



American Conference Institute's 7th National Forum on

OFF-LABEL COMMUNICATIONS

Evaluating and Revamping Compliance Protocols in the Wake of Unprecedented Settlements

July 14-15, 2010 • The Union League • Philadelphia, PA

Government Enforcement Panel Featuring:

Virginia Gibson

Assistant U.S. Attorney and Chief, Civil Division U.S. Attorney's Office, Eastern District of Pennsylvania

Paul Kaufman

Chief of Civil Healthcare Fraud U.S. Attorney's Office Eastern District of New York

Michael E. Little

Deputy Medicaid Inspector General Division of Medicaid Investigations Office of the Medicaid Inspector General (New York, NY)

Marilyn May

Deputy Chief Affirmative Civil Litigation U.S. Attorney's Office, Eastern District of Pennsylvania

Practical Real World Solutions From:

Boston Scientific

Cephalon

Covidien

Eli Lilly

Luitpold Pharmaceuticals, Inc.

Medtronic

Novartis

Pfizer

sanofi-aventis

Teva North America

Leading experts in compliance, regulatory affairs and ethics will share their best practices and insights on how to:

- **CREATE** a robust compliance program designed to minimize off-label risks
- **IMPLEMENT** the FDA's new guidance on social media tools
- **DETECT** the current triggers for government investigations and individual liability
- **MINIMIZE** the risks of sending sales reps into the field
- **MANAGE** and **DEFEND AGAINST** whistleblower and relator allegations
- **DISSECT** the criteria laid out in Corporate Integrity Agreements
- **MINIMIZE** exposure to product liability and consumer class action risks

POST-CONFERENCE WORKSHOP

Proactively Preparing for and Managing an Off-Label Investigation

July 16, 2010 • 9:00 a.m. – 12:00 p.m.

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“The quality of the speakers and the hand-out material was outstanding. Best collection of speakers at a conference I have attended in the last two years.”

– Cynthia Shumate, *Vice President, Legal Affairs, PDL Biopharma Inc*

Off-Label Promotions Can Cost Billions in Fines – Are You Sure You’re Compliant?

In the last twelve months, several major pharmaceutical and device companies have been assessed **record-breaking fines** by the government for off-label promotion. Penalties are not stopping at just fines. The states are now going after individuals responsible for corporate compliance programs and drug advertising. Increasingly complex **Corporate Integrity Agreements** are becoming part of negotiated settlements. In addition, pharmaceutical and medical device companies are becoming extremely vulnerable with their global operations, which are under great scrutiny from federal and state prosecutors, members of Congress, and potential whistleblowers. If your company isn’t up to speed on the latest FDA guidance and interpretation of the rules, yours could be the next company landing in the headlines. To manage off-label risks with confidence and mitigate potential liability, you must be savvy with regard to what conduct is triggering government investigations and litigation, and how you need to adjust your compliance efforts and be ready to defend against any investigation or claim.

Uncover and Proactively Address Any Potential Violations of the FDA’s Off-Label Promotion Rules

American Conference Institute’s 7th National Forum on Off-Label Communications will provide you with the most up-to-date tools for tackling the challenges associated with drug and device promotion. You will hear about successful compliance plans, effective business practices, and winning litigation tactics from leading in-house counsel, compliance and regulatory officers, and expert attorneys who represent the pharmaceutical and device industries. In addition, leading government prosecutors will be on-hand to provide insights on recent government investigations.

Don’t miss this opportunity to answer your probing questions and obtain the information you need from the leading experts in the field, as you network with your peers and colleagues from across the country. Delegates will also benefit from the extensive written materials prepared especially for this conference. Register now by calling 888-224-2480, faxing your registration form to 877-927-1563 or registering online at www.americanconference.com/offlabel.

