Enforcement, Litigation, and Compliance Conference

For the Drug, Device, Food, and Tobacco Industries

December 11-12, 2019
Renaissance Downtown Hotel | 999 9th St NW | Washington, DC 20001

Wednesday, December 11

8:00–8:45 AM	**Registration and Continental Breakfast**
8:45–9:00 AM	**Welcome and Opening Remarks** **Amy Comstock Rick**, President & CEO, Food and Drug Law Institute
9:00–9:30 AM	**Keynote Address** **David Morrell**, Deputy Assistant Attorney General, Consumer Protection Branch, Civil Division, US Department of Justice
9:30–10:45 AM	**Compliance Central with FDA Center Compliance Directors: Part I** This two-part session will address FDA's top compliance issues, enforcement priorities, and goals for 2020. Hear directly from each FDA Center Compliance Director, learn how industry should focus its compliance efforts, and what to expect when you don't follow FDA regulations. **Donald Ashley**, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA **Erin Keith**, Associate Director for Compliance and Quality, Center for Devices and Radiological Health, FDA **Melissa Mendoza**, Deputy Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, FDA *Moderated by* **Thomas J. Cosgrove**, Partner, Covington & Burling LLP
10:45–11:15 AM	**Coffee and Networking Break**
11:15 AM–12:30 PM	**Compliance Central with FDA Center Compliance Directors: Part II** **Eric Nelson**, Director, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, FDA **Michael W. Roosevelt**, Deputy Director, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA **Ann L. Simoneau**, Director, Office of Compliance and Enforcement, Center for Tobacco Products, FDA *Moderated by* **Suzan Onel**, Partner, Kleinfeld, Kaplan & Becker, LLP
12:30–12:45 PM	**Transition**
12:45–1:45 PM	**Networking Luncheon**

1:45–2:45 PM **Concurrent Breakout Sessions:**

- **Data Integrity: Quality by Design, Comparability Data, and the Application Integrity Policy**
  This session will focus on recent FDA compliance and enforcement trends regarding data integrity in clinical research, marketing applications, and commercial manufacturing. Speakers will first address the relevant differences between data to be collected for drugs, biologics, and tissue products, and will discuss newly emerging data integrity issues that affect both non-clinical and cGMP data practices. Next, speakers will discuss strategies to implement systems to detect and correct errors in real time. Speakers will then discuss the relationship between analytical results and data integrity, as well as FDA's new warning letter language regarding OOS investigations. Lastly, speakers will address FDA's expectations regarding data integrity remediation, implications for companies that do not successfully respond to FDA data integrity concerns in warning letters, and whether the Application Integrity Policy is still a viable enforcement option.

  David L. Chesney, Principal and General Manager, DL Chesney Consulting, LLC
  Mark Levi, Senior Consultant, Parexel International Corporation
  Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf Health, Inc.
  Moderated by **Cathy L. Burgess**, Partner, Alston & Bird LLP and Member, FDLI Board of Directors

- **Post-Market Safety: Medical Device Safety Action Plan, Medical Device Safety Communications, and Post-Market Safety Reporting Requirements for Combination Products**
  FDA compliance activity in the medical device and combination product post-market area has seen an uptick outside of the traditional inspection space. FDA has adopted new ways of addressing post-market compliance, largely driven by the Emerging Signals Guidance and CDRH's Medical Device Safety Action Plan. Examples of the oversight include publication of safety alerts and healthcare professionals' communications, as well as advisory committee meetings to review the safety profile of devices in response to an identified trend. While not enforcement actions, these communications can be highly consequential, up to an including a cessation of product sales. In addition, FDA's final rule on post-market safety reporting requirements for combination products was published in December 2016, with compliance dates of July 2020 for constituent-part based reporting by combination product applicants using FAERS and eMDR, and January 2021 for applicants using VAERS. This session will explore CDRH's greater use of safety alerts, including when they are issued, their impact, how companies can respond, and what combination product manufacturers can learn as they prepare for new post-market requirements.

Kristin R. Davenport, Of Counsel, Covington & Burling LLP
William A. McConagha, Partner, Sidley Austin LLP
Anne K. Miller, Principal Legal Counsel, Medtronic

- **FSMA Enforcement Actions Begin: Trends and Unanswered Questions**
  The Food Safety Modernization Act (FSMA), the largest reform to food safety laws in over 70 years, was enacted in 2011, and implementation and enforcement are now in full swing. As the paradigm shift to focusing on preventing food safety risks is being implemented, what are the critical questions regarding inspections and enforcement that have gone unanswered, and how are companies handling these issues? Speakers will also delve into enforcement of the Foreign Supplier Verification Program (FSVP), where FDA has recently issued its first warning letter.

