From **American Conference Institute**, the creator of **Fraud and Abuse in the Sales and Marketing of Drugs** and **Reducing Legal Compliance Risk in the Sales and Marketing of Medical Devices** comes:

# Life Sciences Compliance Boot Camp

**An Intense Primer on Regulatory and Compliance Fundamentals for Emerging and Established Pharmaceutical, Biotechnology, Biopharmaceutical and Medical Device Companies**

June 28-29, 2010 • Hyatt Regency Mission Bay Spa and Marina • San Diego, CA

## Distinguished Co-Chairs:

*Carolyn McElroy*
Vice President and General Counsel
Pacific Pulmonary Services
(Novato, CA )

*Debra Wong Yang*
Partner & Co-Chair, Crisis Management Practice Group and White Collar Defense and Investigations Practice Group
Gibson, Dunn & Crutcher LLP
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**Renowned compliance officers and in-house counsel as well as leading attorneys will help you fine-tune your compliance 'know-how' as they provide insights into compliance hotspots on the horizon and strategies for perfecting your compliance program.**

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- ASSESS your **compliance needs** to effectively BUILD and FORTIFY your compliance **infrastructure**
- COMPREHEND how **government enforcement trends** are shaping compliance policies
- DECIPER how **aggregate spend legislation** factors into your compliance program
- SEE how **price reporting and reimbursement** may become the next compliance hot spot
- UNDERSTAND the scope of **Medical Affairs** compliance and how it is an essential component of your comprehensive compliance program
- MITIGATE compliance risk in **clinical trials and R&D**
- DETERMINE **SOX** applicability
- RECOGNIZE **HIPAA** and other **privacy** concerns
- APPRECIATE the unique role of **cGMPs** and **QS** in compliance programs – especially in light of the **FDA's new enforcement initiative**
- DEVELOP innovative **audit and risk evaluation** techniques

## June 30, 2010

FCPA and Export Compliance 101:
The Essential Guide for Life Sciences Companies

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Vice President
and General Counsel
Pacific Pulmonary Services
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*Debra Wong Yang*
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Practice Group and White Collar Defense
and Investigations Practice Group
Gibson, Dunn & Crutcher LLP
(Los Angeles, CA)

SPEAKERS:

*Jenny R. Alonso*
Senior Director
Legal Affairs - Compliance
Prometheus Laboratories Inc.
(San Diego, CA)

*Sanjay Bhandari*
Partner
Baker & McKenzie LLP
(San Diego, CA)

*Scott Cunningham*
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(New York, NY)

*Justin Humphreys*
Manager, Ethics & Compliance
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(San Diego, CA)

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Global Medical Affairs
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(Irvine, CA)

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Senior Counsel
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(New York, NY)

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*Natasha Leskovsek*
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*Melissa B. Mannino*
Of Counsel
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(Washington, DC)

*Christina M. Markus*
Partner & Deputy Chair
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& Hampton LLP
(San Diego/Del Mar, CA)

*George Ng*
Senior Counsel & Director
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(Irvine, CA)

*Wes Porter*
VP, Ethics & Compliance
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(Washington, DC)

*Judith A. Waltz*
Partner
Foley & Lardner LLP
(San Francisco, CA)

*Michele Yelmene*
Vice President of Regulatory Affairs
Adventrx Pharmaceuticals
(San Diego, CA)

# Who You Will Meet

- ✓ **In-house counsel and executives and directors responsible for:**
  - **Compliance**
  - **Sales and Marketing**
  - **Medical Affairs**
  - **Regulatory Affairs**
  - **FDA and Food and Drug Regulation**
  - **QA/QC**
- ✓ **Law firm attorneys practicing in pharmaceutical, food and drug and health care law responsible for:**
  - **Compliance**
  - **Fraud and abuse**
  - **White Collar Crime and Government Investigations**

## ACI's

## Life Sciences Compliance

## S E R I E S

For the last 10 years, **ACI** has been on the forefront of providing the life sciences industries with the finest programs addressing every facet of compliance - from regulation to enforcement to implementation. We are proud to bring you the latest installment of this series which has been designed to meet your most pressing compliance needs.


