

Pharmaceutical and Medical Device Company's Guide to

OFF-LABEL COMMUNICATIONS

Staying within the legal bounds in a climate of record-breaking settlements

July 15-16, 2009 • The Union League • Philadelphia, PA

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- **INCORPORATE** lessons learned from staggering recent settlements into compliance policies and procedures
- **IMPLEMENT** the FDA's new guidance on scientific reprints
- **DETECT** the current triggers for government investigations and know what to do if you receive a subpoena
- **CONTROL** misconceptions and improper conduct by sales reps
- **PROVIDE** accurate and current assessments of potential off-label risks when engaging in M&A
- **PREVENT** MSLs from blurring the line between medical affairs and sales
- **MINIMIZE** exposure to product liability and consumer class action risks

GOVERNMENT ENFORCEMENT PANEL FEATURING:

Randy S. Chartash
Assistant United States Attorney
Northern District of GA

Daniel R. Miller
Deputy Attorney General & Director
Delaware Medicaid Fraud Control Unit
President, NAMFU

Jeffrey Senger (*invited*)
Deputy Chief Counsel
Food and Drug Administration

Joseph Trautwein
Assistant United States Attorney
Eastern District of PA

POST-CONFERENCE WORKSHOP

Negotiating Settlements of Off-Label Investigations and Enforcement Actions

July 16, 2009 • 3:15 pm – 5:30 pm

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Mitzi G. Cole
Division Counsel
Wyeth Pharmaceuticals

Mark C. Levy
Partner
Saul Ewing LLP

Stuart Kim
Associate General Counsel,
Regulatory Affairs, Covidien

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RECENT SETTLEMENTS HAVE RAISED THE STAKES

Headlines announcing **record-breaking fines** for off-label promotion have put the entire industry on notice. And while the huge dollar amounts involved are attracting wide attention, just as significant are the **additional compliance obligations** that are being agreed to as part of the negotiated settlements. Pharmaceutical and medical device companies are extremely vulnerable with their global operations under great scrutiny from federal and state prosecutors, members of Congress, and potential whistleblowers. Being aware of the current guidelines that regulate and govern off-label communications, including the new guidance on scientific reprints, is the bare minimum you must do. 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.

DON'T BE THE NEXT TARGET OF OFF-LABEL PROMOTION CLAIMS!

American Conference Institute's **6th National Pharmaceutical Counsel's Guide to Off-Label Communications** will provide you with the most up-to-date tools for tackling these challenges. 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 industry. In addition, **leading government prosecutors will be on-hand** to provide insights on recent government enforcement priorities.

Don't miss this opportunity to answer your pressing 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 YOU WILL MEET

- **In-house counsel and senior executives in the pharmaceutical and device industries responsible for:**
 - Sales & marketing
 - Medical affairs
 - Regulatory affairs
 - FDA regulatory matters
 - Ethics & compliance
- **Attorneys practicing in:**
 - Healthcare law
 - Pharmaceutical law
 - FDA regulatory law
 - Food & drug law
 - Product liability
 - Medicare/Medicaid reimbursement

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"Excellent conference; timely information, good speakers, good slides. This was the best conference I have attended on this topic."

Mary Sullivan, Senior Manager, Takeda Pharmaceuticals

DISTINGUISHED FACULTY

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Mitzi G. Cole
Division Counsel, Wyeth Pharmaceuticals

Stuart Kim
Associate General Counsel, Regulatory Affairs, Covidien

Mark C. Levy
Partner, Saul Ewing LLP

Speakers:

Atiba D. Adams
Assistant General Counsel, Pfizer Inc.

Jennifer Bragg
Partner, King & Spalding LLP

Loren Brown
Partner, DLA Piper

Randy S. Chartash
Assistant United States Attorney, Northern District of GA

Mark S. Cheffo
Partner, Skadden Arps Slate Meagher & Flom LLP

Debra S. Dunne
Partner, Stradley Ronon Stevens & Young, LLP

Erik Eglite, DPM, JD
Corporate Compliance Officer, Ovation Pharmaceuticals

Laurence J. Freedman
Partner, Patton Boggs LLP

Arnold I. Friede
Counsel, McDermott Will & Emery

Raymond J. Furey
Compliance Officer, OSI Pharmaceuticals

Thomas M. Gallagher
Partner, Pepper Hamilton LLP

Abhi Gandhi
Commercial Compliance, Actelion Pharmaceuticals US

Christopher R. Hall
Partner, Saul Ewing LLP

Julie Kane
V.P., Ethics and Compliance, Novartis

Sheila Komara
Sr. Medical Science Liaison, Global Medical Affairs, Hospira, Inc.