  Mark C. Levy, Partner, Eckert Seamans Cherin & Mellott, LLC
  Scott MacIntire, Director, Division of Enforcement, ORA, FDA
  Hilary Thesmar, Chief Food & Product Safety Officer and Senior Vice President, Food Safety Programs, Food Marketing Institute
  Moderated by **John F. Johnson**, Senior Associate & Managing Attorney, Benjamin L. England & Associates, LLC | FDAImports.com, LLC

- **Illegal Counterfeit and Compatible Electronic Nicotine Delivery Systems (ENDS) Products: Public Health and Safety Challenges**
  Recently, there has been a proliferation of illegal counterfeit and 'compatible' ENDS products entering the US market. These counterfeit products infringe on intellectual-property rights, are manufactured under unknown quality standards, do not have FDA premarket authorization, and could be contributing to the recent outbreak of illnesses related to vaping both non-tobacco and tobacco products. During this session, speakers will discuss the public health risks and product safety dangers potentially associated with illegal counterfeit and 'compatible' ENDS products in the US and how to combat this issue.

  Parker David Kasmer, Senior Director, Regulatory Integration, JUUL Labs
  Kevin RJ Schroth, Associate Professor, Department of Health Behavior, Society and Policy, Rutgers Center for Tobacco Studies, Rutgers School of Public Health
  Moderated by **Mark J. Vaders**, Counsel, Womble Bond Dickinson (US) LLP

2:45–2:55 PM **Transition**

2:55–3:55 PM **Concurrent Breakout Sessions:**

- **Navigating the Intersection Between Litigation Tactics and Regulatory Issues**
  Regulatory compliance interactions and enforcement actions occur in the ordinary course of business as FDA works with regulated industry. However, these often standard interactions can be taken out of context and used

against a company – and even the FDA – for the purposes of litigation. This panel will address how to navigate and manage interactions between companies and agencies in the event litigation should happen, popular litigation tactics used to attack regulated industries by reframing and misconstruing regulations and enforcement actions, and best practices to manage and defend against them.

Adrienne Franco Busby, Partner, Faegre Baker Daniels LLP
Marta L. Villarraga, Principal, Exponent, Inc.
Beth P. Weinman, Counsel, Ropes & Gray LLP

- **FDA Inspection Developments and Reform – What Lies Ahead for Medical Products**

  In 2018, FDA announced the launch of new inspection protocols, developed through the New Inspection Protocol Project and designed to guide assessment, recording, and reporting of data from surveillance and pre-approval GMP inspections. The goal is to expand the focus of an inspection to assess overall quality systems and operations, rather than focus specifically on GMPs alone. The protocols are being piloted on inspections of sterile injectable facilities, which the agency hopes will increase consistency while also enabling efficient analysis of facilities and quality metrics. The protocols cover 29 elements across six systems for surveillance inspections and 24 elements for pre-approval inspections. This panel will discuss the goals of the new protocols, how the protocols are being implemented in practice, and manufacturers' experiences under the new construct.

  Jonathan Gil, Corporate Counsel, Pfizer, Inc.
  Neeraj D. Pai, Partner, Sidley Austin LLP
  Moderated by **Robert (Bob) A. Rhoades**, Managing Partner, Validant

- **The Current State of Dietary Supplement Enforcement**
  During this panel, speakers will discuss FDA's current practices and goals in regulating dietary supplements and their ingredients, as well as enforcement actions by government agencies including DOJ. The panel will explore recent trends that can be gleaned from warning letters, civil injunction cases, and criminal prosecutions as a basis to discuss the government's current focus regarding supplements and supplement ingredients and how FDA priorities might translate into DOJ action.

  Patrick Runkle, Trial Attorney, Consumer Protection Branch, US Department of Justice
  Jack Wenik, Member of the Firm, Epstein Becker & Green, PC
  Moderated by **Suzie L. Trigg**, Partner, Haynes and Boone LLP

- **The Looming Premarket Submission Deadline for Deemed Tobacco Products: The Road Ahead**
  In the wake of the Maryland District Court's decision in the *American Academy of Pediatrics* case, which moved up the deadline for premarket submissions for deemed tobacco products covered by FDA's compliance policy to May 2020, what will the FDA enforcement landscape look like for these products? Will a meaningful number of companies be able to meet this deadline and survive the filing review? Will companies be able to supplement their submissions? What will enforcement look like for companies that do not meet the deadline?