**Fraud and Abuse in the Sale and Marketing of Drugs**
March 2010
(New York, NY)


**Sales and Marketing of Medical Devices**
April 2010
(Chicago, IL)


**Life Sciences Compliance Boot Camp**
June 2010
(San Diego, CA)

The PhRMA Code, OIG Guidance, AdvaMed Code, the FDA's new enforcement initiative, SOX, HIPAA, FCPA and aggregate spend laws — all have been implemented to prevent abuse in diverse areas and to present a framework for compliance.

Come to the one life sciences compliance event that will allow you to make sense of it all.

Fines in the millions — and now billions of dollars, corporate guilty pleas and individual culpability — these factors demand that every life sciences company, from start-ups to emerging companies to established corporate behemoths have a strong compliance program in place. It is 'mission critical' for in-house counsel and executives at every level to develop a strong understanding of compliance related issues. They must be able to formulate solutions to existing compliance shortcomings and short circuit any potential problems.

To help you with these challenges and to make sense of these myriad laws and regulations, **ACI** has designed this intense two-day 'boot camp' to give in-house counsel and executives — at varying levels — a broad and in-depth understanding of the infrastructure of compliance and insights into how compliance will be affected by new legislation and new and ongoing civil and criminal enforcement actions. This conference will let you recognize the common thread which binds compliance in one area to another and understand how these interdepartmental links coupled with external guidance dictate your compliance protocols.

**Create a flexible and fluid compliance infrastructure.**
**Implement best practices.**
**Fine-tune existing compliance protocols.**

We have gathered a faculty of leading compliance officers, renowned in-house counsel and attorneys – a 'who's who' of compliance experts – who will help you:

- Devise strategies for implementing, improving and refining your compliance infrastructure by:
  - taking stock of your current program and implementing effective changes in light of current events
  - incorporating the best audit and risk evaluation techniques to minimize exposure
  - communicating your compliance platform skillfully
- Understand how new legislation from state aggregate spend laws to the HITECH Act to a possible federal overhaul of health care will affect compliance protocols
- Assess the impact of civil and criminal enforcement actions on:
  - fraud and abuse prevention
  - pricing
  - medical affairs
  - advertising and promotion: regulation, off-label concerns and medical affairs
  - privacy and security
  - manufacturing

Also, in response to your requests we have added an in-depth workshop on **FCPA and Export Control Compliance** — specially tailored for the life sciences industry – which will provide compliance strategies for conducting business in and with foreign nations.

This comprehensive course will provide you with the most practical and up-to-date information available to enhance your compliance knowledge base and enable you to better perform your compliance related job functions. Whether you are a new recruit in the pharmaceutical industry or a seasoned veteran, you will benefit from the in-depth course materials and networking opportunities.

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## Monday, June 28, 2010

7:15 **Registration and Continental Breakfast**

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

*Carolyn McElroy*
Vice President and General Counsel
Pacific Pulmonary Services (Novato, CA )

*Debra Wong Yang*
Partner & Co-Chair, Crisis Management Practice Group
and White Collar Defense and Investigations Practice Group
Gibson, Dunn & Crutcher LLP (Los Angeles, CA)

8:30 **Compliance Program Assessment Strategies: Using Objective Criteria to Evaluate Subjective Needs**

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

- Knowing when it is time to start thinking about a compliance program infrastructure
  - identifying triggers
    - NDA filing
    - NDA approval
- Understanding the link between product commercialization and compliance and how this dictates compliance needs
- Assessing key compliance risk areas based on:
  - product portfolio
  - sales model
  - payor mix
  - co-promotion activity
  - distribution model
  - other considerations
- Identifying the seven key elements of a compliance program under the Federal Sentencing Guidelines
- Formulating a compliance program work plan which fits corporate needs and satisfies the seven elements
  - key considerations for:
    - selecting a chief compliance officer
      - creating a compliance committee
    - establishing a reporting structure
      - defining Board of Directors oversight and responsibility
    - allocating resources
    - creating training programs
    - implementing policies and procedures
    - establishing an auditing and monitoring program
    - creating a disclosure program
    - designing an investigation protocol and corrective action process

9:15 **Morning Coffee Break**

9:30 **Building and Structuring A Compliance Infrastructure for Life Sciences Companies: Legalities and Ethics**