Judy L. Leone
Partner, Dechert LLP

Roger Louis
Senior VP, Healthcare and Regulatory Counsel and
Chief Compliance Officer, Genzyme

Stephen Paul Mahinka
Partner, Morgan, Lewis & Bockius LLP (Washington, DC)

Daniel R. Margolis
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President, NAMFCU

Curt Oltmans
Deputy General Counsel, Novo Nordisk Inc.

Holly A. Pierson
Partner, Nelson Mullins Riley & Scarborough LLP

Ann K. Rosen
Assistant General Counsel, Glaxo Smith Kline

Ina B. Scher
Partner, Davis & Gilbert LLP

Jeffrey Senger
Deputy Chief Counsel, Food and Drug Administration

Erik W. Snapp
Partner, Winston & Strawn LLP

Peter S. Spivack
Partner, Hogan & Hartson LLP

Mary Sullivan
Director, Advertising and Promotion, Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.




Joseph Trautwein
Assistant United States Attorney, Eastern District of PA

Mark J. Wanda
Senior Vice President, Legal Affairs and Deputy General Counsel
Sepracor Inc.





Allen P. Waxman
Partner, Kaye Scholer LLP

8:00 **Registration and Continental Breakfast** ☕

9:00 **Chairs' Opening Remarks**


-  **Mitzi G. Cole**
Division Counsel, Wyeth Pharmaceuticals (Collegeville, PA)
-  **Stuart Kim**
Associate General Counsel, Regulatory Affairs, Covidien (Hazelwood, MO)
-  **Mark C. Levy**
Partner, Saul Ewing LLP (Philadelphia, PA)

9:15 **Dissecting Recent Billion Dollar Off-Label Settlements**

-  **Mark J. Wanda**
Senior Vice President, Legal Affairs and Deputy General Counsel
Sepracor Inc. (Marlborough, MA)
-  **Arnold I. Friede**
Counsel, McDermott Will & Emery (Washington, DC)
-  **Christopher R. Hall**
Partner, Saul Ewing LLP (Philadelphia, PA)
-  **Peter S. Spivack**
Partner, Hogan & Hartson LLP (Washington, DC)
 - Identifying what conduct triggered scrutiny
 - specific alleged sales and marketing practices that advocated unapproved uses
 - role of whistleblowers
 - Assessing the impact of the timeframe of the conduct
 - timelines for the investigations
 - detecting whether there were rule changes during the relevant time periods
 - How the perspective of the government shaped the scope of the investigation
 - coordination of multiple claims
 - role of state prosecutors
 - Contrasting and separating the criminal and civil aspects of the settlements
 - Looking beyond the large financial penalties to evaluate the other key terms in the agreements
 - obligations contained in corporate integrity agreements
 - scope of activities and parties covered under the CIAs
 - impact on interactions with physicians
 - providing for third-party oversight of sales and marketing activities
 - use of IROs
 - additional reporting requirements
 - public web disclosures
 - Identifying the correct takeaways and potential new compliance strategies







10:15 **Morning Coffee Break** ☕

10:30 **Ensuring Compliance with the New FDA Guidance on Journal Reprints**

-  **Ann K. Rosen**
Assistant General Counsel
Glaxo Smith Kline (Research Triangle Park, NC)
- Mary Sullivan**
Director, Advertising and Promotion, Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc. (Ridgefield, CT)
 - Defining acceptable types of clinical studies that can serve as the basis for the articles
 - acceptable journals
 - Meeting the requirements relating to inclusion of accompanying materials
 - Modifying current practices to reflect the new guidance
 - assessing who may now distribute the reprints, and where
 - anticipating potential gray areas in implementing the new guidance
 - eliminating confusion and providing clear internal guidelines
 - ongoing limitations on activities by field reps

- Potential impact of Rep. Waxman's request for re-examination, and potential legislative initiatives which may nullify the FDA's proposal