  Stacey Younger Gagosian, Managing Director, Public Policy, Truth Initiative
  Patricia Miller, Senior Director, PTMA/MRTPA, Altria Client Services LLC
  James M. Solyst, VP, Federal Regulatory Affairs, Swedish Match North America
  Moderated by **Stacy L. Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP and Member, FDLI Board of Directors

3:55–4:15 PM **Coffee and Networking Break**

4:15–5:15 PM **In the Crosshairs of FDA Enforcement and Congressional Investigations: Lessons for Managing Responses**

House and Senate authorizing and appropriations committees increasingly conduct formal and informal investigations of FDA compliance and enforcement matters, such as food recalls, pharmacy compounding, and drug contamination. Sometimes, these investigations are just inquiries to FDA, but often they involve information requests or subpoenas to companies. While companies respond to these subpoenas, they also must cooperate with FDA and other investigations. Simultaneously responding to different types of investigations is complicated, and a company must comply but also bear in mind that the information may be used in other settings. Information that a company provides to Congress will often become public at a much earlier stage than in other types of investigations. This panel will address best practices for managing simultaneous investigations, including how to comply with information requests, manage public relations and crisis response, and how to mobilize potential allies that could help in the congressional probe.

Karen Elizabeth Christian, Partner, Akin Gump Strauss Hauer & Feld LLP
Gustav Eyler, Director, Consumer Protection Branch, US Department of Justice
Margaret E. Krawiec, Partner, Skadden, Arps, Slate, Meagher & Flom LLP
Moderated by **Howard R. Sklamberg**, Partner, Akin Gump Strauss Hauer & Feld LLP

5:15–7:30 PM **FDLI 2019 Annual Holiday Reception**

Thursday, December 12

8:00–9:00 AM **Optional CLE Ethics Session:**
Attorney–Client Privilege Issues During Internal Investigations
As an attorney, what are your obligations when advising and counseling a company during the process of an internal investigation? What information is privileged, and is there information that will be in your client's best interest to disclose? During this panel, speakers will discuss ethical issues attorneys must consider during internal investigations and how best to handle issues that arise.

John T. Bentivoglio, Partner, Skadden, Arps, Slate, Meagher & Flom LLP
William Gould, Partner, Holland & Knight LLP

8:30–9:10 AM **Registration and Continental Breakfast**

9:10–9:15 AM **FDLI Welcome and Remarks**
Laura Brown, Director, Educational Programs, Food and Drug Law Institute

9:15–9:45 AM **Keynote Address**
Stacy Cline Amin, Chief Counsel, FDA

9:45–10:45 AM **Top Legal Threats and Trends Facing FDA-Regulated Companies**
What are the top litigation and enforcement trends impacting companies? During this session, panelists will address enforcement trends and emerging areas of government focus that are important for to consider when developing a compliance strategy and navigating the demanding regulatory regimes for FDA-regulated companies. Speakers will also address False Claims Act liability post-Escobar, where regulatory non-compliance can lead to False Claims Act liability, and DOJ's recent Guidance on cooperation credit in False Claims Act matters.

Hannah R. Bornstein, Partner, Nixon Peabody LLP
Lauren Misztal, Associate General Counsel, Legal Investigations, Mallinckrodt Pharmaceuticals
Jonathan M. Phillips, Partner, Gibson, Dunn & Crutcher LLP
Moderated by **Michael Paddock**, Partner, Sheppard Mullin Richter & Hampton LLP

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

11:00–11:55 AM **Concurrent Breakout Sessions:**

- **Helping FDA and DOJ Tame the Wild West: Private Actions, the Lanham Act, and the Possible Future of FDCA Enforcement**
  The FD&C Act does not include a private right of action – only the Agency can enforce FDA law and regulations. Traditionally, courts have been reluctant to entertain private lawsuits under the Lanham Act and unfair trade practice laws as a back door to enforcing FDA laws. However, a recent

court ruling in *POM Wonderful v. Coca Cola* has changed the Lanham Act landscape, opening the door to private lawsuits for unfair competition related to FDA, particularly related to unfair competition from unapproved products, dietary supplements, compounded products, off-label promotion, and even counterfeiters and diverters. Hear from experts on what *POM Wonderful* and subsequent cases mean for industry, and how these cases are shaping FDA policy and enforcement actions.

