Advertising & Promotion for Medical Products Conference

October 17-18, 2019
Renaissance Downtown Hotel
999 Ninth Street, NW | Washington, DC 20001

Agenda Subject to Change

Advertising & Promotion for Medical Products Conference Planning Committee Co-Chairs:

Paul Savidge, US General Counsel, Spark Therapeutics
Ellen Schumacher, Executive Director, Commercial Regulatory Affairs, Bristol-Myers Squibb Company

Wednesday, October 16

5:00 – 7:00 PM **Out-of-Towners Reception**

Thursday, October 17

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 (FDLI)
Paul Savidge, US General Counsel, Spark Therapeutics, and Co-Chair, Advertising & Promotion for Medical Products Conference Planning Committee

9:00 – 9:45 AM **Keynote Address**
Lowell Schiller, Principal Associate Commissioner for Policy, FDA

9:45 – 10:45 AM **Enforcement Update**: **Department of Justice and Office of the Inspector General**
This session will cover how the Department of Justice and the Department of Health and Human Services' Office of the Inspector General are enforcing off-label promotion and other advertising and promotion-related allegations. Speakers will discuss emerging theories for enforcement, including wire fraud, mail fraud, and conspiracy under Title 18. Lastly, speakers will consider forward-looking goals and priorities for holding companies accountable in this space.

Gustav Eyler, Branch Director, Consumer Protection Branch, U.S. Department of Justice
Mary Riordan, Senior Counsel, Office of Counsel, Office of the Inspector General, U.S. Department of Health and Human Services
Moderated by **Jennifer Bragg**, Partner, Skadden, Arps, Slate, Meagher & Flom LLP, and Chair, FDLI Board of Directors

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

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

- **Patient Engagement: Challenges of Engaging Patients and Patient Groups**
  During this session speakers will discuss how to lawfully engage patients and patient groups in areas such as unbranded disease awareness, branded patient ambassadors, and patient support programs and access. Speakers will discuss FDA regulations and historic enforcement trends as well as cover issues including overstating efficacy, broadening indication, quality of life, importance of imagery, and patient profiles.

  Ryan Hohman, Vice President-Public Affairs, Friends of Cancer Research
  Tim Kreidler, Sr. Director of Regulatory Affairs-Commercialization, Dermira, Inc.
  Jennifer Romanski, Principal, Porzio, Bromberg & Newman, P.C.
  Moderated by **Abraham Gitterman**, Associate, Arnold & Porter LLP

- **Payor Guidance Follow Up: Execution and Real World Challenges**
  Now that the Payor Guidance is over a year old, what challenges are companies encountering in communicating health care economic information to payors? How are they overcoming these challenges? This panel will provide helpful examples and solutions for industry.

  Michael S. Labson, Partner, Covington & Burling LLP
  Paul Savidge, US General Counsel, Spark Therapeutics and Co-Chair, Advertising & Promotion for Medical Products Conference Planning Committee
  Jay Weaver, Associate Vice President, Pharmacy at Blue Cross and Blue Shield of Illinois, Montana, New Mexico, Oklahoma & Texas
  Moderated by **Wayne Pines**, President, Regulatory Services and Healthcare, APCO Worldwide

- **Effective and Meaningful Fair Balance/Risk Disclosure**
  This panel will explore the challenging task of ensuring fair balance and risk disclosure in product advertising. Speakers will discuss ways FDA has approached this issue in the past in terms of the "Brief Summary and Adequate Directions for Use" draft guidance, and the effect of the anticipated final rule on the "Major Statement for Direct-to-Consumer Advertisements." Examples will be provided regarding how companies have tackled fair balance in various formats and how risk disclosure may be impacted in the future by ongoing research from FDA's Office of Prescription Drug Promotion (OPDP).

  Bryant Godfrey, Counsel, Arnold & Porter LLP

Richard Lem, Associate Director, Advertising and Promotion, North American Regulatory Affairs, Bayer HealthCare, Inc.

12:15 – 1:15 PM **Networking Luncheon**

1:15 – 1:30 PM **Transition**

1:30-2:45 PM **Concurrent Breakout Sessions will address pressing advertising and promotional issues as they affect the pharmaceutical, medical device, and veterinary medicine industries. Case studies will focus on specific issues and examples.**

Pharmaceutical Case Study:
This interactive session will explore a case study addressing a prescription drug product's proposed promotional materials. It will include review and discussion of the implications of the "Consistent with the FDA-Required Labeling" (CFL) guidance on these materials and how to apply it effectively.

Cynthia Meyer, Partner, Kleinfeld, Kaplan & Becker, LLP
Jack A. Scannelli, Head- Regulatory Advertising & Promotion, Novartis Pharmaceuticals Corporation
Moderated by **Rebecca Burnett**, Executive Director and Head of Strategic Services, Framework Solutions

Medical Device Case Study:
This session will review promotional materials for a medical device that treats atrial fibrillation. This case study will examine several examples of how the company can effectively and compliantly maneuver its way through social media, including re-tweeting posts authored by health care professionals who are both directly and indirectly involved in these devices.

