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CBI's 10th Annual

Guidelines for Disseminating Off-Label Information

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Communicate Medical Information in a Changing Legal and Regulatory Landscape

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October 16-17, 2008 • Sheraton Premiere at Tysons Corner • Vienna, VA

Conference Chairman:

Wayne Pines, President, Regulatory Services and Healthcare, **APCO Worldwide;** Former Chief of Consumer Education and Information, Chief of Press Relations and Associate Commissioner for Public Affairs, **FDA**

Featured Prosecutors' Perspectives:

The Purdue Pharma OxyContin® Settlement — Off-Label Promotion through Misbranding

John Brownlee, Former U.S. Attorney, **U.S. Attorney's Office for the Western District of Virginia**

Understand the Criteria Government Uses in Building an Off-Label Case

Michael Loucks, First Assistant U.S. Attorney, **U.S. Attorney's Office for the District of Massachusetts**

Linda Wawzenski, Assistant U.S. Attorney, Deputy Chief, Civil Division, **U.S. Attorney's Office for the Northern District of Illinois**

John Brownlee, Former U.S. Attorney, **U.S. Attorney's Office for the Western District of Virginia**

Ioana Petrou, Assistant U.S. Attorney, **U.S. Attorney's Office for the Northern District of California**

States Ramp Up Off-Label Prosecutions via National Training Initiatives and Use of Diagnosis Codes to Measure Damages

Daniel R. Miller, Deputy Attorney General, **Office of the Attorney General, Delaware;** Vice President, **National Association of Medicaid Fraud Control Units (NAMFCU)**

Content Highlights:

- Implement internal processes that ensure compliant dissemination of information and literature at medical meetings
- Leverage scientific information through published documents and communications with HCPs and P&T committees
- Detail the submission process of off-label information to select guidelines and compendia
- Determine the immediate practical applications of the FDA Draft Guidance for Industry on "Good Reprint Practices"

Industry Perspectives from:

- Cephalon
- Eli Lilly and Company
- EMD Serono
- TAP Pharmaceuticals
- Talecris Biotherapeutics
- sanofi-aventis

AND! An Update on FDA's Regulatory Oversight of Advertising and Promotion for Medical Devices

Ann Simoneau, Regulatory Counsel, **CDRH, FDA**

PLUS! CHOOSE FROM TWO PRE-CONFERENCE WORKSHOPS — THURSDAY, OCT. 16, 2008

A. Dissect a Corporate Integrity Agreement to Analyze Current Systems and Processes

B. Auditing and Monitoring MSL Practices to Ensure Compliance

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A Dissect a Corporate Integrity Agreement to Analyze Current Systems and Processes

UPN 453-999-08-335-L03-P

Many of the recent government settlements with pharmaceutical, medical device and biotechnology companies have resulted from allegations that the company engaged in illegal off-label promotional activities. These settlements usually require the company to operate under a Corporate Integrity Agreement (CIA). In this workshop, session leaders dissect a mock off-label CIA and highlight the unique features and requirements that a company typically has to fulfill under this type of CIA. The workshop leaders help you determine whether your company has the requisite systems and processes in place to both meet the requirements of the CIA and address the risks associated with dissemination of off-label information.

7:30 *Workshop Registration and Continental Breakfast*

8:30 *Workshop Leaders' Welcome and Opening Remarks*

I. Evaluate Recent Off-Label Settlements with CIAs

- Dissect recent off-label cases

II. Identify Recent Trends in CIAs

- Assess the current business risk environment
- Investigation, damage analysis and negotiation processes

III. Interactive Case Study — Evaluating CIA Preparedness

- Discuss how compliance officers manage a CIA
- Discuss what needs to be done to prepare the organization for a CIA
  - * select an IRO
  - * develop work plans for staff and IRO
  - * update compliance policies and procedures
  - * evaluate readiness of systems
  - * effectively train employees
  - * train vendors to work under a CIA
  - * implement appropriate monitoring and auditing processes

IV. Explore Ways to Put Lessons Learned from CIAs into Operation

12:00 *Close of Workshop A*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

— About Your Workshop Leaders —

Paul J. Silver is Managing Director at **Huron Consulting Group**. Mr. Silver has twenty years of experience in the pharmaceutical, medical device, healthcare and consumer products industries, specializing in compliance and regulatory matters. He regularly works with in-house counsel, corporate compliance officers and senior operations professionals, as well as the outside legal counsel who support these professionals.

