Pharmaceutical and Medical Device Manufacturers’ Guide to

OFF-LABEL COMMUNICATIONS

Practical strategies for protecting your company in a climate of heightened government scrutiny

July 16-17, 2008 • The Union League, Philadelphia, PA

Government Enforcement Insights From:

Virginia Gibson
Assistant United States Attorney
Eastern District of Pennsylvania

David A. Hart
Senior Assistant Attorney General
Oregon Department of Justice (Salem, OR)

Paul Kaufman
Assistant United States Attorney
Chief, Health Care Fraud
Eastern District of New York (Brooklyn, NY)

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

Compliance officers, corporate counsel, MSLs and leading practitioners will share their best practices and insights on how to:

• IMPLEMENT the FDA’s proposed guidance on scientific reprints
• CREATE a compliance/training program which takes into account what sales reps actually face in the field
• INCORPORATE lessons learned from recent government enforcement actions into compliance policies and procedures
• CONDUCT an internal investigation to uncover off-label violations
• MINIMIZE product liability risks in off-label usage situations

Practical, real-world solutions from:

• Allergan
• Ovation Pharmaceuticals
• Gilead
• Pfizer
• Organon
• Wyeth

Master Class
Friday, July 18, 2008
Responding to Off-Label Investigations and Enforcement Actions

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Government enforcement agencies are cracking down on off-label violations

Pharmaceutical and medical device manufacturers continue to be in the government’s crosshairs. Since 2004, there have been eleven off-label related cases settled with the government, and it is estimated that there are still 100 more cases in the pipeline. Enforcement agencies have warned that off-label marketing will continue to be a focus of anti-fraud enforcement efforts over the next several years and medical device companies will face particularly aggressive prosecution. In addition to government enforcement efforts, manufacturers must also contend with "creative" theories of liability being put forth in civil lawsuits. The lower court decision in Clark v. Pfizer Inc, wherein the court held that a manufacturer of an innovator drug is liable for off-label generic use, was a major departure from existing case law and will be a huge blow to manufacturers if upheld.

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Prepare to deal with the increased scrutiny

Understanding the distinction between what is and is not permissible regarding off-label promotions is important. But, what companies really struggle with is how to stop off-label violations from happening. With that in mind, the focus of this year’s Guide to Off-Label Communications is on the practical application of case law and guidelines. Our faculty of experts will provide concrete examples of how to deal with problematic sales activities and how to create and enforce compliance policies that truly work. In addition, there will be a strong emphasis on government enforcement trends, managing government investigations, and government settlement agreements. Further enhance your conference experience by attending the master class on Responding to Off-Label Investigations and Enforcement Actions.

Don’t miss this unique opportunity to benchmark your practices against others in the industry. Obtain answers to your most pressing questions and get the information you need from experts in the field. 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.

Join us at: THE UNION LEAGUE

The Union League, which occupies an entire city block in the center of Philadelphia’s commercial and cultural district, is a shining jewel of history in a city defined by such treasure. Founded in 1862 as a patriotic society to support the policies of President Abraham Lincoln, The Union League has hosted U.S. presidents, heads of state, industrialists, entertainers and visiting dignitaries from around the globe. The classic French Renaissance-styled League House, with its brick and brownstone façade and dramatic twin circular staircases leading to the main entrance, is listed in the National Historic Register, and dates back to 1865, when the Broad Street building was completed. Adorning the walls and hallways is the League’s distinguished art collection, artifacts imbued with the heritage and culture of its membership. The collection is a rich, historical chronicle of Philadelphia’s unique imprint upon the American landscape from the nineteenth century to today.

