



# MEDICAL AFFAIRS

December 7 - 8, 2009 | The Union League | Philadelphia, PA

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President

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(Former, Business Ethics & Compliance Officer, Organon USA Inc., now Schering-Plough Corp.)



**Larri A. Short**

Partner

Arent Fox LLP

and faculty members from such leading companies as:

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Renowned Medical Affairs executives and compliance officers from leading pharmaceutical, biotechnology and device manufacturers and their counsel will provide insights on the latest legal and regulatory challenges affecting your department and help you:

- **IDENTIFY** necessary disclosures and exceptions under various state Physician Payments Sunshine Acts and proposed similar federal legislation
- **ASSESS** the impact of the 16 recommendations of the IOM Conflicts of Interest Report on your department's structure
- **CREATE** an atmosphere of transparency and neutrality for your CME and related grant programs in accordance with the revised PhRMA and AdvaMed Codes
- **ESTABLISH** new guidelines for scientific authorship and the dissemination of medical articles in accordance with leading medical writers associations
- **DESIGN** metrics to track MSL activities regarding off-label communications
- **ALIGN** the goals of both medical and commercial advisory boards without compromising ethics
- **RECONCILE** domestic and international protocols for clinical trials
- **COMPREHEND** departmental responsibilities under FDAAA relative to clinical and post-clinical phases – database registries, REMS, post-marketing studies, label changes
- **PREVENT** behaviors that have led to recent government investigations and enforcement activities which have directly impacted medical affairs departmental activities and personnel

Conference Registration includes choice of:

- A** Medical Affairs Boot Camp – A Drill-Down on the Legal, Regulatory and Compliance Fundamentals Necessary to Departmental Functions and Infrastructure  
December 7, 2009 • 8:30 a.m. to 12:00 p.m.  
or
- B** Master Class on Counseling Medical Affairs and Sales and Marketing on Appropriate Interdepartmental Interfaces Relative to Promotions, Publications, Post-Marketing Studies and the Use of Consultants in a Time of Reform  
December 8, 2009 • 2:00 p.m. to 5:00 p.m.

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Transparency • Disclosure • Conflicts Avoidance • Propriety • Reform  
 Prepare to respond to a new call of action for Medical Affairs.  
 Attend the *only* event specifically designed for the Medical Affairs  
 community by Medical Affairs professionals.

The Revised PhRMA Code, the IOM Conflicts of Interest Report, Physician Payments Sunshine Acts – all collectively have worked to reshape the role of Medical Affairs in your company. In this era of health care reform, the responsibilities, challenges and risks for Medical Affairs have never been greater. As a Medical Affairs professional, you must now not only be the gatekeeper of scientific information and integrity, but must also ensure that the use of such information is above reproach and that there is transparency in all actions and matters within your department's purview. This is especially true as both Medical Affairs personnel and their activities have over the course of the last few years become subject to the same investigations and enforcement actions which have long plagued sales and marketing.

Now is the time to come to the one event that has consistently allowed Medical Affairs professionals and their counsel to benchmark their compliance strategies and protocols against new and evolving standards.

A faculty of leading Medical Affairs professionals – from department heads to compliance officers and counsel – will prepare you to meet your department's challenges head-on by providing you with:

- Critical updates on how state and federal activity relative to the Physician Payments Sunshine Act and new association reports and guidances such as the IOM Conflicts of Interest Report and revised PhRMA and AdvaMed Codes will impact – or have already impacted – various departmental practices relative payment disclosures, consultative and interdepartmental relationships and boundaries, advisory boards, and CME and related grant-making responsibilities
- Techniques for safeguarding the integrity of scientific research vis-à-vis medical publications and MSL communications and ensuring that this information does not become marketing fodder
- Analyses of key FDAAA provisions affecting the Medical Affairs function in the clinical and post-clinical phases and strategies for implementing best practices relative to reporting requirements and protocols under the Act
- An in-depth review of government enforcement actions involving the Medical Affairs function and protective measures you can implement to reduce your risk of such scrutiny

You will also be able to further enhance your skills and knowledge by attending the following specialized classes designed for both new and more experienced Medical Affairs professionals:

- Medical Affairs Boot Camp – A Drill-Down on the Legal, Regulatory and Compliance Fundamentals Necessary to Departmental Functions and Infrastructure
- Master Class on Counseling Medical Affairs and Sales and Marketing on Appropriate Interdepartmental Interfaces Relative to Promotions, Publications, Post-Marketing Studies and the Use of Consultants in a Time of Reform

Attend this conference and have the unique opportunity to network with your Medical Affairs peers and colleagues as every iteration of this event to date has had a **98% average Medical Affairs professional attendance rate.**

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## WHO YOU WILL MEET:

Pharmaceutical, Biotechnology, and Medical Device Executives, Directors, Officers and Legal Counsel with responsibility for:

- Medical/Scientific Affairs
- Medical Science Liaisons
- CME/Grants
- Research and Development
- Sales and Marketing
- Compliance
- Legal and Regulatory Affairs

Law firm counsel representing pharmaceutical, biotechnology, and medical device companies, practicing in:

- Pharmaceutical/Biotechnology/Medical Device/Life Sciences
- Off Label/Sales & Marketing Scientific Communication Compliance
- FDA, Health Care Regulatory Law
- Food and Drug

## DISTINGUISHED FACULTY

### Co-Chairs

**Retta M. Riordan**  
 President, Riordan Consulting LLC (Westfield, NJ)  
*(former Business Ethics and Compliance Officer, Organon USA Inc., now Schering-Plough Corp.)*

**Larri A. Short**  
 Partner, Arent Fox LLP (Washington, DC)

### Speakers

**Ann Beasley Bacon**  
 Vice President, Integrity and Compliance  
 Compliance Officer - Vaccines, Americas  
 Novartis Vaccines and Diagnostics (Cambridge, MA)

**Joseph Camardo, MD**  
 Senior Vice President, Global Medical Affairs  
 Wyeth Pharmaceuticals (Collegeville, PA)

**David Davidovic**  
 Senior Director, Commercial Strategy  
 Genentech, Inc. (South San Francisco)

**Sujata T. Dayal**  
 Corporate Vice President &  
 Chief Compliance Officer, Biomet, Inc. (Warsaw, IN)

**Howard L. Dorfman**  
 Counsel, Ropes & Gray LLP (New York, NY)

**Frank Fazio, R. Ph.**  
 Principal, Porzio, Bromberg & Newman, P.C. (Morristown, NJ)

**Arnold I. Friede**  
 Of Counsel, McDermott Will & Emery LLP  
 (Washington, DC) *(former FDA Associate Chief  
 Counsel and former Senior Corporate Counsel, Pfizer)*

**Charlene A. Gallagher**  
 Senior Division Counsel, Vaccines  
 Wyeth Pharmaceuticals (Collegeville, PA)

**Thomas M. Gallagher**  
 Partner, Pepper Hamilton LLP (Philadelphia, PA)

**Wendy C. Goldstein**  
 Partner, Epstein Becker & Green, P.C. (New York)

**Steven T. Guymon**  
 Director, Global Ethics/Compliance Business Liaisons  
 Eli Lilly and Company (Indianapolis, IN)

**Robert F. Kaper, MD**  
 Vice President, Medical Affairs, Cephalon Inc (Frazer, PA)

**Carol E. Landsman**  
 Director, Navigant Consulting, Inc. (Lawrenceville, NJ)

**Christina M. Markus**  
 Partner, King & Spalding LLP (Washington, DC)

**George Ng**  
 Corporate Counsel, Director of Intellectual Property  
 Spectrum Pharmaceuticals (Irvine, CA)

**Saroj Rai**  
 Director, Vaccines MSL Team  
 Novartis Vaccines and Diagnostics (Cambridge, MA)

**Linda Pissott Reig**  
 Principal, Porzio, Bromberg & Newman, P.C. (Morristown, NJ)

**Marc J. Scheineson**  
 Partner, Alston & Bird LLP (Washington, DC)

**Beate Stych, MD**  
 Vice President, Medical Affairs  
 Regeneron Pharmaceuticals, Inc. (Tarrytown, NJ)

**Josephine M. Torrente**  
 Director, Hyman, Phelps & McNamara, P.C. (Washington, DC)

**Seth B. Whitelaw**  
 Compliance Officer, Global R&D  
 GlaxoSmithKline (King of Prussia, PA)

**Laura A. Wittenuer**  
 Ethics and Compliance Officer, LRL  
 Eli Lilly and Company (Indianapolis, IN)

PRE-CONFERENCE WORKSHOP | 8:30 a.m. – 12:00 p.m.

