American Conference Institute's **Forum on**

Promotional Review Compliance for Drugs and Devices

Earn CLE Credits

Navigating an uncertain legal and regulatory environment while ensuring a "fair balance" of "truthful and non-misleading" promotional messages

January 11-13, 2016 | The Union League | Philadelphia, PA

Insights From a Government Official:

Jacob T. Elberg
Chief, Health Care & Government Fraud Unit
U.S. Attorney's Office, District of New Jersey

Michael S. Macko
Assistant U.S. Attorney
U.S. Attorney's Office, Eastern District of Pennsylvania

Jay S. Speers
Counsel
Medicaid Fraud Control Unit
Office of the Attorney General of New York State

Benchmark Best Practices with Industry Thought Leaders From:

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Novartis Pharmaceuticals Corporation
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Vertex Pharmaceuticals

As promotions for pharmaceutical products and medical devices continue to attract attention and scrutiny from the government and the plaintiffs' bar, this interactive forum will help you develop best practices for all of your promotional activities to minimize legal and regulatory risk. Uniquely designed to provide you with a high level, substantive discussion of the current state of the ad/promo space, topics to be addressed include:

- Examining the impact of *Amarin Pharma Inc. v. FDA* on off-label marketing of drugs and devices
- Understanding pre-approval communications including the consequences of SEC disclosures to investors
- Maintaining control over promotional material on Internet/Social Media platforms
- Assessing the risks and benefits of compiling pharmacoeconomic data as part of a promotion
- Implementing strategies to remain compliant when marketing to physicians, health care providers, and other third parties
- Identifying specific considerations when promoting a medical device

Test your knowledge of everything that you learned during the main conference at the collaborative post-conference workshop:

Interactive Mock PRC: Managing a Promotional Review Meeting from Start to Finish Through Specific Case Studies and Examples

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One recent study estimates that, between 1996 and 2005, total real spending on pharmaceutical promotions rose from US$11.4 billion to US$29.9 billion in the US (the only country for which expenditure on all major marketing and sales activities is available). Another study suggests that the true figure (including meetings and e-promotions) is closer to US$57.5 billion in real terms.[1]

The legal and regulatory space for promotion of drugs and devices has continued to evolve at a rapid pace over the last few months. As drug and device manufacturers pursue ever more innovative and creative strategies to spread awareness of their products, they must ensure that they remain compliant of FDA guidelines. With so many potential areas for legal and regulatory pitfalls, it is important to obtain a big picture overview of the challenges associated with promoting a drug or a device. This unique and interactive forum will help you understand the entire legal, regulatory, and political background affecting the promotion and advertising of drugs and devices.

Learn About Recent Developments That Will Impact Your Next Promotion

The industry anxiously awaits how the recent decision in *Amarin Pharma Inc. v. FDA* will affect off-label marketing and exactly what type of communication is permitted under the ruling. **American Conference Institute's Promotional Review Compliance for Drug and Devices** will help you comprehend the limits and boundaries of the *Amarin* case on off-label marketing. While the industry examines the impact of the case outside of the Second Circuit, it is clear for now that *Amarin* will impact drug and devices companies beyond their marketing efforts in areas such as the approval process and government enforcement. In addition to a thorough discussion on off-label marketing, this conference brings you cutting edge and up-to-date information from the nation's most prestigious pharmaceutical and medical device manufacturers so that you can benchmark your practices against those of leading companies.

Hear From Key Government Enforcers and Regulators

Attend this event and learn to position yourself so that you can preemptively fend off promotional challenges and respond successfully to government queries about your promotional activities. An esteemed faculty comprised of top in-house counsel, leading law firms, and regulatory affairs experts will help you understand and analyze recent litigation trends, enabling you to create compliant promotional materials and insulate your company from such activity. In addition, you will have the opportunity to hear from state and federal regulators at the forefront of advertising and promotion enforcement.

Maintain Control Over Promotions on Social Media

Given the constant and increased communication between patients, doctors, companies, bloggers, and patient advocates on social media, drug and device manufacturers must develop a comprehensive strategy on how to maximize the benefit of Internet and social media platforms. ACI's forum will help you examine what your options are when responding to misinformation about your product on social media, and ensure a fair balance when communicating the risks and benefits.