Timothy J. Nugent, CPA is Managing Director at **Huron Consulting Group**. Mr. Nugent has eighteen years of experience providing advisory and audit services to the pharmaceutical and healthcare industry. Mr. Nugent specializes in assisting pharmaceutical manufacturers in all aspects of government and commercial contracting and administration. He regularly works with internal counsel, corporate compliance officers, senior professionals and outside legal counsel that support these professionals.

Tracy Mastro is a Director in **Huron Consulting Group's** Pharmaceutical and Health Plans practice. She has more than twenty years of experience in the health sciences industry. Ms. Mastro works primarily with pharmaceutical and biotechnology companies, specializing in regulatory compliance and risk mitigation, particularly in the areas of sales and marketing, medical affairs and clinical trials. She regularly conducts compliance assessments related to specific brands, product areas, third-party vendors and clinical studies, specializing in anti-kickback and off-label promotion issues. Ms. Mastro also serves as the project lead on several Independent Review Organization ("IRO") engagements for pharmaceutical and biotechnology clients. She regularly works with clients' in-house legal counsel, outside legal counsel, compliance officers and senior operations professionals. She has a B.S. in Biology, an MBA and has been trained as a Clinical Research Monitor.

Karen Lowney is Senior Director of Global Compliance at **Cephalon**. She has responsibility for managing compliance across business units in the U.S. and overseas. Ms. Lowney was previously the Director of International Compliance at **Schering-Plough**, where she was responsible for implementation of compliance initiatives within the Global Pharmaceutical Business, coordination of their compliance officer network and ensured policies, procedures and processes adhered to corporate guidelines as well as local laws, codes and regulations. Prior to Schering-Plough, she was an Internal Audit Manager as **PricewaterhouseCoopers** and **Solutia, Inc.**

B

Auditing and Monitoring MSL Practices to Ensure Compliance

UPN 453-999-08-336-L03-P

MSLs are continuing to be scrutinized in the industry through new regulations surrounding CME, anti-kickback, grants, product safety and off-label regulations that all relate to their role in the healthcare arena. One way to ensure compliance and also measure effectiveness of MSLs is by auditing and monitoring their activities. Many MSLs serve as the eyes and ears of an organization so it is critical that appropriate standards on policy and reporting are in place to ensure a proper channel of communication. In this workshop, identify key components of an efficient auditing and monitoring program to ensure MSLs operate effectively and compliantly.

7:30 *Workshop Registration and Continental Breakfast*

8:30 *Workshop Leader's Welcome and Opening Remarks*

I. Strategies to Train and Monitor MSL Activity

- Options for training
  - * methods to ensure knowledge of policies and company compliance regulations
  - * methods to establish or maintain subject matter qualification
- Techniques for monitoring
  - * field observations — the pros and cons

II. Compliant Documentation Practices

- Documentation systems — Functional access control
  - * identify frequency of documentation
  - * discuss who is managing documentation
  - * compare other internal/external roles
  - * examples of alternate practices
- Examine Medical Liaison activities outside the U.S.
  - * how they are similar and different

III. MSL Audit Experiences

- Evaluation of MSL programs in practice
- External provider's role and responsibility in auditing
- Identify audit outcomes
- Implement corrective action, remediation and disciplinary action

IV. Implement an Oversight Committee

- Strategic committee development
- Implementation strategies

V. Update on Reprint Dissemination

- Examine the FDA Draft Guidance on "Good Reprint Practices"
- Discuss how this effects MSL activities