(Registration and Continental Breakfast Begins at 7:30 a.m.)

## Medical Affairs Boot Camp – A Drill-Down on the Legal, Regulatory and Compliance Fundamentals Necessary to Departmental Functions and Infrastructure

Arnold I. Friede  
Of Counsel  
McDermott Will & Emery LLP (Washington, DC)  
*(former FDA Associate Chief Counsel  
and former Senior Corporate Counsel, Pfizer)*

Linda Pissott Reig  
Principal  
Porzio, Bromberg & Newman, P.C. (Morristown, NJ)

Beate Stych, MD  
Vice President, Medical Affairs  
Regeneron Pharmaceuticals, Inc. (Tarrytown, NJ)

Seth B. Whitelaw  
Compliance Officer, Global R&D  
GlaxoSmithKline (King of Prussia, PA)

### Moderator:

Carol E. Landsman  
Director  
Navigant Consulting, Inc. (Lawrenceville, NJ)

*This hands-on workshop will provide you with an in-depth overview of the key competencies and latest legal and regulatory developments affecting the medical affairs function. The workshop leaders will lay the necessary foundation for you to comprehend thoroughly the legal and regulatory parameters as well as compliance protocols and infrastructure of this unique department. This session will also provide essential information to new medical affairs professionals, and serve as an up-to-the minute critical refresher for more experienced professionals, as well as their counsel and advisors in preparation for the complexities of the medical affairs challenges presented during the main conference.*

### Understanding the Legal and Regulatory Framework for the Medical Affairs Function

- Defining “medical affairs” within the purview of the Codes and Guidance
- Identifying applicable provisions in the OIG Guidance, PhRMA Code, AdvaMed Code and other guidance documents
- Review of critical changes in the revised PhRMA Code of 2008
  - breakdown of ‘dos’ and ‘don’ts’ for sales force interaction with doctors and health care professionals
  - exploring proper interactions between sales and medical affairs
- FDA off-label use guidance
  - establishing procedures for the proper dissemination of off-label information
    - good reprint practice
- Guidance from other regulatory bodies to keep in mind:
  - in the U.S.:
    - AMA; IOM; NIH
    - AAMC; ACCME
  - in the EU and Asia:
    - EMEA; SFDA

- Key provisions in the Food and Drug Administration Amendments Act of 2007 (FDAAA) that are applicable to the medical function:
  - clinical trial registries
  - clinical trials disclosure requirements
  - pharmacovigilance requirements
    - post-marketing clinical trials requirements
  - labeling and promotional restrictions
  - REMS
- Defining the role and duties of medical affairs at the clinical stage and post-clinical stage in view of new laws, regulations, and guidances
- Anti-Kickback Statute and Safe Harbor Regulations
  - understanding these laws and their applicability to the actions of the medical function and the medical affairs/sales and marketing interface
- Stark Law
  - identifying the applicability of Stark to certain medical affairs functions and interactions regarding physicians
- Physician Payments Sunshine Acts
  - understanding their impact on medical affairs protocols

### Overview of Terminology and Key Documents that are Essential to the Medical Affairs Function

- Protocol documents
  - how is a protocol defined?
  - what should/must a protocol document contain?
  - drafting strategies
- Promotional documents
  - what constitutes a promotional document?
  - what information should/must a promotional document contain?
  - protocols for the distribution of promotional documents
- Industry-sponsored vs. industry-supported: defining these terms and how they are applied to publications and research
- MI/PI Call Centers and related documentation and communications
- MSLs: understanding how they differ from your sales force in terms of scope of duties and function
- KOLs: who are they and how are they chosen, what role do they serve?
- Advisory Boards: understanding their function
  - criteria for selection of members
  - governance