Post-Conference Workshop to Test What You Learned During the Program

ACI's post-conference workshop will give you the knowledge needed to develop compliant promotions while minimizing the legal and regulatory risks. In this comprehensive workshop—**Interactive Mock PRC: Managing a Promotional Review Meeting from Start to Finish Through Specific Case Studies and Examples**—you will learn how to end up with a promotion that satisfies each business, legal, and regulatory requirement.

Register now to save your spot at this timely conference by calling **888-224-2480** or by visiting **www.AmericanConference.com/PromotionalReview**

I look forward to seeing you in January!

Very truly yours,

Bolam Kim, Esq.
Legal Analyst & Conference Director

Who You Will Meet

In-house counsel and business executives responsible for:

- Advertising, marketing, and promotions
- Sales
- Compliance
- Marketing
- Regulatory Affairs
- Medical Affairs
- Promotional Review
- Medical Communication/Information

Outside counsel who specialize in:

- Advertising
- FDA Regulatory
- Product Liability

[1] PricewaterhouseCoopers, Pharma 2020: Marketing the Future. What Path Will You Take?

7:30 Registration and Continental Breakfast

8:30 **Co-Chairs' Opening Remarks**

Sue Duvall
Sr. Director, Head International Regulatory Advertising and Promotion
AbbVie
(North Chicago, IL)

Karen Weaver
Chief Counsel - Regulatory
Becton Dickinson & Co.
(San Diego, CA)

8:45 **The Politics and Policies for Promotion of Drugs and Devices: Outlining Political, Legal, Regulatory, and Industry Developments to Boost Promotional Review Efforts**

Geoffrey M. Levitt
Associate General Counsel
Regulatory, Environmental and Global Supply
Pfizer Inc.
(New York, NY)

Alan G. Minsk
Partner
Arnall Golden Gregory LLP
(Atlanta, GA and Washington, DC)

Due to recent developments, the promotion and advertising of drugs and devices is entering uncharted waters. Given groundbreaking court developments, the rapid evolution of social media technology, and FDA's ongoing review of its regulation in this area—all taking place in the aftermath of the Affordable Care Act—drug and device manufacturers are still untangling the exact implications of these legal and regulatory developments for their promotional activities. This panel will provide an overview of the current political, legal, and regulatory landscape shaping industry policies. Points of discussion will include:

- Considering key legal and regulatory activity in 2015 to isolate trends in future enforcement activity
- Exploring the increase in discussion of quality measures and quality metrics
  - Developing quality metric information to use as a promotional tool
  - Training your staff to speak with physicians on what can or cannot be said
- Understanding the state of disease awareness ads after FDA withdrawal of guidance
- Reviewing how recent court cases impact off-label communications about drugs and devices
- Survey and status of pending bills potentially impacting the promotion of drugs and medical devices

9:30 **FDA Updates: Focusing on the Key Areas of Enforcement and Compliance for 2016 and Beyond**

Joshua M. Eizen
Chief Compliance Officer, Senior Counsel
Actelion Pharmaceuticals US, Inc.
(South San Francisco, CA)

Heidi Gertner
Partner
Hogan Lovells US LLP
(Washington, DC)

Gary C. Messplay
Partner & Co-Chair of FDA Practice
Hunton & Williams LLP
(Washington, DC)

10:15 **It's a Brave New World: Real World Strategies for Understanding What Kind of Off-Label Marketing Is Allowed Or Is Still Off-Limits Post-*Amarin***

James M. Beck
Counsel
Reed Smith LLP
(Philadelphia, PA)

Michelle M. Kloecker
Director and Pharmaceutical Counsel, Global Oncology
Novartis Pharmaceuticals Corporation
(East Hanover, NJ)

Saul Howard Perloff
Partner
Norton Rose Fulbright US LLP
(San Antonio, TX)

