American Conference Institute's 13th National Forum on

FRAUD AND ABUSE IN THE SALE AND MARKETING OF DRUGS

Reducing Legal Risks and Strengthening Compliance Efforts in the Face of Unprecedented Government Scrutiny

March 20–22, 2013 • ONE UN New York • New York, NY

Gain Government Insights From:

Mary E. Crawley (Invited), Assistant U.S. Attorney
Eastern District of Pennsylvania

Gejaa Gobena, Assistant Chief, Criminal Division-Fraud Section, U.S. Department of Justice

David Hart, Assistant Attorney in Charge, Financial Fraud/Consumer Protection Section
Oregon Department of Justice

Paul Kaufman (Invited), Assistant U.S. Attorney, Chief of Civil Healthcare Fraud
U.S. Attorney's Office, Eastern District of New York

Michael Martinez, Executive Assistant U.S. Attorney
U.S. Attorney's Office, District of New Jersey

Margaret Moore, Deputy Chief, Civil Medicaid Fraud Division, Texas Office of the Attorney General

Keith V. Morgan, Assistant U.S. Attorney, Deputy Chief, Civil Division, District of Columbia District, U.S. Department of Justice

Robert E. O'Neill, U.S. Attorney
U.S. Attorney's Office, Middle District of Florida

Jack W. Pirozzolo, First Assistant U.S. Attorney
U.S. Attorney's Office, District of Massachusetts

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

Wendy L. Weiss, Assistant U.S. Attorney, Chief, Civil Fraud Section, U.S. Attorney's Office, Central District of California

Network with an exceptional faculty of pharmaceutical fraud and abuse experts:

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MEDA Pharmaceuticals
Medicis
Millennium: The Takeda Oncology Company
Novo Nordisk
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Current and former prosecutors, preeminent in-house counsel, industry insiders, and leading attorneys will help you:

- **Pinpoint** specific sales and marketing practices which may raise red flags for state and federal **enforcers**
- **Guard** proactively against impermissible **off-label promotion** risks and **predict** the definition of off-label post-*Coronia*
- **Revamp** compliance programs in light of recent False Claims Act (FCA) investigations into alleged **GMP violations**
- **Minimize** global **anti-bribery** risks and **Foreign Corrupt Practice Act (FCPA)** violations when managing a global sales and marketing force
- **Formulate** legal and equitable defenses to counter a prosecution for **individual liability** and **avoid** the acts or omissions which may lead to an *Park* doctrine prosecution

PLUS, just in time for Sunshine Act implementation in the Spring of 2013, please join us for an **Advanced Focus on Building a Dynamic Aggregate Spend System in Compliance with Federal Sunshine Mandates**, an interactive half-day session designed to strengthen compliance systems in anticipation of intense examination by the government and whistleblowers.

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"A total of 74 additional settlements, totaling $10.2 billion in financial penalties, were reached between the federal and state governments and pharmaceutical manufacturers between November 2, 2010 and July 18, 2012, with the first half of 2012 alone already representing a record year for both federal ($5.0 billion) and state ($1.6 billion) financial recoveries." [1]

The government has made it clear that pharmaceutical companies are under a microscope, and the prosecutions will keep coming. Attend the leading conference which at which to gain the advanced strategies to bulletproof already-robust compliance plans and gain the competitive advantage.

In 2012, federal and state enforcement authorities have aggressively continued their pursuit of pharmaceutical companies for noncompliant sales and marketing practices, resulting in high profile investigations and record-breaking fines: *$3 billion awarded against a major company stemming from unlawful promotion and kickbacks… $1.5 billion awarded against a company for unlawful promotion… $1.2 billion awarded against a company for unlawful promotion.* In response to the challenges facing the pharmaceutical industry in this daunting climate, **13th National Forum on Fraud and Abuse in the Sale and Marketing of Drugs** provides a forum for **the key players- top federal and state prosecutors, preeminent corporate counsel, and leading counsel**- to come together to give you a specific action plan to bolster your sales and marketing compliance regime and combat the next wave of fraud and abuse allegations.