### Designing an Appropriate and Compliant Infrastructure for your Medical Affairs Department

- Designing a structure to prevent your medical affairs department from becoming an arm of your sales force
- Customizing a plan for smaller companies and bigger companies
  - how to incorporate big company safe guards into the medical affairs functions of smaller companies
  - establishing and defining duties and departmental functions
  - defining governance within the reporting structure
- How to form effective advisory committees for both the sales and medical functions

12:00 **Workshop Ends**

## MAIN CONFERENCE

### 12:30 Registration Begins

### 1:15 Co-Chairs' Opening Remarks

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Retta M. Riordan  
President  
Riordan Consulting LLC  
(Westfield, NJ)  
*(former Business Ethics & Compliance Officer,  
Organon USA Inc., now Schering-Plough Corp.)*

Larri A. Short  
Partner  
Arent Fox LLP  
(Washington, DC)

### Reshaping the Medical Function for a Time of Health Care Reform

### 1:30 Physician Payments Sunshine Act(s): Requirements and Consequences for Medical Affairs Departments

---

Christina M. Markus  
Partner  
King & Spalding LLP (Washington, DC)

Seth B. Whitelaw  
Compliance Officer, Global R&D  
GlaxoSmithKline (King of Prussia, PA)

- Review of current federal bills and key provisions
- Overview of similar state laws that have been enacted
  - similarities and differences in the Maine, Massachusetts, Minnesota, Vermont, West Virginia, and District of Columbia laws
    - which other states have pending laws and how do their proposed requirements compare with other established state laws and pending federal legislation?
  - identifying which payments need to be disclosed under these laws
    - factoring-in carve-outs and exceptions: clinical trials
- Pre-emption: understanding the consequences for your compliance strategy if the federal bill does not contain a preemption provision
- Identifying departmental functions, responsibilities and personnel that are affected by these disclosure laws
- Developing and implementing a compliance program that accounts for all physician payments that are required to be disclosed under these acts
  - coordinating responsibilities for payment tracking with the sales and marketing function

### 2:30 An Analysis of The IOM Conflict of Interest Report: A Call to Action for Medical Affairs

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Joseph Camardo, MD  
Senior Vice President  
Global Medical Affairs, Wyeth Pharmaceuticals (Collegeville, PA)

Charlene A. Gallagher  
Senior Division Counsel, Vaccines  
Wyeth Pharmaceuticals (Collegeville, PA)

- Overview of the IOM Report on the Conflict of Interest in Medical Research, Education, and Practice
  - emphasizing prevention as opposed to remediation
  - examining the Report's sixteen areas of recommendation
- Assessing recommendations specific to the pharmaceutical, biotechnology and medical device industries with respect to:
  - disclosure of individual and institutional ties to industry
  - Congressional creation of a national reporting program
  - gifts
  - ghostwriting
  - consultative relationships with physicians and medical affairs
  - use of drug samples
  - CME and grants
- Exploring the parallels between the IOM recommendations and:
  - other Codes and guidance documents
  - recent laws, pending legislation and regulation
- Understanding the Report's true implications for industry and healthcare reform
- Re-defining the responsibilities of the medical function vis-à-vis the Report's recommendations
- Designing a pro-active conflicts of interest policy that is consistent with the Report's recommendations

### 3:15 Afternoon Refreshment Break

### 3:30 Continuing Medical Education (CME) and Related Grant Challenges: Redesigning Current Practices to Comply With New Guidelines

---

David Davidovic  
Senior Director, Commercial Strategy  
Genentech, Inc.  
(South San Francisco)

Retta M. Riordan  
President  
Riordan Consulting LLC  
(Westfield, NJ)  
*(former Business Ethics & Compliance Officer,  
Organon USA Inc., now Schering-Plough Corp.)*

Larri A. Short  
Partner  
Arent Fox LLP  
(Washington, DC)