12:00 *Close of Workshop B*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

— About Your Workshop Leader —

Jeffrey Spears, Pharm.D., is Director of Medical Affairs at **Talecris Biotherapeutics** in Research Triangle Park, North Carolina. He is responsible for coordinating many of the U.S. medical and scientific affairs activities, including managing the Investigator Initiated Trials program. For the past year, Dr. Spears led the Medical Science Liaison Team at Talecris. He is also responsible for interfacing between research and development and the commercial organization. Dr. Spears has more than twelve years of experience in the pharmaceutical industry. Prior to joining Talecris, Dr. Spears was Senior Director of Medical Education at **EMD Pharmaceuticals** in Durham, North Carolina. EMD is a U.S. affiliate of **Merck KGaA**, in Darmstadt, Germany. At EMD, he was responsible for the field-based medical program, continuing medical education and non-certified medical education grants and health outcomes. Prior to joining EMD, Dr. Spears held a similar position of Executive Director of Medical Services at **Mylan Bertek Pharmaceuticals**. Dr. Spears attended the University of Cincinnati, in Cincinnati, Ohio, where he received his Bachelor of Science degree in pharmacy and a Doctor of Pharmacy degree. He completed his residency in Hospital Pharmacy at the University of Cincinnati Medical Center. He also completed graduate-level coursework in business administration at the University of Central Florida in Orlando. He is past chair of the Health Industry Manufacturers Association Health Information System Committee's Task Force on Administrative Simplification and has also served as an officer/ executive committee member of several regional pharmacy associations.

Steve Guymon is the U.S. Medical Compliance Officer for **Eli Lilly and Company**. He is a graduate of the University of Utah and a Certified Compliance and Ethics Professional through the Society of Corporate Compliance and Ethics. He has nineteen years of experience in the pharmaceutical industry and has worked in roles in compliance, training, sales and research operations. He joined Eli Lilly and Company in 1996 and has held a variety of roles within Lilly. Prior to Lilly, he was employed by **Upjohn Pharmaceuticals** and the **Center for Intraocular Lens Research at the University of Utah**. The past several years, his work has focused on the development and implementation of an effective Compliance program for Medical Affairs and Medical Research staff. He has also led the development and implementation of training systems.

"This conference provided invaluable information for our development of compliance policies and procedures for disseminating off-label information."

— 2007 Attendee, Brian Pilcher, Vice President, Medical Affairs, **Bioform Medical**

MAIN CONFERENCE

Day One — Thursday, October 16, 2008

12:00 *Main Conference Registration*

1:15 *Chairman's Welcome and Opening Remarks*

Wayne Pines, President, Regulatory Services and Healthcare, **APCO Worldwide;** *Former Chief of Consumer Education and Information, Chief of Press Relations and Associate Commissioner for Public Affairs,* **FDA**

Mr. Pines is an international consultant on crisis management, regulatory issues, advertising and promotion and media strategies. He is the author or editor of several books about FDA regulatory processes, crisis management and the FDA. He wrote the FDA Advertising and Promotion Manual. *He co-authored the recently-published* Pharmaceutical Risk Management: Practical Applications. *He edited* A Practical Guide to Food and Drug Law and Regulation, How to Work with the FDA *and* FDA: A Century of Consumer Protection *and three books on crisis management. Mr. Pines is on the boards of Scolr Pharma, The Patient Channel, Excel Life Sciences and the FDA Alumni Association and is chairman of the board of the MedStar Research Institute. He is president of the Alliance for a Stronger FDA, a coalition seeking to educate the Congress and Administration about the need for more appropriated funds for FDA.*

Strategies to Be Compliant with Off-Label Use

1:30 **Examine the Risks of Pre-Approval Promotion of Pipeline and In-Line Compounds**

One of the areas where experts expect increased regulatory scrutiny is over pre-approval promotion as distinct from off-label promotion. There is an enhanced focus on the scientific exchange of information at analysts' meetings for the investor community and within press releases discussing pipeline compounds and in-line compounds. While the scientific exchange of information in the media does receive some protection from government scrutiny, companies that overstate the benefits and understate the risks of any product — regardless of approval status — or otherwise draw conclusions of safety and efficacy for unapproved products are unlikely to receive immunity from prosecution. This session discusses pre-approval promotion and examines whether government regulators and prosecutors are taking a keen interest in these issues.

- Explore the current regulatory and legal landscape with regard to pre-approval promotion as compared to off-label promotion
- Understand the rules of the road for investor and other communications for pipeline or in-line compounds
- Understand the difference between scientific exchange and promotion

Michael A. Misocky, R.Ph., J.D., CHC, President, **Misocky Consulting Group**

Extended Panel Discussion

2:15 **Strengthen the Role of Medical Affairs Personnel with the Dissemination of Information to HCPs and Decision-Making Bodies**

UPN 453-999-08-337-L03-P

The role of Medical Affairs in the clinical support of products each year becomes increasingly more valuable to companies. Dissemination of medical information and literature is a critical component of successful scientific exchange. With greater confidence in the technology to use biomarkers, imaging and diagnostic techniques as well as personalized response to therapies (personalized medicine) and data collection of patients, Medical Affairs personnel are able to leverage scientific information through published documents and communications with HCPs and P&T committees. In this panel, discuss ways to strengthen the role of Medical Affairs personnel in the dissemination of scientific information.