*Pamela J. Naughton*
Partner
Sheppard Mullin Richter & Hampton LLP
(San Diego/Del Mar, CA)

*George Ng*
Senior Counsel & Director of Intellectual Property
Spectrum Pharmaceuticals, Inc., (Irvine, CA)

*T. Reed Stephens*
Partner
McDermott Will & Emery LLP (Washington, DC)

- Learning to use the seven elements to design a flexible and global program that can adapt to corporate growth
  - thinking of compliance in global terms – *i.e.,* integral and comprehensive as well as potentially international
- Collaborating with existing departments and corporate functions to establish compliance structure and get necessary "buy-in"
  - importance of top brass taking ownership of compliance program
- Examining compliance program implementation *vis-a-vis* existing company structure
  - which person/department is the best choice to start a compliance program?
    - Legal?
    - HR?
- Appointment of a compliance officer
  - understanding why this may be the most critical component of a compliance program
  - review of compliance officer provisions in recent CIAs
  - special considerations for small to mid-sized companies
  - reporting structure for compliance
    - to whom should the compliance officer report?
      - Board of Directors? Legal?
    - and to whom should the CO never report?
- Where should the compliance department ultimately be placed?
  - can compliance objectives/duties be shared among various departments?
    - separation of departmental duties and implementation of safe guards
  - dotted line reporting responsibilities
    - compliance liaisons
- Why compliance should be separate from legal

11:00 **Government Agencies and Guidance Documents: Understanding the Framers and Framework of Life Sciences Compliance**

*Gary C. Messplay*
Partner
Hunton & Williams LLP (Washington, DC)

*Seth Rodner*
Senior Vice President & Chief Compliance Officer
Medicis Pharmaceutical Corporation (Scottsdale, AZ)

*Key agencies*

- Identifying key government agencies and their compliance oversight powers
  - HHS
    - OIG
    - CMS
    - FDA
  - DOJ
- Non-governmental agencies of which you should also be aware
  - IOM
  - NIH
  - ACCME

*Key Guidances: Government and Industry*

- An overview of the key life sciences compliance guidances concerning interactions with health care professionals
  - breakdown of "dos and don'ts" for sales force interaction with doctors and health care professionals via the Codes and Guidances
    - The PhRMA Code
    - The OIG Guidance
    - The AdvaMed Code
- Understanding the relationship between the guidances and the Federal Sentencing Guidelines.
- Incorporating the tenets of guidance documents into your compliance program
- Examining the 'voluntary' nature of the Codes and Guidances
  - when are they not voluntary?
    - California law
    - Massachusetts law
    - Nevada law
    - DC law
- Turning these external guidance documents into a workable and expandable compliance program tailored to meet the evolving needs of your company

12:15 **Networking Luncheon**

1:30 **Aggregate Spend Laws and Other New Legislation Concerning Interactions with Health Care Professionals and Their Impact on Compliance**

*Jenny R. Alonso*
Senior Director, Legal Affairs - Compliance
Prometheus Laboratories Inc. (San Diego, CA)

*Jody Gleason*
Director, Ethics and Compliance
CareFusion (San Diego, CA)

*Katherine A. Lauer*
Partner
Latham & Watkins LLP (San Diego, CA)

- Overview of existing state aggregate spend laws, *i.e.*, Physician Payment Sunshine laws and the importance of developing compliance protocols to fit their requirements
- Similarities and differences between various state aggregate spend law reporting requirements
  - Maine
  - Massachusetts
  - Minnesota
  - Vermont
  - West Virginia
  - District of Columbia
- Identifying required disclosures under these laws
- Review of carve-outs and exceptions
- Review of pending federal aggregate spend legislation
  - preemption considerations
- How to develop compliance protocols that account for state requirements and have flexibility to account for the proposed federal law should it pass

2:45 **Afternoon Refreshment Break**

3:00 **SOX Compliance Safeguards for Life Sciences Companies**

*Kent W. Easter*
Shareholder
Stradling Yocca Carlson & Rauth (Newport Beach, CA)