- Exploring the current CME and grant landscape: understanding why we are where we are
  - review of key provisions in association guidances:
    - ACCME
    - PhRMA
    - AdvaMed
  - assessing governmental guidances in this area:
    - FDA
    - OIG
  - examining government scrutiny relative to CME and related grant-making
    - Congressional hearings
    - state and federal enforcement activities
  - what can we glean from settlements and related CIAs in this area?
- Critical considerations in CME-related grant decisions relative to the current compliance landscape

- understanding the importance of creating an atmosphere of transparency in the grant-making function
- incorporating protective measures to ensure that grant-making decisions are separate from the sales and marketing functions
- exploring grant concerns relative to off-label promotion
- maintaining neutrality in CME programs and taking steps to prevent promotional content or intent
- examining ethical concerns in the relationship between CME and industry
- differentiating between grants to universities and non-profits as compared to grants to industry
- Strategies for developing a compliant grant process
  - where should grant-making authority reside?
  - developing objective guidelines for grant awards and reviewing existing guidelines under new rules
  - effectively establishing and utilizing a grant committee
  - tracking of grants
  - determining budget and finance issues
  - creating guidelines for how and by whom decisions concerning program content and faculty should be made
  - use of outside CME provider companies vs. universities
- Exploring the future of CME funding
- Speaker programs vs. CME programs
  - identifying differences between Speaker programs and CME programs
  - implementing safeguards to ensure that CME programs are not Speaker programs in disguise
  - setting compensation for speakers
  - training speakers

4:30 **New Publication Strategies for Medical/Scientific Research: Establishing Guidelines for Authorship and Publication in a Culture of Compliance**

Frank Fazio, R. Ph.  
Principal  
Porzio, Bromberg & Newman, P.C.  
(Morristown, NJ)

George Ng  
Corporate Counsel, Director of Intellectual Property  
Spectrum Pharmaceuticals  
(Irvine, CA)

- Establishing internal guidelines for authorship qualification in the writing of scientific articles
  - peer review articles
  - white papers
- Examining association positions on authorship and publication of scientific articles
  - WAME
  - European Medical Writers Association
- Developing guidelines for the dissemination of medical and scientific articles
  - review of the FDA's Good Reprint Practice policies concerning articles involving off-label use
    - *Washington Legal Foundation v. Henney*
- Exploring ethical consequences relative to the role of marketing in authorship and article dissemination
  - ghostwriting: prevalence and dangers

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

7:30 **Continental Breakfast** 🍳

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

8:30 **MSLs: A New Look at Qualifications, Duties and Responsibilities Relative to Off-Label Communications**

Ann Beasley Bacon  
Vice President, Integrity and Compliance  
Compliance Officer - Vaccines, Americas  
Novartis Vaccines and Diagnostics  
(Cambridge, MA)

Saroj Rai  
Director, Vaccines MSL Team  
Novartis Vaccines and Diagnostics  
(Cambridge, MA)

Marc J. Scheineson  
Partner  
Alston & Bird LLP  
(Washington, DC)

- Reviewing critical MSL competencies
  - scientific degree requirements
  - scientific exchange and discussion of medical information as opposed to promotion of product
  - peer to peer communications
  - networking
- Defining the role of MSLs with respect to the medical affairs and sales and marketing functions
- Revisiting the scope of permissible communications for MSLs relative to:
  - unsolicited questions
  - proactive communications
  - investigational products
  - existing products
  - adverse events information
  - unapproved indications
- Identifying circumstances in which MSLs may discuss off-label uses
  - tie-in with FDA's Good Reprint Practice policies
- Exploring the role of MSLs in CME
- Establishing MSL protocols for off-label communications
  - when should information be communicated orally?
  - pros and cons of adopting a written request from physician only policy
  - designing a program to track and assess off-label communications
- Designing metrics to track MSL activities and effectiveness

9:30 **Analyzing and Avoiding Conflicts of Interest in Medical and Commercial Advisory Boards**

Steven T. Guymon  
Director, Global Ethics/Compliance Business Liaisons  
Eli Lilly and Company  
(Indianapolis, IN)