Madhavi Bellamkonda, Director, Regulatory Affairs, Advertising and Promotion, Abbott Vascular
Lynn Deutsch, Founder, President, Regulatory Promo, LLC
Jeffrey Shapiro, Director, Hyman, Phelps & McNamara, PC
Deborah Wolf, Regulatory Counsel, Division of Premarket and Labeling Compliance, CDRH

Veterinary Medicine Case Study:
This session will provide a case study based on advertising and promotion issues for animal health products. We will discuss animal health product study data requirements, as well as specific requirements for animal health commercial product comparisons versus those for human health. The panel will also explore the difference in enforcement actions taken by Center for Veterinary Medicine (CVM) versus OPDP and the nature of those actions.

Dorothy McAdams, Supervisory Veterinary Medical Officer, Center for Veterinary Medicine, U.S. Food and Drug Administration

Jeannie Perron, Partner, Covington & Burling LLP

2:45-3:00 PM **Networking & Coffee Break**

3:00-4:00 PM **Conversation with Industry: Steps to Take After Receiving a Violation Letter**
After describing the kinds of letters FDA may send a company, speakers will discuss common areas of FDA scrutiny, how to communicate internally about a violation letter, what internal steps to take, and timelines for responding. Speakers will also cover issues such as how to respond when more than one company is involved and special considerations regarding accelerated approvals and combination therapies.

Virginia Foley, Principal Consultant, Opus Regulatory, Inc.
Lauren Miller, Corporate Counsel, Otsuka America Pharmaceutical, Inc.
Dolores Shank-Samiec, Executive Director, Office of Promotion and Advertising Review, Merck & Co., Inc.
Moderated by **Vernessa Pollard**, Partner, McDermott Will & Emery LLP

4:00-5:00 PM **The Evolving Landscape of Drug Pricing Transparency**
Federal and state developments regarding drug pricing transparency are quickly evolving. During this session, panelists will discuss the goals and legal viability of rules and policy statements that have been put forth thus far, as well as recent industry pushback on First Amendment grounds. Speakers will then engage in a discussion about methods companies are using to deal with the recent push for price disclosures and what regulatory implications may ensue if drug pricing measures come to fruition.

Jim Czaban, Partner, DLA Piper LLP (US)
Kelly Goldberg, Vice President, Law/Senior Counsel for Biopharmaceutical Regulation, PhRMA
Colin Goldfinch, Senior Health Policy Advisor, Senate HELP Committee
Moderated by **James Davidson**, Shareholder, Polsinelli PC

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

Friday, October 18

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

8:55– 9:00 AM **Welcome and Announcements**
Laura Brown, Director, Educational Programs, FDLI
Ellen Schumacher, Executive Director, Commercial Regulatory Affairs, Bristol-Myers Squibb Company, and Co-Chair, Advertising & Promotion for Medical Products Conference Planning Committee

9:00 – 10:00 AM **Social Media Platform Advertising: Policies and Considerations**

What are social media companies' policies and approaches regarding industry engagement? This session will feature representatives who navigate social media platforms that grapple with medical product advertising and promotion issues on a daily basis. Speakers will discuss emerging issues, specifically focusing on policies regarding patient engagement, the role of influencers, and drug warnings.

Jason Gordon, Partner, Reed Smith LLP
Dawn H. Lacallade, Vice President, Healthcare, LiveWorld
Tim Wisniewski, Senior Strategist, Wunderman Thompson
Moderated by **Heather Banuelos**, Counsel, King & Spalding LLP

10:00 – 10:45 AM **Lanham Act and Other Private Actions**

This panel will discuss steps companies are increasingly taking to address concerns about competitor promotional activities regarding false or misleading statements. Speakers will explore recent developments in private advertising enforcement and litigation between companies under the Lanham Act, similar state false advertising and unfair trade practice laws, and product liability claims. The Better Business Bureau's National Advertising Division (NAD) process for addressing competitor claims and how sales and marketing can influence a company's ability to fairly defend the company in product liability disputes will also be addressed.

Hal Hodes, Senior Attorney, National Advertising Division
Susan Cook, Partner, Hogan Lovells US LLP
Kirke Weaver, Vice President, Office of General Counsel, Merck & Co., Inc.
Moderated by **Lisa Molot Dwyer**, Partner, King & Spalding LLP

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

11:00 – 12:00 PM **Concurrent Breakout Sessions**

- **FDA Q&A Regarding the Electronic Submissions Guidance Implementation**
  This session will discuss FDA's implementation of, and industry experiences with, the "Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs" guidance. FDA will answer questions industry has about the implementation process.

  Jason Cober, Project Manager Team Lead, Office of Prescription Drug Promotion, CDER, FDA
  Moderated by **Joanne Hathaway,** Manager, Global Regulatory Affairs, Promotion Compliance, Otsuka America Pharmaceutical, Inc.