- When should you start thinking about SOX applicability?
  - is your company about to go public?
  - do you have any plans to eventually go public?
- Identifying the basic components of SOX compliance
- Which SOX requirements are applicable to the life sciences industry?
- Incorporating SOX protocols into your compliance program
  - how criminal liability and whistle blower provisions under SOX should be factored into your compliance program
- Enumerating the responsibilities of the Board of Directors, Audit Committee, CFO and Chief Legal Officer with respect to SOX certification requirements

3:45 **Key Privacy Considerations for Any Life Sciences Compliance Program**

*Jacqueline Klosek*
Senior Counsel
Goodwin Procter LLP (New York, NY)

- Applying HIPAA protocols to pharmaceutical, biotechnology and device companies
- HIPAA Privacy Rule compliance
  - identifying the essential elements of HIPAA privacy compliance and incorporating them into your global compliance plan
- HIPPA Security Rule compliance
  - essential elements, required documentation and risk analysis
- Examining business associate requirements
- Review of provisions under the HITECH Act impacting HIPAA compliance and their applicability to life sciences companies

4:30 **Government Enforcement Trends that Dictate Compliance Protocols**

*Ellen L. Janos*
Member
Mintz Levin Cohn Ferris Glovsky & Popeo PC (Boston, MA)

*John Skousen*
Compliance Officer
Life Technologies (Carlsbad, CA)

- Overview of the federal False Claims Act and state federal anti-kickback laws as they apply to the life sciences industries
  - safe harbors
- How actions brought under these laws against life sciences companies have used "real world" applications of the Codes and Guidance to prove violations
- TAP: an examination of the case that started it all and why it is still significant for compliance
- Exploring the evolution of enforcement actions from sales and marketing violations through medical affairs deviations
  - *Neurontin*
  - *Synthes*
  - *Harkonen*
  - *Zyprexa*
  - *Bextra*

- Reviewing circumstances in which corporate executives and employees have been indicted in addition to the company
- Exploring settlements and Corporate Integrity Agreements (CIAs)
  - understanding the terms of CIAs and what compliance lessons can be gleaned from them
- Predictions for future enforcement trends
  - pricing and reimbursement?
- Implementing best practices through compliance protocols to avoid situations giving rise to violations

5:45 **Conference Adjourns to Day Two**

## Tuesday, June 29, 2010

7:45 **Continental Breakfast**

8:30 **Co-Chairs' Opening Remarks and Recap of Day One**

8:45 **Medical Affairs: Understanding Its Role in Your Compliance Program**

*Scott Cunningham*
Partner
Covington & Burling LLP (Washington, DC)

*Steven P. James, MD, MBA*
Vice President, Global Medical Affairs
Allergan (Irvine, CA)

*Robyn B. Stanton*
Division Counsel, Legal Regulatory & Compliance
Abbott Vascular (Santa Clara, CA)

- Defining medical affairs within the purview of the Codes and Guidance
- Understanding the importance of medical affairs compliance to your overall global compliance program
- Reviewing critical changes in the PhRMA Code 2008 relative to medical affairs compliance
  - CME
  - grants
  - promotional materials
- How pharmacovigilance and adverse events reporting under FDAAA should be factored into your compliance program
- How medical affairs has become a hot bed of compliance enforcement actions
- Exploring the proper relationship between sales and marketing and medical affairs
- Developing guidelines for post-marketing studies
- Examining off-label use concerns
  - guidelines for off-label communications
  - role of MSLs in these communications
- Advisory board protocols

10:00 **Morning Coffee Break**

10:15 **Managing Compliance Risks in Clinical Trials and R&D**

*Natasha Leskovsek*
Partner
Cooley Godward Kronish LLP (Washington, DC)

*Michele Yelmene*
Vice President of Regulatory Affairs
Adventrx Pharmaceuticals
(San Diego, CA)

- How to develop a comprehensive compliance program relative to clinical trials and R&D
- Compliance considerations for:
  - subjects
  - investigators
  - sites
  - CROs and other vendors
  - financing
- Clinical trials registration and results requirements under FDAAA
- Review of PhRMA's Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results
  - clinical trial registries
  - summaries of all clinical-trial results
  - ghostwriting prohibitions
  - disclosure of financial conflicts of interest

11:15 **Price Reporting and Reimbursement Compliance**

*Joan D. Mimnaugh*
Senior Director, Pricing & Contracting
Santarus, Inc. (San Diego, CA)