Attendees of this event will:

- Hear directly from **multiple panels of current and former prosecutors including a dozen current state and federal enforcers** who will share inside insights into government enforcement priorities and prepare for how prosecutors will continue to use the most powerful tool in their arsenal, the False Claims Act, in 2013.
- Benchmark best compliance practices against leading companies such as **Allergan, Aptalis, Astellas, Avanir Pharmaceuticals, Eli Lilly and Company, Endo Pharmaceuticals, Grifols Therapeutics Inc., Ironwood, Johnson & Johnson, LEO Pharma, MEDA Pharmaceuticals, Millennium: The Takeda Oncology Company, Medicis, Novo Nordisk, Pfizer, Sandoz, UCB** and many more who will share strategies on intensive training, monitoring and supervision of sales and marketing forces.
- Take away cutting-edge knowledge to guard proactively against whistleblowers' suits and to prevent being on the receiving end of a subpoena stemming from allegations of false claims, anti-kickback violations, and off-label promotion made in the sales and marketing process.
- Gain advanced strategies to implement immediately to meet the massive challenge of aggregate spend compliance in our full-day **Advanced Focus on Building a Dynamic Aggregate Spend System in Compliance with Federal Sunshine Mandates**, a session designed to prepare you for increasingly aggressive enforcement activity and public scrutiny just in time for the database to go public in early 2013.

Prosecutors are using all the tools at their disposal to ensure that fraud and abuse by device pharmaceutical companies are brought to the light and punished. Do not miss your chance to be part of the most comprehensive forum to formulate innovative solutions for crafting and implementing compliant sales and marketing plans that will withstand scrutiny, boost profits and, most importantly, ensure patient safety.

Register today by calling **888-224-2480**, fax your form to **877-927-1563**, or online at **www.AmericanConference.com/FADrugs**

[1] "Pharmaceutical Industry Criminal and Civil Penalties: An Update." http://www.citizen.org/hrg2073, September 27, 2012.

Who You Will Meet

From Pharmaceutical and Biotech Companies:

- General Counsel
- Legal Affairs Directors
- Compliance Officers
- Regulatory Affairs Directors
- Marketing and Sales Executives
- Commercial Operations Directors
- QA/QC Directors

Attorneys Specializing in:

- Fraud and Abuse
- Qui Tams
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- Pharmaceutical, Drug and Healthcare Government Investigations

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Head of Sales, American Conference Institute
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Day 1– March 20, 2013

7:30 **Registration and Continental Breakfast**

8:15 **Co-Chairs Opening Remarks**

Andy Rittenberg
Associate General Counsel
Gilead Sciences, Inc. (Foster City, CA)

Brien O'Connor
Partner
Ropes &Gray, L.L.P. (Boston, MA)

8:30 **Mastering the Evolving Off-Label Landscape: Finding Footing on an Increasingly Slippery Slope**

Paul Kaufman (Invited)
Assistant U.S. Attorney
Chief of Civil Healthcare Fraud
U.S. Attorney's Office, Eastern District of New York
(Brooklyn, NY)

Elona Kogan
Vice President- Legal Affairs Department
Avanir Pharmaceuticals (Aliso Viejo, CA)

Deborah A. Logan
Senior Counsel, Research & Development
Endo Pharmaceuticals Inc. (Chadds Ford, PA)

Brien O'Connor
Partner
Ropes & Gray, L.L.P. (Boston, MA)

Emily R. Schulman
Partner
Wilmer Cutler Pickering Hale and Dorr LLP (Boston, MA)
(Former Assistant U.S. Attorney, U.S. Attorney's Office for the District of Massachusetts)