11:15 **Enforcers' Panel: Identifying Enforcement Trends**

-  **Randy S. Chatash**
Chief, Economic Crime Section, United States Attorney's Office
Northern District of Georgia (Atlanta, GA)
-  **Daniel R. Miller**
President, National Association of Medicaid Fraud Control Units
Deputy Attorney General & Director,
Delaware Medicaid Fraud Control Unit (Wilmington, DE)
-  **Jeffrey Senger (invited)**
Deputy Chief Counsel
Food and Drug Administration (Washington, DC)
-  **Joseph Trautwein**
Assistant U.S. Attorney
District of Eastern Pennsylvania (Philadelphia, PA)
-  **Holly A. Pierson**
Partner, Nelson Mullins Riley & Scarborough LLP (Atlanta, GA)
(former Assistant U.S. Attorney, Western District of North Carolina)
- Moderator:**
-  **Thomas M. Gallagher**
Partner, Pepper Hamilton LLP (Philadelphia, PA)

As developments in 2009 have resoundingly demonstrated, off-label promotion is a major focus of anti-fraud enforcement. Record-shattering settlements have surpassed the billion dollar level, and it has been estimated that at least a hundred cases remain in government pipelines. It is critical for pharmaceutical and device manufacturers to understand what activities trigger government scrutiny and how an investigation is focused. Hear from top prosecutors with hands-on experience in major off-label investigations in this interactive setting. Points of discussion will include how different agencies are currently coordinating their efforts, recent initiatives, and investigatory prioritizations.

12:30 **Networking Luncheon for Speakers and Delegates** 🍽️

1:45 **Retooling Your Compliance Program in the Wake of Recent Massive Settlements**

-  **Mitzi Cole**
Division Counsel, Wyeth (Collegeville, PA)
-  **Julie Kane**
Vice President, Ethics and Compliance
Novartis Pharmaceuticals Corporation (East Hanover, N.J.)
-  **Roger Louis**
Senior VP, Healthcare and Regulatory Counsel and
Chief Compliance Officer, Genzyme (Cambridge, MA)
-  **Jennifer Bragg**
Partner, King & Spalding LLP (Washington, DC)
 - Drawing the right line between lawful scientific exchange and off-label promotion
 - determining how your company will define "off-label" communications
 - operating in areas where there is little practical guidance
 - making certain that conduct scrutinized in recent investigations is squarely addressed
 - Incorporating the current PhRMA and AdvaMed Codes, OIG and FDA Guidelines, Fraud and Abuse Safe Harbors, and the Federal Sentencing Guidelines into off-label controls
 - Determining whether to incorporate off-label related obligations in recent settlements and CIAs into the compliance program
 - Defining the parameters of appropriate responses to unsolicited off-label inquiries
 - what can sales reps communicate about the product?
 - what information can they disseminate?
 - Identifying acceptable activities the sales force can engage in when new information becomes available
 - Recognizing and allowing for situations sales reps actually face in the field
 - Answering common questions
 - how should companies handle free text?
 - how should policies be worded?

- Determining how to manage National Account Managers (NAMs) and their use of pharmacoeconomic data
- Evaluating the impact of financial incentive programs on promotional practices
- Gaining corporate-wide acceptance and buy-in to avert “push back” from marketing
- Benchmarking and reporting your compliance program: tips for quantifying your compliance efforts
- Deterring qui tam whistleblower suits through proactive compliance measures
 - establishing a hotline for reports of noncompliance
 - developing a reward program for employees who report wrongdoing
 - conducting internal investigations and audits
 - implementing effective organizational ethics and compliance programs
- Being prepared to field government inquiries and document requests

3:00 Afternoon Coffee Break ☕

3:15 Minimizing the Risk of the Sales Force Crossing the Line



Raymond J. Furey

Compliance Officer, OSI Pharmaceuticals (Melville, NY)

Abbi Gandhi

Commercial Compliance

Actelion Pharmaceuticals US (South San Francisco, CA)



Erik W. Snapp

Partner, Winston & Strawn LLP (Chicago, IL)

- Providing guidance on the off-label promotional practices that drew scrutiny in recent investigations
 - when use of certain words and slogans may be deemed inappropriate
 - risks associated with sales reps being in the operating room
- Utilizing effective training techniques
 - updating training efforts to address issues in current investigations
 - testing for knowledge retention
 - weighing the benefits and detriments of web-based training programs
 - providing examples of inappropriate promotion activities
 - maintaining an ongoing training regimen
- Establishing a monitoring program that is not impractical based on a sales rep's day-to-day routine
 - modeling the monitoring program on what the government would find to be sufficient
- Incorporating random audits into the monitoring program to ensure compliance
- Effectuating the implementation of procedures to control off-label communications
- Understanding the significant role of Medical Information Departments in tracking off-label activities
- How to conduct an investigation of specific sales activities to uncover off-label violations
- Establishing consequences for noncompliance: evaluating the effectiveness of sanctions and other disciplinary actions