2015 marked the latest decision for drug and device companies challenging FDA's regulation of off-label marketing. Notwithstanding years of heavy scrutiny and enforcement by FDA, DOJ, and FCA relators on matters of off-label marketing activity, a federal court in *Amarin Pharma Inc. v. FDA* ruled in favor of the drug manufacturer. The court held that a drug manufacturer could constitutionally make truthful and not misleading promotional statements, even if they were off-label. However, *Amarin* leaves the industry with many unanswered questions which this panel will examine. Points of discussion will include:

- Reviewing the continuing tension between the First Amendment and the FDA's regulation of off-label speech
- Comprehending how *Amarin Pharma Inc. v. FDA* impacts the prohibition on truthful and not misleading speech
- Delving into how the procedures Amarin Pharma followed allowed it to achieve a favorable First Amendment result
- Forecasting *Amarin's* impact outside of the Second Circuit
  - Predicting whether *Amarin* will be appealed
- Exploring specific examples and case studies of what may and may not allowed under *Amarin*
- Responding to unsolicited requests for off-label information about drugs and medical devices, and what the medical science liaison cannot say about a drug or device
- Addressing company responsibilities when a third-party posts an off-label use of a product on social media
  - Analyzing examples of how to respond and how not to respond on social media
- Evaluating best practices for disseminating off-label scientific or medical information
- Knowing when off-label information can, and cannot, be provided to patients, physicians, and third-party administrators

- Understanding whether the FDA's guidance on good reprint practices for the distribution of medical or scientific articles can be used to bolster *Amarin* challenges
  - Assessing when dissemination of scientific or medical information becomes off-label marketing
- Examining the scope of the Amarin decision and whether it can be applied to other FDA-regulated products (e.g., medical devices, OTC drugs, dietary supplements)

11:15 Morning Refreshment Break

11:30 **Drafting Specific Compliant Materials During the Pre-Approval Stage: Reminder Ads, Investor Statements, Press Releases, and Disease Awareness Communications**

Jennifer Santos
Sr. Corporate Counsel
Vertex Pharmaceuticals
(Boston, MA)

Cristin McArdle
Commercial Counsel
Alkermes, Inc.
(Waltham, MA)

- Understanding what you must communicate versus what you cannot say before a product has been approved
- Exploring SEC requirements and statements to investors during clinical trials
  - Reviewing the Orexigen disclosures and comprehending how things went awry
  - What are the potential consequences when issuing an improper investor statement or SEC filing?
    - » e.g., warning letters, cancellation of clinical trial, shareholder lawsuits, government investigation, criminal indictment
- Examining the do's and don'ts for press releases and other communications with investors and the general public
  - Are press releases considered "promotion"?
  - Highlight on FDA enforcement
  - Delving into whether and when press releases should go through the promotional review committee
- Institutional and Coming Soon Advertisements
  - Knowing what you can and cannot say through examples of non-compliant ads
- Reminders about Scientific Exchange: What can Clinical and Medical departments say before approval?
- Analyzing the benefits and risks of launching a disease awareness program before approval
  - Is this considered "promotion?"
  - What is permissible to say in a disease awareness statement?

12:30 Networking Luncheon

1:45 **What is a "Promotion?" Developing a Checklist to Go Beyond the "Fair Balance" Requirement for Complete Compliance**

Paul M. Kirsch
Vice President, Regulatory Affairs
Iroko Pharmaceuticals, LLC
(Philadelphia, PA)

Karen Weaver
Chief Counsel - Regulatory
Becton Dickinson & Co.
(San Diego, CA)

- What is a promotion? Is there a safe harbor under FDA guidance exempting the communication from being treated as a promotion?
- What does "fair balance" mean for a promotion?
  - Exploring the fine balance: efficacy statements; risk and safety information; comparative claims; and indication of a drug or medical device
  - Examining examples of promotions without fair balance to see where manufacturers get in trouble
- Dissecting testimonials from patients or physicians in a promotion
  - Distinguishing between compliant and non-compliant testimonials for a promotion
- Analyzing competitor claims and understanding when a certain claim becomes an unfair comparison
- Reviewing internal corporate controls and balancing risk profiles to determine how to present certain data or information
  - Knowing that what works for one company may not work for another company
- Ensuring that the right amount of context is provided for a certain claim in a promotion
  - Identifying examples of promotional language with misleading context and extracting ideas on how to fix these improper promotions