Who Should Attend:

Counsel and senior executives in the pharmaceutical and device industries with responsibilities for:

- sales and marketing
- medical research
- regulatory affairs
- ethics and compliance
- FDA regulatory matters

Attorneys with practice areas in:

- healthcare
- pharmaceutical
- FDA regulatory law
- food and drug law
- government investigations
- white collar
- product liability

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Wendy Tyler
Head of Sales
American Conference Institute

Tel: 212-352-3220 x242 | Fax: 212-220-4281
w.tyler@AmericanConference.com

Day 1 – Wednesday, July 14, 2010

7:30 Registration and Continental Breakfast

8:30 Co-Chairs' Opening Remarks

Geoffrey Levitt

Associate General Counsel
Worldwide Regulatory and Policy Law
Pfizer, Inc. (New York, NY)

Betsy Van Hecke

Vice President
Ethics & Compliance, Spinal Division
Medtronic (Minneapolis, MN)

8:45 Presenting Product Information Using Social Media Tools Without Running Afoul of Off-Label Guidelines

Mark DeWyngaert, PhD

Managing Director
Huron Consulting Group (New York, NY)

Priya Mannan

Executive Director and Associate General Counsel
Novartis Institutes for BioMedical Research Inc.
(Cambridge, MA)

Edward M. Basile

Senior Partner
King & Spalding LLP (Washington, DC)

Sheila W. Sawyer

Partner
Waller Lansden Dortch & Davis LLP (Nashville, TN)
(former Assistant U.S. Attorney, Massachusetts)

- Assessing the impact of social media on pharmaceutical and device promotional activities
- Assigning responsibility for monitoring social media
 - putting together a task force
 - creating a monitoring team
- Keeping track of internet advertising to ensure off-label rules are not violated
- Applying current FDA guidelines to new and emerging technologies
 - understanding which mediums apply
- Defining how the FDA enforces drug and device promotion among internet channels
 - applying current rules until internet specific guidelines are developed
- How should product information be presented using various social media tools to ensure that the user has access to a balanced presentation of both risks and benefits of medical products?

- What are the responsibilities of the pharmaceutical and device companies for comments and/or adverse events that users post on Facebook or YouTube?

10:00 Morning Coffee Break

10:15 Avoiding Indictment When the FDCA is Violated

Paula Taylor Whitfield

Deputy General Counsel
Eli Lilly & Co. (Indianapolis, IN)

Adam S. Hoffinger

Partner
Morrison Foerster (Washington, DC)
(former Assistant U.S. Attorney,
Southern District of New York)

Holly A. Pierson

Of Counsel
Morris, Manning & Martin, LLP (Atlanta, GA)
(former Assistant U.S. Attorney, Western District
of North Carolina)

Simone E. Ross

Of Counsel
Covington & Burling LLP (Washington, DC)
(former Assistant Counsel, Office of Professional
Responsibility, U.S. Department of Justice)

- Analyzing the increasing trend in the pursuit of executives and employees in their individual capacities
- What behaviors and activities are triggering individual prosecution/indictment?
- How can executives insulate themselves from individual liability?
- Extending liability to executives under a strict liability theory for misdemeanor violations of the FDCA
- Managing ambiguous off-label activities to minimize the risk of individual liability
- Minimizing individual liability by complying with FDA guidelines and seeking counsel to advise on company marketing practices

11:30 Ensuring Article Reprints Adhere to FDA Guidelines

Brian A. Dahl

Director of Compliance
Teva North America (Kansas City, MO)

John Manthei

Partner
Latham & Watkins LLP (Washington, DC)

Alan Minsk

Partner

Arnall Golden Gregory LLP (Atlanta, GA)

- Defining acceptable types of clinical studies that can serve as the basis for the articles
- Considering the product liability ramifications of article reprints
- Serving policy interests by disseminating truthful and non-misleading information to health care professionals and patients
- Evaluating the Compliance Department's role in physician-written article reprints
- Distinguishing legitimate scientific exchange from off-label promotion
 - what does it mean to hand out a journal article validating off-label use?

12:45 **Networking Lunch**

2:00 **Managing, Defending and Curtailing Whistleblower and Relator Allegations**

Michele L. Adelman

Counsel

Foley Hoag LLP (Boston, MA)

(former Deputy Chief, Criminal Bureau, Massachusetts Attorney General)

Robert A. Atkins

Partner

Paul, Weiss, Rifkind, Wharton & Garrison LLP (New York, NY)

John N. Joseph

Partner

Post & Schell P.C. (Philadelphia, PA)

(former Assistant U.S. Attorney, Eastern District of Pennsylvania)

Mark Lurie

Principal

Law Office of Mark D. Lurie LLC (Montclair, NJ)