Who You Will Meet

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

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

Attorneys with practice areas in:

- healthcare
- pharmaceutical
- FDA regulatory law
- food & drug law
- government investigations
- white collar
- product liability
- Medicare/Medicaid reimbursement

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

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Wednesday, July 16, 2008

7:00 Registration and Continental Breakfast

7:45 Co-Chairs’ Opening Remarks

Mitzi G. Cole
Division Counsel, Wyeth Pharmaceuticals (Collegeville, PA)

Debra S. Dunne
Partner, Stradley Ronon Stevens & Young, LLP (Philadelphia, PA)

8:00 Exploring the New FDA Guidance on Scientific Reprints

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

R. Bruce Dickson
Partner, Manatt, Phelps & Phillips LLP (Washington, DC)

Andrew R.C. Gaddes
Partner, Dechert LLP (Philadelphia, PA)

- Outlining the provisions of the new guidance – what is the FDA proposing and why?
- How will the guidance enable drug companies to modify their current practices?
  - implementing the proposed “good reprint practices”
- Weighing the pros and cons of the proposed guidance
- Considering Representative Waxman’s response and potential legislative initiatives which may nullify the FDA’s proposal

9:00 Building a Powerhouse Compliance Program: Practical Solutions for Preventing Off-Label Violations From Occurring

Mitzi G. Cole
Division Counsel, Wyeth Pharmaceuticals (Collegeville, PA)

Jeffrey Hesskiel
Vice President, Legal Affairs, Gilead Sciences, Inc. (Foster City, CA)

Michelle Y. Johnson-Lewis
Senior Corporate Counsel, Pfizer Inc (Parsippany, NJ)

Creating Compliance Protocols to Control Off-Label Communications

- Drawing the line between lawful scientific exchange and off-label promotion
  - determining how your company will define “off-label” communications
- Incorporating the PhRMA Code, OIG and FDA Guidelines, Fraud and Abuse Safe Harbors, and the Federal Sentencing Guidelines into off-label controls
- Recognizing and allowing for situations sales reps actually face in the field
- 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
- 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 the current financial incentive program on improper promotional practices
- Incorporating off-label related obligations in recent CIAs into the compliance program

10:15 Morning Coffee Break

10:30 Return from Morning Coffee Break

Training the Sales Force

- Conveying what not to do without making it seem like how not to get caught
- Utilizing effective training techniques
  - testing for knowledge retention
  - weighing the benefits and detriments of web-based training programs
  - updating training efforts to address issues in current investigations
  - providing examples of inappropriate promotion activities
  - maintaining an ongoing training regimen

Monitoring the Sales Force

- Establishing a monitoring program that is not impractical based on a sales rep’s day-to-day routine
- Effectuating the implementation of procedures to control off-label communications
- Understanding the significant role of Medical Information Departments in tracking off-label activities
- Incorporating random audits into the monitoring program to ensure compliance
- Modeling the monitoring program on what the government would find to be sufficient
- How to conduct an investigation to uncover off-label violations
- Establishing consequences for noncompliance: evaluating the effectiveness of sanctions and other disciplinary actions

12:30 Networking Luncheon

1:30 Ensuring MSLs Stick to the Science

Archie Stone, Ph.D.
Regional Director, Allergan (Raleigh-Durham, NC)

Michael Labson
Partner, Covington & Burling LLP (Washington, DC)

- Effectively and legitimately utilizing MSLs
  - defining their roles: what exactly can MSLs do in this era of heightened scrutiny?
  - determining which department MSLs belong in
  - assessing the value of an MSL
- 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
  - avoiding legal risks
- Monitoring MSLs to prevent fraud and abuse
  - creating an internal audit program
  - recognizing warning signs that indicate the MSL is blurring the line between medical affairs and sales
- Identifying examples of MSL off-label communication violations
- Understanding and communicating the legal risks associated with noncompliance
- Integrating the information MSLs gather in the field to improve the effectiveness of your marketing strategy

2:30 Minimizing the Potential for Off-Label Violations When Engaging in Risky Activities

Debra S. Dunne
Partner, Stradley Ronon Stevens & Young, LLP (Philadelphia, PA)
and enjoy a cocktail reception hosted by Dechert LLP

All participants are invited to attend this networking opportunity and enjoy a cocktail reception hosted by Dechert LLP.