4:15 Effectively Using Multiple Communication Channels While Controlling Off-Label Risks



Debra S. Dunne

Partner, Stradley Ronon Stevens & Young, LLP (Philadelphia, PA)

- Understanding the difference between legitimate CME and off-label promotion
- Disseminating information at medical meetings, conferences and trade shows: defining what's appropriate in this gray area
- Understanding the possible legal implications associated with sponsoring events
- Implementing a stringent internal review and approval program
- Utilizing compliant Scientific Advisory Boards
- Avoiding “ghost-writing” allegations
 - analyzing industry standards regarding use of third-party companies to assist with drafting of medical literature
- Assessing the legal risks associated with online communications
 - company sponsored chat rooms
 - product information on company websites

- links from the manufacturer's website to medical information sites
- promotion and medical education: keeping the bright line bright
- Ensuring written materials cannot be used against you in the course of an off-label investigation
 - product brochures
 - representations made to government agencies (i.e. statements made in support of reimbursement)
 - securities filings
 - internal correspondence and sales training manuals

5:00 Conference Adjourns

Day 2 – Thursday, July 16, 2009

8:00 Continental Breakfast ☕

8:45 Co-Chairs' Opening Remarks

9:00 Properly Framing the Role of MSLs to Avoid Promotional Pitfalls

Sheila Komara

Sr. Medical Science Liaison, Global Medical Affairs
Hospira, Inc. (Lake Forest, IL)



Curt Oltmans

Deputy General Counsel, Novo Nordisk Inc. (Princeton, NJ)

- Understanding why MSLs are at the front line of the tension between discussion and promotion
- Knowing exactly what MSLs can and can not do
 - Creating guidelines and defining their roles
- Training MSLs on the limits of communication with physicians
 - differentiating between pre- and post-approval communication
 - defining “unsolicited inquiry” and “fair balanced response”
- Setting boundaries for interaction between MSLs and sales personnel
 - maintaining scientific credibility
 - determining when to permit MSLs to participate in various activities
 - avoiding legal risks for statements made in promotional contexts
- Monitoring MSLs to prevent off-label promotion
 - creating an internal audit program
 - recognizing warning signs that indicate the MSL is blurring the line between medical affairs and sales
- Evaluating potential MSL off-label communication violations
- Understanding and communicating the legal risks associated with noncompliance
- Integrating the information MSLs gather in the field

9:45 Morning Coffee Break ☕

10:00 Knowing What to Do When You Receive a Subpoena: Responding Effectively to Off-Label Investigations and Qui Tam Suits



Laurence J. Freedman

Partner, Patton Boggs LLP (Washington, DC)



Daniel R. Margolis

Partner, Pillsbury Winthrop Shaw Pittman LLP (New York, NY)



Ina B. Scher

Partner, Davis & Gilbert LLP (New York, NY)

- Understanding the key triggers for government intervention and preparing for potential criminal investigation
- Examining the role and impact of whistleblowers in recent government investigations
 - how to proceed once a whistleblower investigation is started
- Fashioning the appropriate response, if any, to
 - untitled letters
 - cyber letters
- Determining whether to make voluntary disclosures when a violation is uncovered internally
- Responding to a subpoena
 - prioritizing what needs to be done first

- mapping out how to handle the types of issues presented
- assessing the time period of the conduct in questions
- exercising proper discretion in weighing possible courses of action
 - potential mitigating factors
- Fielding document requests
 - narrowing the scope
- Conducting an early assessment of the magnitude of the risks
 - damages and civil penalties
 - shareholder actions
 - potential exclusion from CMS programs
 - obligation to adhere to a corporate integrity agreement
 - criminal liability

11:00 Assessing and Managing Risks in Product Liability Cases Based on Off-Label Uses



Atiba D. Adams
Assistant General Counsel, Pfizer Inc. (New York, NY)



Loren Brown
Partner, DLA Piper (New York, NY)



Mark C. Levy
Partner, Saul Ewing LLP (Philadelphia, PA)

- Coordinating matters when a client is facing simultaneous criminal, consumer class action, and product liability claims all based on the same underlying allegations of off label promotion
- Strategies for effective use of discovery
- Anticipating fact issues at trial
- Evaluating under which trial scenario there will be discussion of off-label use
 - official company promotion
 - when a rogue sales representative is doing the promoting
 - activities by doctors
- Determining the extent to which off-label activities impact the dynamics at trial, particularly the roles of the treating physician, the sales representatives, and the sales and marketing departments
- Assessing the strength and applicability of key defenses
 - learned intermediary defense
 - preemption
 - asserting off-label use as a defense
- Knowing when it may be advantageous to advance your case to the jury in an off-label situation
- Defending the manufacturer in light of the recent enforcement landscape
 - relevance and impact of public perceptions relating to civil and criminal penalties