Laura A. Wittenauer  
Ethics and Compliance Officer, LRL  
Eli Lilly and Company  
(Indianapolis, IN)

- How to align the goals of both medical and commercial advisory boards without compromising ethics
- Implementing safeguards to prevent conflicts of interest in medical and commercial advisory boards
  - e.g., designing a research plan vs. getting approval for a particular product
- Assessing KOL placement on boards
  - identifying circumstances when a KOL can sit on both commercial and medical advisory boards
  - making necessary disclosures relative to payments, positions and publications
- Exploring international considerations relative to board placement
  - FCPA concerns: physician as public official quandary
  - foreign protocols for board placement

#### 10:15 Morning Coffee Break ☕

#### 10:30 Medical's Role in Clinical Trials Here and Abroad: Ensuring Compliance with Regulatory Requirements and Protocols

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Howard L. Dorfman  
Counsel  
Ropes & Gray LLP  
(New York, NY)

- Defining the proper role of the medical affairs function at the clinical stage with respect to:
  - recruitment, selection and contracting of investigators and sites
  - communications with investigators
  - communications with R&D
- Coordinating Medical's responsibilities in trials here and abroad
- Developing informed consent practices that comply with both U.S. and international protocols
  - understanding what constitutes informed consent in the target country
  - ethical considerations for placebo groups
- Complying with privacy safeguards in the U.S and abroad
  - EU Data Protection Directive
- Exploring best practices relative to clinical database disclosure requirements under FDAAA relative to ClinicalTrials.gov and ClinicalResults.gov
  - understanding how these requirements apply to trials conducted in other countries
- Examining how PhRMA's revised *Principles on Conduct of Clinical Trials and Communication of Clinical Trials Results* compare to current database disclosure requirements under FDAAA

#### 11:15 FDAAA Title IX: Effectively Dealing with Post-Marketing Safety Requirements and other Pharmacovigilance Concerns

---

Robert F. Kaper, MD  
Vice President, Medical Affairs  
Cephalon Inc  
(Frazer, PA)

Josephine M. Torrente  
Director  
Hyman, Phelps & McNamara, P.C.  
(Washington, DC)

- Assessing how Medical Affairs role in the post-approval phase has been redefined by FDAAA
  - exploring how the following provisions of FDAAA impact departmental functions and responsibilities relative to the post-approval phase:
    - REMS
    - post-marketing requirements
    - labeling changes
- REMS: planning a strategy for responding to the FDA
  - which medical functions should be involved and what other departments should be involved?
  - understanding the elements and complexity that FDA is requiring in its REMS request and what needs to be done to comply
    - REMS involving communication elements only
    - REMS involving restrictive elements to assure safe use
  - exploring the scope of penalties for non-compliance
- Identifying circumstances in which you should recommend a 'REMS-like' plan, i.e., a medication guide, before the FDA requests a REMS
  - advantages vs. disadvantages of a proactive approach
- Exploring post-marketing clinical studies requirements under FDAAA and assessing their impact on your product
- Understanding FDA's new authority over label changes
  - how do the results of post marketing studies tie-in with label changes?
  - how can label changes be negotiated to your best advantage?

#### 12:00 Enforcement Actions Directly Impacting Medical Affairs Departments and Personnel

---

Thomas M. Gallagher  
Partner  
Pepper Hamilton LLP  
(Philadelphia, PA)

- Exploring recent investigations and enforcement activities that have directly impacted the medical affairs function
  - *U.S. v. Synthes*
  - *U.S. v. Harkonen*
  - *U.S. v. Eli Lilly (Zyprexa)*
  - Bextra investigation
- Reviewing circumstances which lead to indictment of corporate executives (including those from Medical Affairs) in addition to that of the corporation
- Comparing new enforcement activities in medical affairs to those employed against the sales function in the past
- Predicting future enforcements action involving the medical affairs function
- Implementing best practices

#### 12:45 Conference Ends

## Master Class on Counseling Medical Affairs and Sales and Marketing on Appropriate Interdepartmental Interfaces Relative to Promotions, Publications, Post-Marketing Studies and the Use of Consultants in a Time of Reform