- Strengthen MSL interaction with physicians
- Examine Medical Affairs personnel interactions with P&T committees and others in managed care
- Mitigate risks in promotion

Moderator: Mark DeWyngaert, Managing Director, **Huron Consulting Group**

Panelists: Elizabeth "Carden" Simcox, Ph.D., Assistant Director, Southeast MERL Team, TAP Medical Affairs, R&D, **TAP Pharmaceutical Products, Inc.**

Jeffrey Spears, Pharm.D., Director, Medical Affairs, **Talecris Biotherapeutics**

3:15 *Networking and Refreshment Break*

Compliant Processes for Distributing and Posting Medical Information

3:45 **Disseminating Information at Medical Meetings — Posters, Slide Decks, Press Releases and Other Materials**

Scientific journal articles are just one form of medical information that companies find value in providing at medical meetings. Posters, slide decks and other materials are also forms of medical communications. In this session, discuss processes to consider at a medical meeting and booth to compliantly disseminate scientific information.

- Considerations for a medical booth
  - * design, staffing, materials, location (conference)
- Identify what information and literature can be distributed at a medical meeting
- Discuss processes for disseminating posters, slides decks, press releases and other materials
- Implement internal processes that ensure compliant dissemination

Anthony Verderese, Director, U.S. Medical Information, **EMD Serono**

4:30 **Copyright Considerations for the Dissemination of Medical Journal Articles and Scientific Reference Materials**

Discuss copyright compliance issues related to journal articles and other scientific reference materials that companies need to disseminate. Learn rules for internal dissemination to field personnel and external distribution to physicians.

- Learn what is copyright protected and what is not
- Discuss fair use
- Compare rules for internal dissemination with rules for external dissemination
- Ensure compliance when disseminating materials
  - * PDFs
  - * documents shared through email
  - * documents shared through hyper-links
  - * international regulations

Stephen K. Garfield, Director, Strategic Account Management, **Copyright Clearance Center**
Jennet Walker, Consultant, **Copyright Clearance Center;** *Former Senior Corporate Counsel,* **Pfizer Inc**

5:15 **Compendia Listings for Off-Label Information — Impact on Patient Care**

Drug compendia listings for off-label information provide guidance to healthcare professionals on the appropriate use of medications for clinical decision making. The Centers for Medicare and Medicaid Services (CMS) and payers utilize selected drug compendia to identify and determine reimbursement coverage for medically accepted off-label uses of drugs and biologic agents. Inclusion of an off-label listing in compendia thereby impacts clinical decision making, reimbursement, patient access and ultimately patient care. In this session, a historical background of CMS policy surrounding compendia is provided in addition to recent changes and developments. The process of submitting off-label information to select guidelines and compendia is also discussed.

- Gain a historical understanding of compendia and the current environment as it relates to CMS
- Discuss the role of compendia as it relates to healthcare professionals and patient care
- List various compendia and differences amongst them
- Understand the submission process of off-label information to select guidelines and compendia

Julia Petses, Pharm.D., Manager, Medical Information Services, **sanofi-aventis**

6:00 *Close of Day One*

6:00-7:00 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

photo by: Photolink / Getty Images

Day Two — Friday, October 17, 2008

7:30 *Continental Breakfast*

8:00 *Chairman's Review of Day One*
Wayne Pines, President, Regulatory Services and Healthcare, **APCO Worldwide;** *Former Chief of Consumer Education and Information, Chief of Press Relations and Associate Commissioner for Public Affairs,* **FDA**

Update on Off-Label Oversight and Enforcement

FDA ADDRESS

8:15 **Update of FDA's Regulatory Oversight of Advertising and Promotion for Medical Devices**

The rules and intricacies for medical device advertising and promotion differ greatly from those that govern drug promotion. In this session, discuss the statute and regulations that cover medical device advertising and promotion and learn the scope of FDA's regulation of devices in regards to off-label promotion.