3:30 Afternoon Coffee Break

3:45 Identifying Enforcement Trends

Virginia Gibson
Assistant United States Attorney
Eastern District of Pennsylvania (Philadelphia, PA)

David A. Hart
Senior Assistant Attorney General
Financial Fraud/Consumer Protection Section
Oregon Department of Justice (Salem, OR)

Paul Kaufman
Assistant United States Attorney
Chief, Health Care Fraud Eastern District of New York
(Brooklyn, NY)

Holly A. Pierson
Partner
Nelson Mullins Riley & Scarborough LLP (Atlanta, GA)
(former Assistant U.S. Attorney, Western District of North Carolina)

Moderator:
Lynn Shapiro Snyder
Partner, Epstein Becker & Green P.C. (Washington, DC)

Off-label promotion has been a major focus of anti-fraud enforcement. Since 2004, there have been eleven off-label related cases settled with the government and at least a hundred cases remain in government pipelines. Pharmaceutical and device manufactures continue to be in the government’s cross-hairs with respect to their off-label activities. In order to avoid becoming the focus of an investigation it is critical to understand what behaviors the government finds problematic. Points of discussion will include:

- Increased prosecution efforts by the states
  - defending federal and state actions at the same time
- Third party liability suits brought by state AGs
- Why some cases are resolved criminally while others are resolved civilly
- Coordination among agencies
- Criminal liability for individuals

5:15 Conference Adjourns to Day 2

5:15 Cocktail Hosts: Dechert LLP

Day Two Thursday, July 17, 2008

8:00 Continental Breakfast

9:00 Co-Chairs’ Opening Remarks

9:15 Modifying Compliance Policies in Response to Government Enforcement Activities

Retta M. Riordan
Compliance Department
Business Ethics and Compliance Officer
Organon, a part of Schering-Plough Corporation (Roseland, NJ)

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

Judith Waltz
Partner
Foley & Lardner LLP (Washington, DC)

- FDA (DDMAC)
  - using the latest enforcement letters on off-label promotion to identify the FDA’s current priorities and future initiatives
  - interpreting and applying the FDA Guidelines
  - determining the appropriate response, if any, to untitled letters
  - establishing an action plan and timeline for complying with: untitled/ warning letters
  - corrective advertising
  - promotional labeling recalls
  - preclearance

- OIG
  - understanding the implications of increased OIG scrutiny
  - utilizing OIG Guidance and advisory opinions to formulate policies on off-label communications

- State AGs
  - analyzing key legislation and regulation: everything from consumer protection statutes to unfair competition
  - monitoring and navigating compliance with multiple state laws

10:30 Morning Coffee Break

10:45 Preventing and Defending Qui Tam Suits and False Claims Liability Based on Claims of Off-Label Promotion

Erik Eglite
V.P., Chief Corporate Compliance Officer and Corporate Counsel
Ovation Pharmaceuticals, Inc. (Deerfield, IL)

Susan L. Burke
Partner
Burke Pyle LLC (Philadelphia, PA)

Mark Levy
Partner
Saul Ewing LLP (Philadelphia, PA)

- Understanding the powerful financial incentive for whistleblowers to report noncompliance
- Anticipating qui tam 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
- Examining the key triggers for government intervention and preparing for potential criminal investigation

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• Understanding the basis of the claim: how off-label communications can lead to the filing of false claims for government reimbursement
• Recognizing the magnitude of the risks associated with False Claims liability
  - treble damages
  - civil penalties
  - exclusion from CMS programs
  - obligation to adhere to a corporate integrity agreement
  - criminal liability
• Considering the potential impact of state and municipal False Claims legislation
• Raising defenses based on the:
  - FDCA
  - FCA

12:00 Networking Luncheon

1:15 Recognizing and Reducing Risks Associated With the Dissemination of Clinical Trial Information

Elizabeth Jobes
Senior Compliance Counsel, Cephalon, Inc. (Frazer, PA)

Thomas E. Merchant
Consultant
(formerly with R&D Legal Risk Management for GlaxoSmithKline)

Kelly (Nikki) Reeves
Partner, King & Spaulding (Washington, DC)