- Understanding the potent financial incentive for whistleblowers to report noncompliance
 - how to best minimize the liability risk from whistleblowers
- Demonstrating to the government that your company has responded, investigated, and took corrective action
- Examining the key triggers for government intervention
 - how to proceed once a whistleblower investigation is started
- How to defend against a whistleblower or relator allegation
 - FDCA
 - FCA

3:15 **Afternoon Coffee Break**

3:30 **Utilizing Corporate Integrity Agreements to Reduce Fraudulent Activities**

Edward Nowicki

Deputy Compliance Officer – Global Programs, Senior Corporate Counsel, Corporate Compliance Pfizer Inc. (New York, NY)

Barry H. Boise

Partner

Pepper Hamilton LLP (Philadelphia, PA)

John S. Rab

Partner

Morgan, Lewis & Bockius LLP (Washington, DC)

- Negotiating a CIA with the Office of Inspector General
- Developing written standards and policies
 - compliance officers
 - communications hotline
- Implementing a comprehensive employee training program
- Establishing a confidential disclosure program
- Performing monitoring and review procedures to eliminate fraudulent activities
- Looking at current CIAs to determine what is permissible for reprints

4:30 **Developing Defensive Strategies for Minimizing Manufacturer Liability When Physicians Utilize Products for Off-Label Purposes**

Stephen D. Brody

Partner

O'Melveny & Myers LLP (Washington, DC)

John R. Washlick

Member, Co-Chair of the Health Law Practice Group Cozen O'Connor (Philadelphia, PA)

- Determining a manufacturer's liability when an off-label use goes wrong
- Physicians turning down prestigious academic appointments in order to collect money from pharmaceutical companies
- Assessing the legal risks associated with providing monetary incentive for a physician to prescribe a drug for an off-label purpose
- Identifying manufacturers' relationship to CME
- Monitoring specific payments to healthcare professionals to ascertain if they are being paid to promote off-label

5:30 **Conference Adjourns to Day 2**

Day 2 – Thursday, July 15, 2010

8:00 **Registration and Continental Breakfast**

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

9:00 **An Allergan Case Study:
Using the 1st Amendment to Argue Against
Allegations of Off-Label Marketing**

Stuart Kim

Associate General Counsel,
Regulatory Covidien (Hazelwood, MO)

Geoffrey Levitt

Associate General Counsel,
Worldwide Regulatory and Policy Law
Pfizer, Inc. (New York, NY)

Michele Hirshman

Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
(New York, NY)

- What's at stake in the Allergan case?
- Examining the interplay between risk communication and off-label speech
- Looking at the impact of government enforcement practices on the free exchange of scientific information about medical products
- Striking the right balance between FDA control of drug labeling and patients' and professionals' interest in robust communication on the safe use of drugs

10:15 **Morning Coffee Break**

10:30 **Spotlight on Enforcement: New Trends
Triggering Off-Label Investigations**

Virginia Gibson

Assistant U.S. Attorney and Chief, Civil Division
U.S. Attorney's Office, Eastern District of Pennsylvania

Paul Kaufman

Chief of Civil Healthcare Fraud
U.S. Attorney's Office Eastern District of New York

Michael E. Little

Deputy Medicaid Inspector General
Division of Medicaid Investigations
Office of the Medicaid Inspector General (New York, NY)

Marilyn May

Deputy Chief, Affirmative Civil Litigation
U.S. Attorney's Office, Eastern District of Pennsylvania

Thomas S. Crane

Partner
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
(Boston, MA)
(former Counsel, Office of Inspector General)

Moderator

John E. Kelly

Senior Counsel
Fulbright & Jaworski LLP (Washington, DC)
(former Assistant Chief for Health Care Fraud,
U.S. Department of Justice)

Off-label promotion is a major focus of anti-fraud enforcement. The government continues to reach record-shattering settlements with both the pharmaceutical and device manufacturers. In the last year, billions of dollars have been paid in order to resolve these claims. Evidenced by these settlements, the government is signaling that it intends to continue enforcing the laws governing the activities of large pharmaceutical companies, small companies, and medical device companies. It is imperative for pharmaceutical and device manufacturers to understand what activities trigger increased scrutiny and how a government investigation begins. Hear from top prosecutors who have handled these off-label cases as they discuss:

- Creating a new schematic for issuing warning letters
- Escalating spending on fraud investigations
- Balancing the competing interests of DOJ and the FDA

12:00 **Networking Lunch**

1:15 **Training the Sales Force: Minimizing
the Risks of Sending Your Sales Team
Into the Field**

Jean Poulos, MS, MBA

Vice President of Quality and Regulatory Operations
Luitpold Pharmaceuticals, Inc. (Shirley, NY)

Peter S. Reichertz

Partner
Sheppard, Mullin, Richter & Hampton LLP
(Washington, DC)

Kyle Sampson

Partner
Hunton & Williams (Washington, DC)
(former Chief of Staff, U.S. Department of Justice)

- Utilizing effective training techniques
 - scenario training
 - module testing
 - maintaining ongoing training
- Teaching the sales force how to deal with a physician who uses a product for both on and off-label indications

- Establishing sanctions and disciplinary actions for noncompliance
- Preparing sales reps for depositions when the company is engaged in litigation
- Creating a practical monitoring program based on a sales rep's day-to-day routine
- Defining the parameters of appropriate responses to unsolicited off-label inquiries
- Identifying acceptable activities the sales force can engage in when new information becomes available

2:15 **Distinguishing Between Off-Label Guidelines for Device vs. Pharmaceutical Companies**

Thomas Lynch

Senior Corporate Counsel
Boston Scientific (Maple Grove, MN)

David L. Rosen

Partner
Foley & Lardner LLP (Washington, DC)

- Learning from device manufacturers' litigation
 - *U.S. v. Stryker*
- Training of physicians on the use of medical devices that are known to be used only for an off-label purpose
- Identifying the criteria for answering a physician's questions on off-label use
- Following FDA off-label promotion guidelines
 - pharmaceutical regulation through DDMAC
 - no DDMAC for devices

3:15 **Afternoon Coffee Break**

3:30 **Building a Robust Compliance Program: Practical Solutions to Prevent Off-Label Violations**

Susan Hart-White

Associate General Counsel
Regulatory Law, Privacy & Policy Group
sanofi-aventis (Bridgewater, NJ)

Karen Lowney

Senior Director - Global Compliance
Cephalon (Frazer, PA)

Gary W. Thompson

Senior Counsel
Akin Gump Strauss Hauer & Feld LLP (Washington, DC)
(former Senior Counsel, Office of Counsel to the Inspector General)

- Benchmarking and reporting your compliance program
 - how to quantify compliance efforts

- Drawing a line between the lawful scientific exchange of information and off-label promotion
- Ensuring effective and compliant Medical Affairs communication
- Defining the boundaries of appropriate responses to unsolicited off-label inquiries
- Evaluating new marketing plans to ensure compliance with off-label promotion guidelines

4:30 **Conference Concludes**

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

POST-CONFERENCE WORKSHOP

Friday, July 16, 2010

9:00 a.m. – 12:00 p.m.
(registration begins at 8:15 a.m.)

PROACTIVELY PREPARING FOR AND MANAGING AN OFF-LABEL INVESTIGATION

Daniel R. Margolis

Partner

Pillsbury Winthrop Shaw Pittman LLP (New York, NY)

(former Assistant U.S. Attorney, Southern District of New York)

Emily R. Schulman

Partner

Wilmer Cutler Pickering Hale and Dorr (Boston, MA)

(former Assistant U.S. Attorney, Massachusetts)

As pharmaceutical and medical device manufacturers face a growing number of off-label investigations and enforcement actions from the FDA, DOJ, and state attorneys, and settlements become more costly and complex, it is increasingly important to know how to manage an off-label investigation.

As the panelists walk through the essential elements of an effective internal investigation, they will focus on key decision points and considerations for in-house counsel along the way. This timely interactive workshop will provide advanced discussion of strategies for deciding, among other things:

- Determining the scope of the investigation
- Knowing to whom the investigators should report and in what form
- Dealing with employees during the investigative process
- Managing various aspects of e-discovery
 - cost containment
 - review
 - production
- How to manage interactions with the Government during the investigation and in settlement negotiations



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Friday, July 16, 2010
9:00 a.m. – 12:00 p.m.

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PRIORITY SERVICE CODE

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ORGANIZATION _____

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