- Define off-label use for a medical device
- Gain insight into FDA areas of concern
  - * patient safety and off-label
- Discuss the marketing review that device companies need to submit
  - * how to advertise a device
  - * oversight on other communication where off-label issues can arise
    - > press releases, posters, other materials
    - > promotion over the Internet

Ann Simoneau, Regulatory Counsel, **CDRH, FDA**

9:00 **Analysis of Off-Label Enforcement**

UPN 453-999-08-338-L03-P

These sessions look at recent warning letters and the current status of off-label cases and analyzes the significant trends of current civil and criminal prosecutions to understand the factors driving enforcement. Discuss FDA's advertising and promotional oversight and examine how it relates to potential off-label violations. Analyze recent cases to determine trends in off-label promotion within a company. Identify safe guards companies can take based on lessons learned from recent enforcement.

I. FDA Compliance Actions on Advertising and Promotion and their Relationship to Off-Label, False Claims Act and Consumer Fraud Litigation

- FDA Warning Letters and other compliance actions
  - * broadened indications
    - > overstated or unsubstantiated efficacy or superiority claims
    - > minimized or omitted risks
    - > other hot button areas

Arnold I. Friede, Counsel, **McDermott Will & Emery;** *Former Senior Corporate Counsel,* **Pfizer Inc;** *Former Associate Chief Counsel,* **FDA**

II. Lessons Learned from the Latest Off-Label Enforcement

- Top executives' liability
- Off-label pediatric promotion
- Damage analysis

Stephen Payne, Partner, **Sidley Austin**

10:00 *Networking and Refreshment Break*

Prosecutors' Perspectives on Off-Label Enforcement

10:30 **The Purdue Pharma OxyContin® Settlement — Off-Label Promotion through Misbranding**

UPN 453-999-08-339-L03-P

Case Study

In May 2007, the Purdue Frederick Company, Inc., along with its President, Chief Legal Officer and former Chief Medical Officer were convicted of misbranding Purdue's addictive and highly abusable drug OxyContin. Purdue and the three executives paid a total of $634,515,475. OxyContin is a Schedule II prescription pain relief medication, classified as having the highest potential for abuse of legally available drugs. The Purdue Frederick Company, Inc., and the three executives admitted that Purdue fraudulently marketed OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support these claims and without Food and Drug Administration approval of these claims. In this case study, hear directly from the U.S. Attorney who led the investigation that resulted in one of the largest financial penalties ever imposed on a drug company.

John Brownlee, Former U.S. Attorney,
U.S. Attorney's Office for the Western District of Virginia

11:00 **Understand the Criteria Government Uses in Building an Off-Label Case**

As evidenced in the Purdue case, the government has shown that enforcement against illegal off-label promotion remains a top priority. In this panel discussion, hear from prosecutors in prominent U.S. Attorneys' Offices on what they look for as they build a case. Also, learn what criteria are applied when determining how much to settle a case for and how important company compliance programs are in mitigating risks. Finally, discuss how new FDA guidance may affect the way prosecutors consider reprint dissemination activity.

PANEL

- Discuss criteria used in recent enforcement actions
- Learn safeguards to help minimize violations
- Explore areas that should still be considered high risk for enforcement activity, despite the new guidelines for reprint dissemination that FDA proposes

Moderator: David E. Matyas, Member of the Firm,
Epstein, Becker and Green P.C.

Panelists:

Michael Loucks,
First Assistant U.S. Attorney,
U.S. Attorney's Office for the District of Massachusetts

John Brownlee,
Former U.S. Attorney,
U.S. Attorney's Office for the Western District of Virginia

Linda Wawzenski,
Assistant U.S. Attorney, Deputy Chief, Civil Division,
U.S. Attorney's Office for the Northern District of Illinois

Ioana Petrou, Assistant U.S. Attorney,
U.S. Attorney's Office for the Northern District of California

12:30 *Luncheon and Presentation*
Analyzing the Political Landscape for Communicating Medical Information

UPN 453-999-08-340-L03-P

John Kamp, Executive Director,
Coalition for Healthcare Communication

1:45 **States Ramp Up Off-Label Prosecutions via National Training Initiatives and Use of Diagnosis Codes to Measure Damages**