- Describing the regulatory and enforcement environment regarding the reporting of clinical trial results
- Providing accurate and current clinical trial information while avoiding allegations of off-label promotion
  - what clinical trial information can be provided?
  - to what extent is advanced stage clinical trials’ information permissible?
- Assessing the liability risks associated with conducting and reporting results of clinical trials on non-labeled indications
- Addressing the legal challenges presented by investigator initiated studies
- Sharing clinical trial results with managed care organizations
- Examining First Amendment implications of the dissemination of off-label clinical trial information
- Establishing the internal policies and procedures to address potential liability and legal risk associated with dissemination of clinical trial information

2:15 Afternoon Coffee Break

2:30 Tackling the Reimbursement Issues Associated with Off-Label Uses

Esther R. Scherb
Counsel, Latham & Watkins LLP (Washington, DC)

Dina Wizmur
Deputy General Counsel, Medicare Rights Center (New York, NY)

• Evaluating Medicare Part D and off-label coverage implications
• Examining the FDA’s proposed regulation regarding compendia
  - new processes for adding compendia to the approved list
  - adding new journals which can be consulted for off-label uses related to the treatment of cancer
• Update on the Layzer v. Leavitt litigation
• Communicating with payors: what are the legal parameters?
• Understanding how CMS reimbursement decisions will impact decisions in the Medicaid and private payor market
• Reviewing Medicaid compendia processes and standards
• Disseminating data for formulary decision-making
• Avoiding traps in discounts and pricing arrangements

3:30 Managing Product Liability Risks Based on Off-Label Uses

Sean Fahey
Partner, Pepper Hamilton LLP (Philadelphia, PA)

Hope S. Freiwald
Partner, Dechert LLP (Philadelphia, PA)

- Evaluating the three scenarios:
  - official promotion – when the company is promoting off-label
  - home cooking – when a rogue sales representative is doing the promoting
  - practice of medicine – when the doctor decides
- Determining the extent to which off-label activities affect the dynamics at trial – particularly the roles of the treating physician, the sales representatives, and the sales and marketing departments
- Learned intermediary defense – which can become much more contentious and difficult to analyze
  - preemption defense – is it in serious jeopardy or is it still viable?
  - liability case – how could it be strengthened or weakened by the particular off-label circumstances?
- Advancing your case to the jury in spite of, or even by taking advantage of, the off-label situation presented
- Assessing the impact of government enforcement on litigation – it may not be as bad as you think
- Asserting off-label use as a defense – in the right jurisdiction, it can be a silver bullet
- Defending the manufacturer in light of the new preemption landscape
  - what defenses to warning claims are available if the product was used off-label?

4:30 Conference Concludes

Responding to Off-Label Investigations and Enforcement Actions

Friday, July 18, 2008
9:00 a.m. to 12:00 p.m. (Registration opens at 8:00 a.m.)

Beth Moskow-Schnoll
Partner, Ballard Spahr Andrews & Ingersoll, LLP (Wilmington, DE)

Robert Ullmann
Partner, Nutter McClennen & Fish (Boston, MA)

As pharmaceutical and medical device manufacturers face a growing number of off-label investigations and enforcement actions, it is more important than ever to know how to react when the government comes knocking. This interactive master class will provide a nuts and bolts guide on how to respond to a government action.

- Uncovering violations before the government becomes aware of them
  - determining whether or not to make a voluntary disclosure
  - which agency do you disclose to?
  - OIG
  - FDA
- What do prosecutors look at when pursuing allegations of off-label communications?
  - internal documents that provide a road map for prosecutors
  - posting of clinical trial results to a registry database
- Responding to a subpoena
- What do you do if you have a whistleblower action started against you?
  - what defenses to warning claims are available if the product was used off-label?

Settlements

- Summarizing 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?
- 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
5th Annual

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July 16-17, 2008 • The Union League, Philadelphia, PA

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APPROVING MANAGER ___________________________ POSITION ___________________________
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5th Annual

Master Class
Friday, July 18, 2008

Responding to Off-Label Investigations and Enforcement Actions

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VENUE: The Union League
ADDRESS: 140 South Broad Street, Philadelphia, PA 19102
RESERVATIONS: 215-587-5070

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