2:45 Afternoon Refreshment Break

3:00 **Top 5 Ways to Manage Risk and Remain Compliant When Promoting to Health Care Providers, Including Training the Sales Team and Deciphering Fair Market Value for Speaker Payments Payments**

Noellyn Davies
Associate Director, Senior Counsel
Boehringer Ingelheim Pharmaceuticals
(Ridgefield, CT)

Stefanie A. Doebler
Special Counsel
Covington & Burling LLP
(Washington, DC)

Promotional activities targeted to health care professionals remain a core component of drug and device marketing. Navigating this complex area involves a critical understanding of what a "promotion" entails, as well an overview of how the Sunshine Act and various states' transparency acts have impacted the promotion of drugs and devices. Speakers will provide specific examples of how to comply with various PhRMA, federal, and state rules when designing a speaker or educational in-office program. Points of discussion shall include:

- Guiding the sales reps and promotional speakers to help them understand the types of prohibited speech when promoting to HCPs
  - Maintaining control over interactions between physicians and sales reps to ensure communications remain compliant
  - Training sales reps to respond appropriately to HCP requests
  - Monitoring promotional activities to confirm compliance with company policies
- Determining when a speaker program may be appropriate while balancing the risks and benefits

- Navigating the Anti-Kickback Statute to ensure that there is no undue influence
- Exploring the factors involved in selecting speakers and why it matters for promotion of drugs and devices
- Understanding how to apply fair market value when deciding how much to pay a speaker
- Determining whether to permit speakers to edit presentations

- Arranging a promotional program in a physician's office
  - Deciphering the regulatory and industry standards
  - Evaluating the differences in risk between in-office programs and speaker programs
- Evaluating the implications of Open Payments data related to promotional activities

4:00 **Specific Considerations for Medical Device Promotion**

Anne K. Walsh
Director
Hyman, Phelps & McNamara PC
(Washington, DC)

- Does FTC, FDA, or both govern?
- Can I talk about specific uses covered by the general clearance?
- How can I talk to doctors about a specific use?
- Has FDA provided any guidance on this issue?
- Can I explain to doctors how to use a medical device?
  - How do I mitigate the risks associated with this activity?
  - Can reps be in the Operating Room?
- What about reimbursement discussions?

5:00 Conference Adjourns to Day Two

DAY 2 – TUESDAY, JANUARY 12, 2016

7:45 Continental Breakfast

8:45 **Co-Chairs' Opening Remarks**

Sue Duvall
Sr. Director, Head International Regulatory Advertising and Promotion
AbbVie
(North Chicago, IL)

Karen Weaver
Chief Counsel - Regulatory
Becton Dickinson & Co.
(San Diego, CA)

9:00 **Surviving the Unknown: Learning From Missteps in Internet/Social Media Platforms and Developing Best Practices to Avert Future Mistakes**

Glenn Byrd
Senior Director, Promotional Regulatory Affairs
AstraZeneca
(Gaithersburg, MD)

James Ewing
Director, Promotional Regulatory Affairs
Jazz Pharmaceuticals
(Philadelphia, PA)

Pamela Politis
Senior Director, Regulatory Counsel
Incyte Corporation
(Wilmington, DE)

- Dissecting the FDA's draft guidances on promoting a drug or a medical device on Internet/Social Media platforms
- How do you ensure a fair balance of the communication of risks and benefits?
  - Assessing the impact of Google's ad policies on Internet promotions
  - Examining monitoring considerations for promotional materials on Internet/Social Media platforms
- Exploring issues related to responding to third-party misinformation about a drug or a medical device
  - Considerations for how to respond to third-parties and what type of information to include in a response
- How and when do you fulfill regulatory submission requirements?
- Training the sales reps on best practices for social media
- Mobile apps for the life sciences industry
  - When is an app app a promotional product?
  - How do you provide fair balance for an app?
  - Can you report adverse events for an app?
- Analyzing the factors that may lead you to not use social media to promote a product
- How does a drug or device company's Internet or social media presence impact its responsibility to monitor adverse events?
- Reviewing examples of bad social media practices: what you should not do on social media platforms
  - Understanding what companies could have done to comply with social media guidances