- Identifying specific promotional and non-promotional activities likely to trigger government scrutiny in the off-label arena
  - o Examining the DOJ's increase in off-label investigations in 2012: an overview of notable investigations and settlements which will impact your sales and marketing practices
  - o Understanding the interplay between the False Claims Act and the *Park* Doctrine in the off-label arena
- Setting up the off-label showdown: Analyzing the potentially game-changing First Amendment protection challenges
  - o *United States v. Caronia*
  - o *Sorrell v. IMS Health, Inc.*
  - o *Par Pharmaceutical, Inc. v. U.S. Food and Drug Administration*
- What are the implications for current settlements and CIAs if the pending First Amendment challenges are successful?
- Analyzing the continued viability of the misbranding theory
- Towing the line between knowledge of off-label use and promotion
  - o Clearly delineating the parameters of what is considered promotional marketing when citing off-label studies in medical journals and professional articles
  - o To what extent can you use industry publications referencing off label uses?
- Revamping training and monitoring processes for MSLs and sales representatives to minimize off-label risks
  - o Eliminating sales force incentives which may give rise to off-label promotion

9:45 **Morning Meet and Greet Coffee Break**

10:00 **Responding to the Expansion of the False Claims Act to Cover Good Manufacturing Process Standards**

Robert E. O'Neill
U.S. Attorney
U.S. Attorney's Office, Middle District of Florida
(Tampa, FL)

Wendy L. Weiss
Assistant U.S. Attorney
Chief, Civil Fraud Section
U.S. Attorney's Office, Central District of California
(Los Angeles, CA)

Ronald H. Levine
Principal
Post & Schell, P.C.
(Former Criminal Division Chief, United States Attorney's Office for the Eastern District of Pennsylvania)

Carlton E. Wessel
Partner
DLA Piper (Washington, DC)
(Former Assistant United States Attorney, District of New Jersey)

- Revamping internal auditing systems and compliance programs in light of recent investigations and settlements stemming from allegations of GMP violations
- Steps to minimize long-term reputational risk and products liability risk stemming from a GMP-related investigation
- Was the $90 million dollar GMP decision in 2012 a one-off or was it blood in the water for the *qui tam* bar?
- Examining how a GMP violation becomes a FCA case
  - o Analyzing current OIG and DOJ FCA initiatives and enforcement priorities
  - o Forecasting how the government under the Obama administration will continue to use the FCA as the most powerful tool in its arsenal to detect and prevent fraud and abuse
  - o What other enhanced enforcement tools can pharmaceutical companies expect to see in 2013?
  - o How does the government evaluate the credibility of a whistleblower?

11:15 **Minimizing Global Fraud and Abuse Risk When Adhering to Increasingly Stringent FCPA and Bribery Act Mandates**

Gejaa Gobena
Assistant Chief, Criminal Division- Fraud Section
U.S. Department of Justice (Washington, DC)

Michael Martinez
Executive Assistant U.S. Attorney
U.S. Attorney's Office, District of New Jersey (Newark, NJ)

Karah Parschauer
Vice President, Assistant General Counsel
Allergan, Inc. (Irvine, CA)

Sue Seferian
Health Care Compliance Officer
Johnson & Johnson (Titusville, NJ)

Steven S. Michaels
Counsel
Debevoise & Plimpton LLP (New York, NY)
(Former First Deputy Attorney General, State of Hawaii)

- Avoiding the perception of corruption or kickbacks when working with doctors and vendors who are also state officials
  - o Identifying who may be considered a government official when statutory definitions, regulatory guidance, and case law vary by region
  - o Competing against local companies in cultures where gift giving is the norm
- Pinpointing common business practices which may subject you to liability amidst heightened DOJ scrutiny and increased cooperation with the SEC and foreign prosecutors
- Diligently monitoring relationships with foreign agents which may make pharmaceutical companies particularly vulnerable to an FCPA or anti-bribery investigation
  - o CROs
  - o Consultants
  - o Distributors
- Coordinating efforts between in-house and outside counsel and local counsel when handling an FCPA or anti-bribery investigation
- Working with the Serious Fraud Office to ensure cooperation with investigations stemming from alleged violations of the Bribery Act
  - o Examining the implications of the Bribery Act in the sales and marketing arena
  - o Analyzing how far the Bribery Act's extraterritorial reach will extend with respect to actions taken by a parent company versus a subsidiary or affiliate
- Strengthening compliance programs when working in high risk emerging markets including Eastern Europe, Latin America, China and India
  - o Forming exit strategies for areas high on prosecutors' radars and known bribery indexes?
- Fostering proper and ethical behavior through demonstrated compliance with voluntary industry codes