Lisa M. Dwyer, Partner, King & Spalding LLP
Charles N. Jolly, Of Counsel, Baker Donelson
Moderated by **John Claud**, Assistant Director, Consumer Protection Branch, US Department of Justice

- **Developments in Enforcement of CBD and Cannabis Products**
  The US market has been flooded with CBD products since the 2018 Farm Act was signed into law on December 20, 2018, but with no federal regulations concerning the manufacturing, marketing, or sale of CBD and CBD-containing products, we look to the only official guidance issued thus far: warning letters and state actions. Marketing CBD products for therapeutic purposes online has been at the core of these warning letters, but what does that mean for CBD products that do not include therapeutic claims? This panel will discuss the most recent warning letters, address enforcement actions at the state level, analyze the potential for increased enforcement in this area, discuss enforcement priorities for products making egregious claims, and brainstorm how CBD manufacturers can remain "compliant" in this uncertain regulatory environment.

  Frederick (Rick) Ball, Partner, Duane Morris LLP and Treasurer, FDLI Board of Directors
  Richard Cleland, Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices, FTC
  Aaron Negangard, Chief Deputy Attorney General, Indiana
  Moderated by **Libby Baney**, Partner, Faegre Baker Daniels LLP

- **An Update on Tobacco Litigation and Enforcement Actions**
  This session will feature a round-up of recent court decisions, pending cases, and state and federal enforcement actions that either have or likely will impact the tobacco and nicotine products industry. Topics will include: litigation to postpone or remove the May 12, 2020 premarket application deadline; state and private litigation against ENDS manufacturers; federal and state efforts to ban flavors; and a discussion of recent FDA warning letters.

  J. Benneville (Ben) Haas, Partner, Latham & Watkins LLP
  Eric Heyer, Partner, Thompson Hine LLP

11:55 AM–12:00 PM **Transition**

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

- **An Assist for Litigants Challenging Governmental Actions: Implications of the Supreme Court's Decision on Agency Deference**
  In litigation challenging FDA actions under the Administrative Procedure Act, courts have long deferred to FDA's interpretation of its own regulations, which means in practice, the agency almost always prevails. Recently, the Supreme Court revisited this deference doctrine in the case *Kisor v. Wilkie*. Although the Court did not invalidate the doctrine it did articulate numerous restrictions on judicial deference. These restrictions could affect the outcome of future litigation challenging FDA actions by increasing the situations in which courts may invalidate FDA's interpretation of its own regulations. The panel will discuss the potential implications of *Kisor v. Wilkie*.

  Charles Biro, Trial Attorney, Consumer Protection Branch, US Department of Justice
  Daniel Jarcho, Partner, Alston & Bird LLP
  Moderated by **James N. Czaban**, Partner, DLA Piper LLP

- **Importing Products into the US and Navigating Import Alerts**
  This panel will take a practical look at issues companies face while importing FDA-regulated commodities into the US. After a short introduction to the import process, panelists will discuss and offer insight on issues including: prior notice, import orders and the differences between import alerts (IA) and import bulletins (IB), FSMA's FSVP, third party certification of high-risk foods, suspension of registration, and the differences between importing diverse commodities.

  Desmond Brown, Division of Food Defense Targeting, ORA, FDA
  Ted Poplawski, Special Assistant, Division of Import Operations, ORA, FDA
  Angel Suarez, Independent Consultant, EAS Consulting Group LLC
  Moderated by **Robert Durkin**, Of Counsel, Arnall Golden Gregory LLP

- **Cell and Gene Therapy Compliance and Enforcement**
  FDA has estimated that it has received more than 800 cell and gene therapy INDs, with 200 more expected yearly by 2020. Companies developing these innovative products face many challenges during product development through approval and commercial marketing. This panel will discuss several critical compliance and enforcement challenges facing cell and gene therapy companies, such as: the status of recent stem cell compliance and enforcement actions and pending litigation and whether FDA poised to take more action at the end of the enforcement discretion period next year to further define 351 vs. 361 products; and compliance challenges during the clinical study phase, including transitioning from clinical to commercial manufacturing. What can companies learn from pending actions against Novartis/Avexis for data manipulation? Are there other compliance concerns?

Perham Gorji, Deputy Chief Counsel for Litigation, Office of the Commissioner, FDA
Katie Laney, Principal Consultant, Validant
Melissa Mendoza, Deputy Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, FDA
Moderated by **Kalah Auchincloss**, Senior Vice President, Regulatory Compliance & Deputy General Counsel, Greenleaf Health, Inc.

1:00–2:15 PM **Luncheon Address: Seventh Annual Eric M. Blumberg Memorial Lecture**
Richard M. Cooper, Senior Counsel, Williams & Connolly LLP
Introduced by **Jennifer L. Bragg**, Partner, Skadden, Arps, Slate, Meagher & Flom LLP and Chair, FDLI Board of Directors

2:15 PM **Conference Adjournment**