Twenty-two states now have their own False Claims Acts. By coordinating with the National Association for Medicaid Fraud Control Units (NAMFCU) these states are focusing their efforts on off-label cases. The NAMFCU — whose members include all 49 states with MFCUs — is coordinating this effort through its Global Case Committee, its *Qui Tam* subcommittee and its Training Committee. Since January 2007, these groups have planned and executed large scale, national training efforts specifically dedicated to training MFCU personnel on the investigation and prosecution of global cases, including detailed auditing training designed to accurately measure damages due to illegal off-label marketing. Similar trainings are in the pipeline. Through these efforts, NAMFCU has begun to take a lead role in many global cases and this trend is expected to continue. In this session, hear directly from the Vice President of NAMFCU as he describes the rapidly evolving landscape of state off-label marketing investigations and prosecutions.

Daniel R. Miller, Deputy Attorney General,
Office of the Attorney General, Delaware;
Vice President, **National Association of Medicaid Fraud Control Units (NAMFCU)**

2:30 **The Industry and Dissemination of Medical and Scientific Information — Identifying and Managing Risk in the Aftermath of the FDA Guidance**

Since the Washington Legal Foundation ("WLF") decisions and "sunset" of the FDAMA provisions relating to dissemination of off-label reprints, the pharmaceutical and related industries have labored to develop appropriate procedures for disseminating medically relevant information and to support vital scientific exchange without risking regulatory action or violating compliance standards. FDA has recently issued a Draft Guidance for Industry, "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices." In this session, hear the legal perspective of a veteran industry peer on how he would advise his clients to move forward to identify and manage risk in this new regulatory landscape.

- What are the immediate practical applications of the FDA Guidance?
- Determine how to identify and provide counsel to the appropriate in-house functions
- Evaluate effective methods to integrate the role of the legal and compliance groups in developing company guidance
- Evaluate the company risk profile in the broadest context

Howard L. Dorfman, Counsel, **Ropes & Gray LLC;**
Former Vice President, Associate General Counsel,
Bayer HealthCare, LLC

3:15 *Close of Conference*

DON'T MISS OUR CO-LOCATED EVENT!

Attend the ***Bio/Pharmaceutical and Medical Device Forum on Compliant Compensation Arrangements with Physicians and Hospitals***, which is co-located with this summit and takes place on October 15, 2008. **Special pricing available when you register for both events! Visit www.cbinet.com/agreements**

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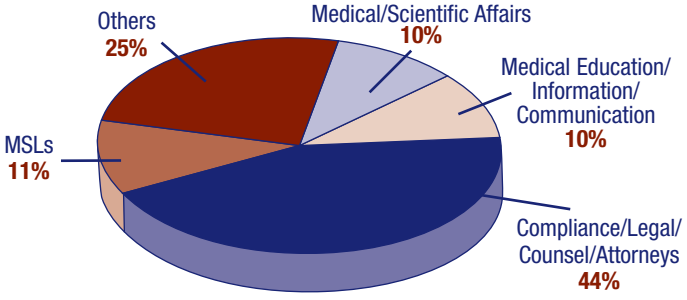

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Communicate Medical Information in a Changing Legal and Regulatory Landscape

October 16-17, 2008 • Sheraton Premiere at Tysons Corner • Vienna, VA

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Top 10 Reasons to Attend:

1. Hear directly from FDA, DOJ, AG and U.S. Attorneys' Offices
2. Analyze factors driving off-label enforcement
3. Learn the scope of FDA's regulation of promotion over the Internet
4. Network with peers on compliant use of medical information
5. Dissect a mock off-label CIA
6. Hear strategies to ensure compliance of MSL activities
7. Discuss pre-approval scientific exchange of information
8. Examine literature distribution at medical meetings
9. Strengthen Medical Affairs communications with HCPs and P&T Committees
10. Understand the submission process to compendia

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Main Conference & Workshop	$1,995	$1,695
Main Conference only	$1,695	$1,395
Workshop only	$895	$895
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(1-Day Seminar only)	$1,095	$995
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Payment Options: Payment in full is required to process registration. Please call with any payment questions.

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Please photocopy this form for additional delegates.

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5 EASY WAYS TO REGISTER

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