12:30 **Networking Lunch**

1:45 **The Era of Individual Liability: Defining Counsel's and Responsible Corporate Officer's Legal and Ethical Obligations in Light of the Reinvigorated Park Doctrine**

ETHICS

Mary E. Crawley (Invited)
Assistant U.S. Attorney
Eastern District of Pennsylvania (Philadelphia, PA)

Dan S. Dunham
Vice President, Chief Compliance Officer
Aptalis Pharma US, Inc. (Bridgewater, NJ)

Paula Taylor-Whitfield
Deputy General Counsel
Eli Lilly and Co., Inc. (Indianapolis, IN)

Linda Pissott Reig
Shareholder
Buchanan Rooney & Ingersoll, P.C. (Newark, NJ)

- Formulating legal and equitable defenses to counter a prosecution for individual liability
- Living under a microscope: Recognizing and avoiding the acts or omissions which may lead to an individual FDA or DOJ investigation or prosecution
  - o The importance of leaving a paper trail
  - o Following OIG guidance: what's new in this year's work plan
  - o Showing compliance with voluntary industry codes
  - o Mandatory compliance certifications by executives
- Best practices when responding to a government investigation: Accurately representing yourself and producing documents to avoid false claims or obstruction allegations
- Understanding the more stringent strict liability standard which allows the government to prosecute corporate officers in the absence of criminal intent or knowledge of wrongdoing
- Analyzing the government rationale behind exclusion and successfully forming arguments to argue against such an extreme punishment
  - o Is the door open for exclusion even in the absence of a *Park* conviction?

3:00 **Afternoon Networking Coffee Break**

3:15 **The Best Defense: Revamping Compliance Programs Based on Takeaways from Recent Corporate Integrity Agreements**

Thomas W. Beimers
Counsel
Faegre Baker Daniels LLP (Minneapolis, MN)
(Former Senior Counsel, Office of the Inspector General, Department of Health and Human Services)

Lisa M. Noller
Partner
Foley & Lardner LLP (Chicago, IL)
(Former Assistant U.S. Attorney, U.S. Attorney's Office for the Northern District of Chicago)

Constance A. Wilkinson
Member
Epstein Becker & Green, P.C. (Washington, DC)

- Lessons to be learned from recent CIA agreements: separating out individual considerations and identifying across-the-board negotiation points
  - o How much of your global and domestic business will be covered by the CIA?
  - o What kind of monitoring controls and systems need to be implemented?
  - o What kind of restraints on HCP relationships will you enter into?
- What trends about OIG priorities can be extrapolated from recent CIAs?
  - o How real is the possibility of divesting errant companies of their intellectual property rights?
- Determining the ramifications for multi-violators
- Insights into what approaches have been successful for other companies working with the OIG
- Creating a cooperative relationship with your appointed monitor and communicating effectively with the OIG during the pendency of the CIA
- Proactively fortifying your compliance system based on the requirements of other pharmaceutical and medical device CIAs before negotiating with the government
- Understanding what life under a CIA is like

4:15 **Side Effects May Include Warning Letters: Tailoring a Compliant Pharmaceutical Company Social Media Policy While Establishing a Virtual Presence**

Michelle M. Kloecker
Associate General Counsel
Sandoz Inc. (Princeton, NJ)

John C. Serio
Partner
Seyfarth Shaw LLP (Boston, MA)

Marian J. Lee
Partner
King & Spalding LLP (Washington, DC)

