Advertising & Promotion for Medical Products Conference

October 16-17, 2018
Renaissance Downtown Hotel
999 Ninth Street, NW | Washington, DC 20001

Agenda Subject to Change

Advertising & Promotion for Medical Products Conference Planning Committee Co-Chairs:
Kellie Combs, Partner, Ropes & Gray LLP
Mark Gaydos, Vice President, Global Regulatory Affairs, Sanofi

Monday, October 15

5:30 – 7:00 PM **Out-of-Towners Reception**
Location: Circa
781 7th St NW, Washington DC 20001
Sponsored by: Skadden, Arps, Slate, Meagher & Flom LLP

Tuesday, October 16

8:00 – 8:45 AM **Registration and Continental Breakfast**

8:45 – 9:00 AM **FDLI Welcome and Opening Remarks**
Amy Comstock Rick, President & CEO, Food and Drug Law Institute (FDLI)
Advertising & Promotion for Medical Products Conference Planning Committee Co-Chair Introduction

9:00 – 9:45 AM **Keynote Address**
Lauren Silvis, Chief of Staff, Office of the Commissioner, FDA

9:45 – 10:45 AM **FDA's Finalized "Consistent with Labeling" and "Payor Communications" Guidance Documents: Changes and Updates**
FDA's Office of Prescription Drug Promotion (OPDP) and other FDA officials will present on the two final guidance documents released this year relating to medical product communications. They will address significant changes and departures from the draft guidance documents as well as FDA's current thoughts behind the changes.

Christine Corser, Analyst, Office of Prescription Drug Promotion, CDER, FDA
Elizabeth Pepinsky, Health Science Policy Analyst, Office of Prescription Drug Promotion, CDER, FDA

Moderated by **Catherine Gray**, Supervisory Consumer Safety Officer, Office of Prescription Drug Promotion, CDER, FDA

10:45 – 11:15 AM **Networking & Coffee Break**

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

- **Consistent with Labeling Final Guidance: Implications for Devices**
  This panel will discuss the impact of the final guidance on device promotion and how to utilize the guidance in practice. Industry speakers will also discuss the interplay between this guidance and other guidances relating to General/Specific Intended Use, and whether the guidance has changed the analysis of whether a specific claim is within the scope of a general clearance. This session will also explore trends and changes in the way FDA is enforcing these issues.

  Vernessa Pollard, Partner, McDermott Will & Emery
  Cassie Scherer, Principal Legal Counsel, Medtronic
  Jeffrey Shapiro, Director, Hyman, Phelps & McNamara, PC
  Moderated by **Sarah Stec**, Senior Counsel, Medical Device Regulatory Law, Johnson & Johnson

- **Consistent with Labeling Final Guidance: Implications for Drugs**
  This session will take a deep dive into how companies have interpreted the final guidance to support promotional and economic communications, including examples of how companies interpret and apply, in new and interesting ways, the draft guidance. Industry speakers will also discuss the related policies and procedures companies have developed in effectuating the recommendations in the draft and final guidance documents.

  Timothy Candy, Principal Consultant, Regulatory Affairs, Opus Regulatory, Inc.
  Sue Gregory, Managing Counsel, Merck & Co., Inc.
  Michael Listgarten, Sr. Associate General Counsel, Genentech, Inc.
  Moderated by **Heidi Gertner**, Partner, Hogan Lovells US LLP

12:30 – 1:45 PM **Luncheon Address**

1:45 – 2:00 PM **Transition**

2:00 – 3:00 PM **Concurrent Breakout Sessions**

- **Medical Devices and IVDs**: **Regulatory Challenges of Advertising and Promotion**
  In the advertising and promotion regulatory realm, medical devices and IVDs present challenges for industry that can differ markedly from other products. How can companies walk the line between "research use only" and approved/cleared diagnostic claims? What is the best way to coordinate companion diagnostic marketing claims with the related drug product? This session will walk through specific scenarios and case studies to help practitioners stay on top of advertising and promotion challenges in this fast-changing space.

  Karen Becker, Managing Director, Translational and Regulatory Sciences, Precision for Medicine
  Jennifer Henderson, Partner, Hogan Lovells US LLP
  Allyson B. Mullen, Attorney, Hyman, Phelps & McNamara, P.C.
  Moderated by **Michael Swit**, Principal, Law Offices of Michael A. Swit

- **Nontraditional Venues: Are They Promotional?**
  This session will explore less traditional but trending methods of advertising and promotion and related risks and evaluate when a company can be held responsible for such communications. Topics and venues to be discussed include: communications made by parties other than the manufacturer or distributor; use of visual aids such as pipeline charts in promotional booths; banner ads on sites where the product sponsor does not control the content; and co-promotion.

  Heather Banuelos, Counsel, King & Spalding LLP
  Kai Peters, Partner, Gordon & Rees LLP
  Jennifer Romanski, Principal, Porzio, Bromberg & Newman, P.C.

- **The Do's and Don'ts of Patient Communications**
  This panel will explore diverse types of communications with patients. Speakers will address the do's and don'ts regarding drug manufacturer programs involving patients, including patient assistance programs, patient ambassadors, and discussion of investigational drugs with patient advocacy groups. Relevant laws, regulations, recent enforcement actions, and industry best practices for engaging in patient activities will be discussed.