10:15 **Top Trends and Red Flags from Government Enforcers on What Will Land Drug and Device Companies in Hot Water**

Jacob T. Elberg
Chief, Health Care & Government Fraud Unit
U.S. Attorney's Office, District of New Jersey
(Newark, NJ)

Michael S. Macko
Assistant U.S. Attorney
U.S. Attorney's Office, Eastern District of Pennsylvania
(Philadelphia, PA)

Jay S. Speers
Counsel
Medicaid Fraud Control Unit
Office of the Attorney General of New York State
(New York, NY)

Moderator:

Kirsten Mayer
Partner
Ropes & Gray LLP
(Boston, MA)

In recent years, the DOJ and FDA have remained active in sustaining enforcement efforts against drug and device manufacturers. Improper promotional activities persisted as a key area of federal government concern and the government settled with various companies for billions of dollars. At the same time, many companies also face parallel state enforcement actions as state attorneys general have become more aggressive in policing deceptive or misleading promotions. This panel of Government Enforcers will examine current trends and their top priorities when enforcing the promotion of drugs and medical devices. Points of discussion will include:

- Exploring recent warning letters or untitled letters to gain insight into top enforcement priorities
- Reviewing recent DOJ False Claims Act cases to design a compliant promotional review system
- Understanding recent trends in government enforcement activity
  - Food and Drug Administration
  - Department of Justice
  - State Attorneys General

11:15 Morning Refreshment Break

11:30 **An Interactive, Hands-On Session on Preparing a Response to FDA: Best Practices, Tips, Tricks, and Pitfalls to Avoid**

Sonali P. Gunawardhana
Of Counsel
Wiley Rein LLP
(Washington, DC)

Marian J. Lee
Partner
Gibson, Dunn & Crutcher LLP
(Washington, DC)

When a company receives an untitled or warning letter from the FDA, it is imperative to craft a well-defined and thoughtful response to minimize the risk of penalties and further enforcement. In this interactive session, speakers will discuss the critical steps to take in response to enforcement correspondence.

- Deciphering the significance and broader consequences of an untitled letter or warning letter
- Coordinating the best team to collaborate on the response
- Taking corrective action to cure a problematic ad or promotion
- Designing a comprehensive system to keep track of all promotional activity in case of frequent turnover at the company
- Best practices for working with sales reps when pulling problematic promotional materials

12:30 Networking Luncheon

1:45 **Proactively Structuring Your Promotional Review Systems By Identifying New Drug and Device Litigation Trends**

Moji James
Senior Vice President & General Counsel
Iroko Pharmaceuticals, LLC
(Philadelphia, PA)

Diane E. Lifton
Partner, Co-Chair of Life Sciences Group, Product Liability Group, and Hiring and Diversity Committee
Hughes Hubbard & Reed LLP
(New York, NY)

- Reviewing the types of litigation that may arise out of promotional activities, including product liability/negligence, misrepresentation/omission, and government action such as the False Claims Act
- Understanding the distinctions among omission claims, misrepresentation claims and product liability/negligence claims
  - Are omission claims on the rise?
  - What is the potential impact of these claims on promotion and advertising?
  - What types of omissions may lead to government enforcement or mass tort claims?
- Analyzing case studies and determining types of activities that raise red flags for private and government action
- Examining whether *Amarin* and off-label marketing will give rise to changes in practice, and potentially to more litigation
- Assessing what kind of information should and should not be included in promotional materials to reduce the risk of litigation
- Best practices for working with the product team, including regulatory, to develop an evidentiary record that will strengthen the company's defenses to future claims

2:45 Afternoon Refreshment Break

3:00 **Considerations for Building a Globally Compliant Promotion Program**

Sue Duvall
Sr. Director, Head International Regulatory Advertising and Promotion
AbbVie
(North Chicago, IL)