*Judith A. Waltz*
Partner
Foley & Lardner LLP (San Francisco, CA)

- Compliance guidelines for participating in Medicare, Medicaid, VA and DoD programs
- Price reporting authorities, programs and vocabulary
  - CMS
    - Medicaid
      - Best Price: AMP
    - Medicare: Parts B and D
      - ASP
      - ASP + 6
      - CAP
      - WAMP
  - VA/ DOD
    - GSA, FSS
- Special pricing and reimbursement compliance concerns for devices
- Devising price reporting strategy assessments
- When and how should companies best communicate changes in price reporting methodologies to appropriate authorities
- Red flags that regulators and enforcers look at when investigating price reporting fraud and abuse?
- How to best involve your compliance department in price and reporting and reimbursement matters
- Why is pricing and reimbursement considered by many as the next compliance enforcement hot spot?

12:30 **Networking Luncheon**

1:45 **Understanding the Importance of cGMP and Quality Systems Compliance in an Era of Heightened FDA Enforcement**

*Christina M. Markus*
Partner & Deputy Chair of the FDA & Life Sciences Group, King & Spalding L.L.P.
(Washington, DC)

- Identifying essential elements of cGMP and quality systems compliance and incorporating them into your global compliance program
- Which departments should coordinate in the development of a proactive and effective quality system?
  - what is the role of compliance in this implementation?
- Examining the FDA's approach to quality systems in light of new agency enforcement initiatives
  - what does the agency expect?
  - what must you now do to demonstrate compliance during an inspection?

2:45 **Afternoon Refreshment Break**

3:00 **Using Audits and Risk Evaluation to Assess the State of Your Compliance Program**

*Justin Humphreys*
Manager, Ethics & Compliance
CareFusion (San Diego, CA)

*Wes Porter*
VP, Ethics & Compliance
CareFusion (San Diego, CA)

- Using risk management principles to develop a meaningful and effective compliance audit program for your compliance department
- Improving existing audit programs through the incorporation of innovative risk management techniques
- Assessing the proper roles of inside and outside auditors
- Analyzing audit results: how to develop strategies for managing and minimizing identified risks
- Safeguarding against unforeseen, undefined risks

4:15 **Conference Ends**



## POST-CONFERENCE WORKSHOP
## WEDNESDAY JUNE 30, 2010, 9:00 AM – 12:30 PM
(Registration opens at 8:00 a.m. – Continental Breakfast will be served)

### FCPA and Export Compliance 101: The Essential Guide for Life Sciences Companies

*Sanjay Bhandari*
Partner
Baker & McKenzie LLP
(San Diego, CA)

*Melissa Mannino*
Partner
Wilson Sonsini Goodrich & Rosati
(Washington, DC)

*Wes Porter*
VP, Ethics & Compliance
CareFusion
(San Diego, CA)

The life sciences industry must think globally – in terms of both product portfolio and international reach. As such, it is essential for FCPA and export control protocols to be addressed in every life sciences compliance program. This intensive workshop will provide you with a compliance blueprint for conducting business in other countries and outline what these protocols require. Points of discussion will include:

*FCPA*

- Overview of The Foreign Corrupt Practice Act (FCPA)
- Evaluation of FCPA risks facing life sciences companies today
- Review of DOJ and SEC FCPA Enforcement Actions which have directly impacted life sciences companies
  - red flags to watch for
- The impact of FCPA in countries where doctors are considered government employees, *e.g.,* National Health Services
- What FCPA compliance and accounting controls does the government expect a life sciences companies to have in place
- Methods for incorporating FCPA protocols into your domestic compliance program

*Export Controls*

- Defining exports and export control compliance
- Identifying key agencies that regulate export transactions
  - who is subject to these rules and when do they apply to activities and persons outside of the U.S.?
- Key export compliance risks for the life sciences industries
- U.S. sanctions and targets: countries?; individuals?; other entities?
  - what do U.S. economic and trade sanctions prohibit?
- Understanding the meaning of "know your customer"
- Demystifying U.S. antiboycott laws

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POST-CONFERENCE WORKSHOP
JUNE 30, 2010

FCPA and Export Compliance 101:
The Essential Guide
for Life Sciences Companies

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