12:00 Networking Luncheon for Speakers and Delegates

1:15 Due Diligence: Uncovering Off-Label Red Flags When Engaging in M&A



Erik Eglite, D.P.M., J.D.
Vice President, Compliance & Corporate Counsel
Ovation Pharmaceuticals, Inc. (Deerfield, IL)



Stephen Paul Mahinka
Partner, Morgan, Lewis & Bockius LLP (Washington, DC)

- How to uncover issues relating to a target company's products with significant off-label use
- Focusing the analysis within applicable time constraints
- Maintaining secrecy when the proposed acquisition is confidential
- Creating a useful due diligence checklist for off-label risks
- Knowing what should make you need to dig deeper
 - identifying particular practices that might lead to future problems
- Reviewing the company's collaborations and litigation history for red flags
- Quantifying the risks for potential use in negotiations

2:00 Minimizing Purchaser/Consumer Fraud Class Action Off-Label Liabilities



Mark S. Cheffo
Partner, Skadden Arps Slate Meagher & Flom LLP (New York, NY)



Judy L. Leone
Partner, Dechert LLP (Philadelphia, PA)



Allen P. Waxman
Partner, Kaye Scholer LLP (New York, NY)

- Understanding current class action trends and evolving theories based on alleged off-label promotion
 - assessing burdens of proof under state consumer fraud statutes
 - comparing actions brought by individual consumers with claims by third party payors
 - reviewing whether certain forums are more favorable to such actions
- Analyzing recent class action decisions related to actions based on alleged off-label promotion
 - learning from defense strategies where manufacturers successfully defeated plaintiffs' consumer fraud allegations
 - preemption decisions
 - RICO decisions
 - class certification decisions
- Tackling key battleground issues in off-label consumer fraud cases
 - reliance
 - causation
 - tailoring the defense of the case to deal with the unique nature of "no injury" claims
- Challenging class certification
 - discovery issues unique to off-label litigation
 - expert issues arising in claims based on off-label promotion
 - unique evidentiary issues in claims based on off-label promotion
- Scrutinizing unique damages issues
 - weighing the scope of available damages relating to being "misled" into purchasing drugs
- Translating the impact of related product liability claims and government prosecutions based on theories of off-label promotion

3:00 Conference Concludes

WORKSHOP ON NEGOTIATING SETTLEMENTS OF OFF-LABEL INVESTIGATIONS AND ENFORCEMENT ACTIONS



Laurence J. Freedman
Partner, Patton Boggs LLP (Washington, DC)

3:15 pm to 5:30 pm (Registration at 3:00 pm)

As pharmaceutical and medical device manufacturers face a growing number of off-label investigations and enforcement actions, and settlements become more costly and complex, it is increasingly important to know how to negotiate a settlement on the most favorable terms. In addition, achieving "closure" and effectively putting the matter behind you can be extremely difficult. This timely interactive workshop will provide advanced discussion of practical strategies including analysis of:

- Recent off-label related settlements
 - what did companies do or not do and how did it affect the settlement
- Negotiating a settlement agreement
 - what is negotiable?
 - setting non-financial terms requiring greater transparency and oversight
- Agency coordination during the settlement process
- Assessing how a state lawsuit may impact your leverage in settlement negotiations with the federal government and vice versa
- Achieving closure so that the case does not have an ongoing "tail"

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Wendy Tyler
Group Leader & Business Development Executive
American Conference Institute

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OFF-LABEL COMMUNICATIONS

Staying within the legal bounds in a climate of record-breaking settlements

July 15-16, 2009 • The Union League • Philadelphia, PA

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HEAR FROM:

Randy S. Chartash
Assistant United States Attorney, Northern District of GA

Daniel R. Miller
Deputy Attorney General & Director
Delaware Medicaid Fraud Control Unit
President, NAMFCU

Jeffrey Senger (invited)
Deputy Chief Counsel, Food and Drug Administration

Joseph Trautwein
Assistant United States Attorney, Eastern District of PA

POST-CONFERENCE WORKSHOP:
JULY 16, 2009

Negotiating Settlements of Off-Label
Investigations and Enforcement Actions

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