- Utilizing Facebook and other social media sites to increase the visibility of your drug while navigating a potential minefield of liability for third party claims
- Analyzing warning letter trends stemming from social media
  - o Off label promotion
  - o Adverse event reporting
  - o Linking to sponsored and nonsponsored sites
- Finding fair balance when tweeting the risks and benefits of a drug in 130 characters
- Waiting for specific FDA social media guidelines: Ensuring flexibility in your current protocols in anticipation of what the final rules may look like
  - o Extrapolating pointers from FDA's draft guidance on replying to unsolicited requests via social media
- Weighing the effect of comments made on unsponsored sites about the efficacy of your drug
  - o Verifying adverse events on both sponsored and non-sponsored sites: To what extent should you attempt to locate or contact posters?
  - o What is your duty to correct erroneous info on an unsponsored site about your product?
- Determining which communications by third parties companies may lead to an off label promotion warning letter

5:15 **Conference Adjourns to Day 2**

Day 2 – March 21, 2013

8:00 **Continental Breakfast**

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

8:45 **State Attorneys General Spotlight: Preparing for the Next Wave of Enforcement**

David Hart
Assistant Attorney in Charge, Financial Fraud/Consumer Protection Section
Oregon Department of Justice (Portland, OR)

Margaret Moore
Deputy Chief, Civil Medicaid Fraud Division
Texas Office of the Attorney General (Austin, TX)

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

Moderator:

Brien O'Connor
Partner
Ropes & Gray, L.L.P. (Boston, MA)

- Identifying the types of sales and marketing activities that raise red flags for state enforcers and have potential to trigger an investigation
  - o False Claims Act violations
  - o Off-label promotion
  - o Pricing concerns and AWP suits
- Effectively responding to a subpoena when the AG's office comes knocking
- Accounting for both state and federal liability and preparing for increased coordination between enforcement authorities when investigating alleged pharmaceutical sales and marketing misconduct
- The rise in *qui tam* suits: AGs weigh in on the "whistleblowers' bar"
- How and when can state AGs retain private counsel to act as deputies on their behalf in these matters?
- Exploring the trend towards individual liability: what should the industry expect in 2011 and 2012?

10:00 **Morning Coffee Meet and Greet**

10:15 **Fortifying Your Domestic Compliance Program to Avoid and Overcome the Risk of Anti-Kickback Allegations**

Jack W. Pirozzolo
First Assistant U.S. Attorney
U.S. Attorney's Office, District of Massachusetts
(Boston, MA)

Lynn Robson
Executive Director, Legal and Compliance
LEO Pharma Inc. (Parsippany, NJ)

Seth Rodner
Senior Vice President, General Counsel, and Corporate Secretary
Medicis Pharmaceutical Corporation, Inc.
(Scottsdale, AZ)

Vince Farhat
Partner
Holland & Knight (Los Angeles, CA)
(Former Assistant United States Attorney, Central District of California)

- Steering clear of problem areas when successfully launching a new drug which have triggered government scrutiny and kickback allegations:
  - o Clinical trials
  - o Investigator initiated studies
  - o Grants and charitable contributions
  - o Continuing medical education
  - o Speaker bureau arrangements
- Preparing for an increase in whistleblowers' suits alleging pharmaceutical company kickbacks under the FCA
  - o Identifying and deterring conduct which may lead to a whistleblowers' suit premised on sales and marketing practices
  - o Minimizing the chance of retaliation by disgruntled employees
- Complying with voluntary industry codes like the PhRMA code regarding best practices for consulting agreements

- Drafting contracts for consulting arrangements that minimize the potential for fraud and abuse
  - o Assessing fair market value of a healthcare provider's services in order to avoid scrutiny by the government
  - o Performing a thorough business needs assessment in correlation with the services provided
  - o Best practices to validate the price of services in consulting agreements
- Understanding the new lowered intent standard under PPACA: how can companies insulate themselves from liability in the absence of an actual intent or knowledge requirement?