Melissa Smyth
Senior Manager, Global/Area Material Review Team
AbbVie
(North Chicago, IL)

This interactive session will provide direction when developing compliant international advertising and promotional materials for a prescription drug. By providing specific examples, the speakers will help you understand general requirements for materials that can be used worldwide including specific examples in selected countries. In addition, a model for how global materials can be rolled out to various countries will be discussed. Points of discussion will include:

- Basic principles that apply to all countries: Role of IFPMA
- Why one size doesn't fit all but most countries use the same data
- Differences you will find from country to country
- Exploring training issues that can occur
- A model for review and approval of HQ generated materials and how to work with country offices
- Understanding the difference between Corporate materials and countries materials: using Social Media as an example
- Examining your operational systems to ensure that global affiliates are working off the same promotional materials
  - Reviewing key translation issues that occur

4:00 **Compliance in the Use of Healthcare Economic, Quality and Real World Evidence Data**

Janice D. Kam
Assistant General Counsel
Eisai Inc.
(Woodcliff Lake, NJ)

Daniel A. Kracov
Partner
Arnold & Porter LLP
(Washington, DC)

Since the implementation of the Affordable Care Act, drug and device manufacturers are showing increased attention to the development and use of data on health economics, quality of care, and real world evidence. Although little guidance is available from regulators, enforcement efforts are already focused on these critical areas. This session will focus on the risks and best practices associated with communicating health economic data, interactions with customers relating to quality of care and associated measures, and collaborations to develop such data. We will also examine the developing focus on real world evidence, and the compliance considerations associated with developing and communicating real world data to various audiences. Guiding you through specific examples, speakers will discuss:

- Structuring internal functions relating to health economics, quality and real world evidence data and communications
- Examining how to substantiate claims asserting a drug or device's economic impact, and communicate such claims in a compliant manner in various settings
- Developing enforcement theories relating to health economics and quality of care communications and collaborations
- Managing the risks associated with health economic and quality of care collaborations with customers
- Limitations on the use of real world evidence, and opportunities to use such evidence in a compliant manner

5:00 Conference Adjourns

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Wendy Tyler
Director of Sales, American Conference Institute
Tel: 212-352-3220 x5242
w.tyler@AmericanConference.com

POST-CONFERENCE WORKSHOP – WEDNESDAY, JANUARY 13, 2016

(Registration begins at 8:00 AM)

9:00 **Interactive Mock PRC: Managing a Promotional Review Meeting from Start to Finish Through Specific Case Studies and Examples**

James Brandon Keefe
Marketing Leader
AstraZeneca LP
(Wilmington, DE)

Areta L. Kupchyk
Partner
Foley Hoag LLP
(Washington, DC)

Jennifer McGilloway
Director, Advertising and Promotional Compliance,
Global Regulatory Affairs
Allergan
(Irvine, CA)

Matthew Wong, Pharm.D.
Associate Director, Medical Review
Daiichi Sankyo, Inc.
(Parsippany, NJ)

This interactive session will take you through the ins and outs of what to expect in a promotional review committee ("PRC") meeting. Building on the principles learned through the main conference and additional specific examples, you will learn how to prepare for expected and unexpected challenges that can arise throughout the process. This working group will help you comprehend the various responsibilities and goals for each member of the PRC, while helping you end up with a promotion that satisfies each business, legal, or regulatory requirement. Points of discussion shall include:

- Exploring regulatory, legal, medical and marketing member's responsibilities and functions to work efficiently
- Examining options and finding solutions while working in gray areas through case examples on a "mock" promotional review committee
- Sharing tips and best practices for successful review outcomes – managing business related risk while meeting commercial needs

12:00 Workshop Adjourns

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You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

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Promotional Review Compliance for Drugs and Devices

Navigating an uncertain legal and regulatory environment while ensuring a "fair balance" of "truthful and non-misleading" promotional messages

January 11-13, 2016 | The Union League | Philadelphia, PA

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American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "Promotional Review Compliance for Drugs & Devices" conference to receive this rate.

Venue: The Union League
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