues, such as product packaging.

Jonathan Adler, Johan Verheij Memorial Professor of Law, Director, Center for Business Law & Regulation, Case Western Reserve University School of Law
August T. Horvath, Partner, Kelley Drye & Warren LLP
David A. Kluft, Partner, Foley Hoag LLP

1:00–2:00 PM **Luncheon Address: Fifth Annual Eric M. Blumberg Memorial Lecture**
Presidential Ballroom
Ann Wion, former Deputy Chief Counsel for Program Review, Office of the Chief Counsel, FDA
Introduced by **Jeff Gibbs**, Director, Hyman, Phelps & McNamara, PC and Chair, FDLI Board of Directors

2:00 PM **Conference Adjournment**