11:30 **Comprehensive Fraud and Abuse Training and Monitoring Action Plans to Minimize Risk When Sending Your Sales Team Into the Field**

Gary Mendelsohn
Assistant Director, Corporate Compliance
Astellas U.S. (Northbrook, IL)

Palmina M. Fava
Partner
Paul Hastings LLP (New York, NY)

- Ensuring your company message is clear and successfully integrating compliance risk education into sales training from the start
- Creating a real world training program for sales reps and marketers that goes beyond just legalese
  - o Utilizing effective training techniques to test for knowledge retention
  - o Continually updating training efforts to account for current investigations
- Thinking like a sales rep: Understanding what drives successful relationships between your sales force and healthcare providers
- Overseeing sales rep activity and conducting ride-alongs to understand the nature of the interactions between field force personnel and HCPs
  - o Identifying communication strategies to help your reps stay on message when communicating with HCPs in known fraud and abuse liability problem areas including off-label marketing
  - o Creating scenario specific training
- Clearly establishing the consequences of non-compliance and setting forth the attendant sanctions and disciplinary actions

12:30 **Networking Lunch**

1:45 **Steering Clear of Civil and Criminal Liability When Conducting Clinical Trials**

Keith V. Morgan
Assistant U.S. Attorney
Deputy Chief, Civil Division, District of Columbia District
U.S. Department of Justice (Washington, DC)

Eric W. Sitarchuk
Partner Morgan, Lewis & Bockius LLP (Philadelphia, PA)
(Former Assistant U.S. Attorney, Criminal Division, Eastern District of Pennsylvania)

Nicholas C. Harbist
Partner
Blank Rome LLP (Princeton, NJ)

- Pinpointing common clinical trials practices which may raise a red flag for enforcers
  - o Engaging in off-label promotion during a trial
  - o Avoiding anti-kickback concerns with investigator initiated studies
  - o Determining fair market value for the investigator's services
  - o Misstatements of clinical trial data in a new drug application
  - o Failing to report adverse events during a trial
- Exploring prosecutorial tools to pursue False Claims Act liability for wrongful conduct in connection with a trial
- Preparing for the certain prospect of increased monitoring and OIG oversight for clinical trials conducted globally
- Factoring compliance into your clinical trials design and factoring clinical trials into your compliance program design

2:45 **Afternoon Networking Break**

3:00 **Creating a Culture of Compliance: Best Practices for Structuring and Implementing Internal Audits and Seamlessly Responding to a Government Inquiry**

Michael Sullivan
Partner
The Ashcroft Law Firm, LLC (Boston, MA)
(Former U.S. Attorney for the District of Massachusetts)

Stephen C. Payne
Partner
Gibson, Dunn & Crutcher LLP (Washington, DC)
(Former Special Assistant U.S. Attorney for the Middle District of Georgia)

- Using recent government investigations to identify the most overlooked best practices of a robust auditing program for a pharmaceutical company
- What to look out for, what to ask, and who to ask when analyzing the minute details of financial information and sales force expense reports
- Coordinating your legal and compliance departments to have full-bodied internal auditing systems in place to detect potential problems
- Handling complaints from internal abuse hotlines and self-reporting
- Understanding the benefits of self-reporting and identifying when it's in the company's best interest to voluntarily disclose
- Moving quickly if your company is hit with an investigation: best practices from attorneys who have been on the frontlines of an investigation
- Demonstrating corrective action to the government
- Managing cases with multiple agencies including the FDA, DOJ, AG, and SEC stemming from the same conduct
- Negotiating a successful settlement agreement: key takeaways from some of the eye-popping fraud and abuse cases in the past year

4:15 **Main Conference Adjourns**

Media Partners:

Full Day Workshop – March 22, 2013
Advanced Focus on Building a Dynamic Aggregate Spend System in Compliance with Federal Sunshine Mandates

8:15 **Registration and Continental Breakfast**

9:00 **Welcoming Remarks**

9:15 **The Clock is Ticking: Immediate Action Plans for 2013 Tracking**

Daina Selvig
Director, Compliance
Ironwood Pharmaceuticals (Cambridge, MA)