Sujata T. Dayal  
Corporate Vice President & Chief Compliance Officer  
Biomet, Inc.  
(Warsaw, IN)

Wendy C. Goldstein  
Partner  
Epstein Becker & Green, P.C.  
(New York)

Carol E. Landsman  
Director  
Navigant Consulting, Inc.  
(Lawrenceville, NJ)

*The boundaries of interaction between medical affairs and sales and marketing are challenging in theory, but far more challenging in reality — especially with regard to such critical areas as promotions, publications, post-marketing studies and the use of consultants. Recent regulatory and association guidance documents have made these interfaces far more challenging as they call for very strict boundaries to be drawn between these two critical industry functions.*

*This hands-on, interactive master class will be led by a faculty of experienced, senior-level medical affairs professionals, attorneys, and compliance officers who will give you practical firsthand insights into these evergreen challenges which in this time of reform have taken on a new dimension of complexity. They will enable you to put theory into practice as they lead you into various factual scenarios and case studies designed to analyze the real issues and challenges commonly encountered by medical affairs staff in their daily interactions with the sales and marketing function. Combining knowledge sharing, role-playing, and advice in an interesting and diverse environment, this session is an excellent opportunity to learn best practices, share your ideas with your colleagues, as well as hear their thoughts and feedback. Enrollment is limited; the workshop is offered on a first-come, first-served basis.*

*Topics to be discussed include:*

- Drawing the line between medical and marketing
  - advertising vs. education
- Ensuring your marketing, sales, and research departments are adequately trained on the current regulatory guidance
  - bifurcation recommendations – including source of budget/funding for expenditures
  - ensuring compliance with the safe harbor rule in clinical trials/consulting/research agreements
  - the concept of FMV compensation for bona fide work actually performed
  - understanding the “intent” of behavior as a compliance standard
- Addressing promotional and publication dilemmas between the medical and marketing functions
  - analyzing the applicable legal, regulatory and compliance challenges in light of new industry guidance documents, law and regulation
  - responding to unsolicited requests for investigational drug/research information
  - defining the appropriate role of publication agencies
- Specifying appropriate and inappropriate marketing and sales interactions when conducting medical research
- Analyzing Phase IV study requests – motivation vs. objective
- Advising your marketing and sales staff on the boundaries of customer interaction
- Establishing procedures for monitoring field-based personnel
- Analyzing strategies for minimizing research and development and legal costs
- Recognizing when and how to supplement in-house resources and expertise with outside consultants

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Group Leader & Business Development Executive  
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# MEDICAL AFFAIRS

December 7 - 8, 2009 | The Union League | Philadelphia, PA

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Please quote the name of the attendee(s) and the event code 853L10 as a reference.

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### PRE-CONFERENCE WORKSHOP

December 7, 2009

Medical Affairs Boot Camp – A Drill-Down on the Legal, Regulatory and Compliance Fundamentals Necessary to Departmental Functions and Infrastructure

### POST-CONFERENCE MASTER CLASS

December 8, 2009

Master Class on Counseling Medical Affairs and Sales and Marketing on Appropriate Interdepartmental Interfaces Relative to Promotions, Publications, Post-Marketing Studies and the Use of Consultants in a Time of Reform

### Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches, refreshments and complimentary membership of the ACI Alumni program.

### 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 or remove/restrict access to the ACI Alumni program 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, venue or arising from the use or unavailability of the ACI Alumni program.**

### 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: Medical Affairs" conference to receive this rate:

Venue: The Union League  
 Address: 140 South Broad Street, Philadelphia, PA 19102  
 Reservations: 215-587-5570

### Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1-877-927-1563, or email data@AmericanConference.com.

## 5 Easy Ways to Register

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 41 West 25th Street  
 New York, NY 10010

**PHONE** 888-224-2480

**FAX** 877-927-1563

**ONLINE**  
 AmericanConference.com/MedicalAffairs

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### CONFERENCE PUBLICATIONS

To reserve your copy or to receive a catalog of **ACI** titles go to [www.aciresources.com](http://www.aciresources.com) or call 1-888-224-2480.

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