- **How Corporate and Sales Messaging Affects Public Perceptions of a Company's Culture**
  This panel will discuss advertising and promotion dilemmas with which medical product companies often wrestle: balancing marketing important and sometimes lifesaving products, satisfying stakeholders, and ensuring fair balance in claims. Speakers will cover mistakes companies have made in the past that have led to adverse jury verdicts and steps industry can take to lower risk.

  Jodie Floyd, Assistant General Counsel, Eli Lilly and Company
  Keren Tenenbaum, VP and Assistant General Counsel, Head of Legal, Salix at Bausch Health Companies Inc.
  Moderated by **Matthew Keenan**, Law Partner, Shook, Hardy & Bacon LLP

- **Scientific Exchange: Grey Areas and Best Practices**
  What is "scientific exchange?" When is it appropriately used? Where is the line between scientific exchange and off-label promotion? This panel will discuss where these grey areas are and how to use scientific exchange effectively while still complying with regulatory requirements.

  Susan Cantrell, Chief Executive Officer, Academy of Managed Care Pharmacy
  Kellie Combs, Partner, Ropes & Gray LLP
  Mark Gaydos, VP, NA General Medicines & Established Products/US Advertising & Promotion, Global Regulatory Affairs, Sanofi
  Moderated by **Ellen Schumacher**, Executive Director, Commercial Regulatory Affairs, Bristol-Myers Squibb Company, and Co-Chair, Advertising & Promotion for Medical Products Conference Planning Committee

12:00 – 12:15 PM **Transition**

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

1:15 – 2:15 PM **Concurrent Breakout Sessions**

- **FDA's Evolving Approach to Comparative Claims**
  During this panel speakers will discuss some of the challenges of making comparative claims when launching a new therapy into a therapeutic or pharmacological class with a variety of existing approved products. Although the general rule is that comparative claims require substantiating data from two head-to-head registration-quality studies demonstrating very significant differences, some statements about competing products that vary from this standard are expressly permitted by the agency, if properly executed. Speakers will examine how changes under the CFL guidance have affected the ability to make comparative claims, as well as practical strategies to manage risk.

Dara Katcher Levy, Director, Hyman, Phelps & McNamara, PC
Justin Drinkwine, Corporate Counsel, Jazz Pharmaceuticals, Inc.
Coleen E. Klasmeier, Partner, Sidley Austin LLP

- **Use of Influencers in Promotional Advertising**
  In this era of bloggers and celebrity endorsements, this session will discuss how to work effectively with influencers to ensure actions taken and statements made are in compliance with FDA and Federal Trade Commission (FTC) regulations. Speakers will discuss specific issues to watch for when working with influencers in the social media space, how to stem the tide of inaccurate information, and recent enforcement examples.

  Richard Cleland, Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices, Federal Trade Commission
  Lauren Myers, Associate, Kelley Drye & Warren LLP
  Moderated by **Danielle Humphrey**, Counsel, Hogan Lovells US LLP

- **Common Challenges in Device Promotion**
  This session will address how companies deal with common promotional challenges in the face of regulatory uncertainty, as well as associated risks. Issues addressed will include: whether it is "off-label" to make a specific claim when the device has a more general indication for use; how much safety information must be included in device advertisements and promotional labeling; implications of the CFL Guidance as applied to devices; promotion of combination drug/device products and restricted/Rx devices; and preapproval/preclearance promotion.

  Eitan Bernstein, Associate, Latham & Watkins LLP
  Michele Buenafe, Partner, Morgan, Lewis & Bockius LLP
  Sarah Blankstein, Associate, Ropes & Gray LLP
  Moderated by **Sarah Stec**, Senior Counsel, Medical Device Regulatory Law, Johnson & Johnson

2:15 – 2:20 PM **Transition**

2:20 – 3:30 PM **Emerging Technologies Used for Promotion: Regulatory and Legal Issues**
Companies are increasingly using new technologies such as AI/ML, Alexa, disease monitoring apps that include a branded product, and digital advertising at the point of care, including on electronic health records, for promotional purposes. Speakers will discuss benefits and risks of using these technologies to better engage with doctors and patients on product information or disease education, develop precision messaging, probe real world data for development of healthcare economic models, speed access through coverage and reimbursement, identify patient adherence issues, engage with patients, and

anticipate future prescribing trends. Speakers will address privacy issues as well as how to maintain regulatory compliance and ensure best practices.

M. Jason Brooke, Director, Life Sciences Regulatory, Quality & Patient Safety, Navigant Consulting, Inc.
Daniel Kracov, Partner, Arnold & Porter LLP, and Secretary and General Counsel, FDLI Board of Directors
John Vaughan, General Counsel and Chief Compliance Officer, Outcome Health
Dale Cooke, President, PhillyCooke Consulting

3:30 PM **Conference Adjournment**