Roma Tretiak
Senior Director / Group Leader, Transparency
Pfizer Inc (New York, NY)

D. Kyle Sampson
Partner
Hunton & Williams LLP (Washington, DC)

As of press time, the industry is still awaiting final guidance from CMS regarding the nuances of federal disclosure and reporting. This session will help you control the side of the equation you can as an expert faculty of industry insiders help prepare you to account for the finer details in the final law and to anticipate holes in the CMS guidance. Prepare now for the areas anticipated to lead to implementation challenges including:

- Allocating costs across multiple physicians within a practice
- Managing alleged inaccuracies with reported spend
- Submitting reports for companies doing business internationally
- Determining who is a covered manufacturer
- Making payments to teaching hospitals
- Reporting payments on behalf of third parties
- Certifying the accuracy of the data

10:30 **Morning Coffee Break**

10:45 **Building Anticipated Enforcement Priorities into Your Aggregate Spend Compliance Program**

Daniel Best
Senior Manager-Compliance
MEDA Pharmaceuticals (Somerset, NJ)

Kristi M. Sanford, J.D., CHC, CQA
Senior Manager, Compliance
UCB, Inc. (Atlanta, GA)

Colin J. Zick
Partner
Foley Hoag LLP (Boston, MA)

- Strengthening internal auditing and compliance systems in anticipation of intense examination by the government and whistleblowers
  - o Tracking data internally to identify areas of risk proactively
- What have enforcers learned from the spend data received to date?
- Recognizing data which may raise a red flag to enforcers when the database goes public
- Is this low hanging fruit which may trigger an inquiry in a company's sales and marketing practices?

12:00 **Networking Lunch**

1:15 **Preparing for a New Breadth of International Reporting: Risk Mitigation Strategies for Global Spend**

Kevin M. Ryan
Corporate Counsel
Novo Nordisk Inc. (Princeton, NJ)

- Executing a consistent global HCP tracking system: Putting sufficient infrastructure and compliance controls in place
- Preparing for the strictest disclosure law yet: Update on the status of France's transparency law
- Clarifying reporting obligations under federal Sunshine laws for foreign affiliates
  - o Reporting by foreign parent companies for payments made within the U.S.
  - o Reporting by U.S. based companies for payments made outside the U.S.
- How may foreign prosecutors use the data collected under Sunshine for FCPA and anti-bribery investigations?

2:30 **Bracing for the Consequences of Large-Scale Transparency: Preserving Strong Relationships with HCPs and Customers**

Jerald Korn
Deputy Compliance Officer
Millennium: The Takeda Oncology Company
(Cambridge, MA)

Jim Vollins
VP, Senior Assistant General Counsel
Grifols Therapeutics Inc. (Research Triangle Park, NC)

- Advising HCPs about the data which will be publically available
- Communicating ongoing transparency initiatives and educating consumers on the purposes and context of the disclosed data
- Preparing sales reps to respond to HCPs questions about the database
- Ensuring that HCPs understand your company's procedures for resolving disputed data
- Tabulating fair market value for speakers and contracts with physicians
- Exploring how competitors may use the newly disclosed data about your data

3:30 **Workshop Concludes**

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March 20–22, 2013 • ONE UN New York • New York, NY

PLUS, don't miss the in-depth and interactive full-day class just in time for the Sunshine database finally going public in 2013:

Advanced Focus on Building a Dynamic Aggregate Spend System in Compliance with Federal Sunshine Mandates

March 22, 2013 | 8:15 am – 3:30 pm

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Give Jack a call - he's here to help

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The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI** reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **ACI** for changes in program date, content, speakers, or venue.

Hotel Information

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 "ACI: Fraud and Abuse" conference OR Group Code: 1303ACIFRA to receive this rate:

Venue: ONE UN New York
Address: One United Nations Plaza (44th Street between First and Second Avenue), New York, NY 10017
Reservations: (212) 758–1234 or (877) 866–7529

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5 Easy Ways to Register

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New York, NY 10010

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