  Abraham Gitterman, Associate, Arnold & Porter LLP
  Ryan Hohman, Vice President--Public Affairs, Friends of Cancer Research
  Paul Savidge, US General Counsel, Spark Therapeutics

Moderated by **Mark Gaydos**, VP, NA Gen Med & US Advertising & Promotion, Global Regulatory Affairs, Sanofi and Co-Chair, Advertising & Promotion for Medical Products Conference Planning Committee

3:00 – 3:30 PM **Networking Break & Coffee Break**

3:30 – 5:00 PM **Real-World Evidence and Real-World Data: Practices for Promotional Use and Avoiding False and Misleading Communications**
What are the standards for evaluating data and the processes for gathering data, specifically in the context of promotional utilization? How should real-world evidence studies be designed with promotion in mind? How does real-world evidence fit into the framework of the Consistent with Labeling and Payor Communications guidance documents? This session will discuss use of real-world evidence in the promotion of medical products, the coalescing standards for regulatory support and product promotion, practices and strategies for companies considering its use, and how manufacturers can avoid communicating false and misleading medical product claims.

Eric Gemmen, Senior Director, Epidemiology & Outcomes Research**,** Real World Evidence**,** Real World & Analytics Solutions**,** IQVIA, Inc.
Colleen Heisey, Partner, Jones Day
Ellen Schumacher, Executive Director, Commercial Regulatory Affairs, Bristol-Myers Squibb Company
Moderated by **Kellie Combs**, Partner, Ropes & Gray LLP and Co-Chair, Advertising & Promotion for Medical Products Conference Planning Committee

5:00 – 6:30 PM **Networking Reception**

October 17

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

8:40 – 8:45 AM **Welcome and Announcements**
Laura Brown, Director, Educational Programs, FDLI
Advertising & Promotion for Medical Products Conference Planning Committee Co-Chair Introduction

8:45 – 9:45 AM **The First Amendment: Recent Developments and Impacts on Industry**
This session will provide an update on First Amendment issues in the promotional realm. Speakers will discuss how FDA's outlook on product communications, as viewed through the lens of the "Consistent with Labeling" and "Payor Communications" guidance documents and its consideration of real-world evidence, relate to FDA's current approach to First Amendment issues. Speakers will also consider whether FDA's perspective on commercial speech

differs for drugs versus devices; issues related to commercial speech and exclusivity; and potential First Amendment-related reforms.

Jeffrey Chasnow, Senior Vice President and Associate General Counsel, Pfizer, Inc.
Scott Lassman, Partner, Goodwin Procter LLP
Peter Pitts, President, Center for Medicine in the Public Interest
Moderated by **Kelly Goldberg**, Vice President, Law & Senior Counsel for Biopharmaceutical Regulation, PhRMA

9:45 – 10:30 AM **FDA Enforcement Actions and Priorities**

FDA officials from the agency's medical product centers – CDER, CBER, CDRH, and CVM – will discuss recent enforcement actions taken by their offices, the importance of these actions for companies, and enforcement priorities.

Thomas W. Abrams, Director, Office of Prescription Drug Promotion, CDER, FDA
Thomas Moskal, Veterinary Medical Officer, Post-Approval Review Team, CVM, FDA (invited)
Lisa Stockbridge, Supervisory Consumer Safety Officer, Advertising and Promotion Labeling Branch, CBER, FDA
Deborah Wolf, Regulatory Counsel, Division of Premarket and Labeling Compliance, CDRH, FDA
Moderated by **Wayne Pines,** President, Regulatory Services and Healthcare, APCO Worldwide, and Planning Committee Member

10:30 – 10:45 PM **Networking & Coffee Break**

10:45 – 12:00 PM **Promotional Compliance and Liability Risks Beyond FDA**

Advertising and promotion of FDA-regulated medical products faces scrutiny, compliance challenges, and legal risk from multiple actors in the legal system beyond FDA. Government and industry experts will explore the other sources of compliance obligations and risk, including the FTC, state Attorneys General, state and local legislatures seeking to limit or compel speech in advertising, private litigants in Lanham Act lawsuits, and how drug advertising and promotion, including off-label promotion, impacts mass-tort litigation. Speakers will also explore ways to mitigate risks when facing these challenges.

John Bentivoglio, Partner, Skadden, Arps, Slate, Meagher & Flom LLP
Richard Cleland, Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices, Federal Trade Commission
Jason Rose, Partner, Venable LLP
Moderated by **James Czaban**, Partner, Chair, FDA and Medical Products Practice Group, DLA Piper LLP (US)

12:00 – 12:15 PM **Transition**

12:15 – 1:15 PM **Facilitated Table Topic Discussions**

1:15 – 2:30 PM **FDA's Social Science Research**
FDA's social science researchers will offer insight into OPDP's research program and how it supports OPDP's work regulating prescription drug promotion. They will also discuss the application of their findings, including how their research affects FDA's approach to gathering data.

Kevin Betts, Social Science Analyst, Office of Prescription Drug Promotion, CDER, FDA
Amie O'Donoghue, Social Science Analyst, Office of Prescription Drug Promotion, CDER, FDA
Helen Sullivan, Social Science Analyst, Office of Prescription Drug Promotion, CDER, FDA
Moderated by **Kathryn Aikin**, Social Science Team Leader, Office of Prescription Drug Promotion, CDER, FDA

2:30 – 3:30 PM **Social Media: Promotional Utilization and Technological Considerations**
This panel will address both the visible and less-visible aspects of product promotion on the internet. Speakers will consider the technology behind search engine optimization and metadata, which impacts public perception of a product by presenting content. Speakers will also discuss the utilization of visual promotional communications on social media, including space limited platforms, utilization of influencers, independent bloggers, and native advertising.

Mark duPlessis, Celgene Corporation
Jason Gordon, Partner, Reed Smith LLP
Anne Maher, Partner, Kleinfeld, Kaplan & Becker, LLP
Moderated by **Dale Cooke**, President, PhillyCooke Consulting

3:30 PM **Conference Adjournment**