

American Conference Institute's 8th National Conference on

REDUCING LEGAL RISKS IN THE SALE AND MARKETING OF MEDICAL DEVICES

FORTIFYING FRAUD AND ABUSE COMPLIANCE EFFORTS
IN THE FACE OF INCREASING GOVERNMENT SCRUTINY

November 17-18, 2008 – The Allerton Hotel on the Magnificent Mile – Chicago, IL

DISTINGUISHED CO-CHAIRS:



Neal R. Roach, Jr.
Taft Stettinius & Hollister LLP



Tracy Palmer Berns
Associate General Counsel, Covidien

Hear these regulators and enforcers clarify
the legality of practices and relationships:

Bryan H. Benesch
CDRH, FDA

Thomas J. Meier
Branch Chief, SEC

Virginia A. Gibson
U.S. Attorney's Office, E.D. Pa.

Laura G. Hoey
U.S. Attorney's Office, E.D. Ark.

Ana Maria Martinez
U.S. Attorney's Office, S.D. Fla.

Sean R. McKenna
U.S. Attorney's Office, N.D. Tex.

Jeremy M. Sternberg
U.S. Attorney's Office, D. Mass.

Hank Bond Walther
Crim. Div. Fraud Section, U.S. DOJ

Linda A. Wawzenski
U.S. Attorney's Office, N.D. Ill.

Special Session on *Ongoing Monitoring
in the Industry and the Evolving Role of the
Independent Corporate Monitor*, led by:



David Samson
Wolff & Samson PC
former New Jersey Attorney General



David N. Kelley
Cahill Gordon & Reindel LLP
former U.S. Attorney, S.D.N.Y.

17 experienced in-house attorneys and compliance officers from these companies:

**Animas • Bard • Bayer • BD • Biomet • Covidien • Cyberonics
GE Healthcare • Hospira • Medtronic • Roche Diagnostics • Siemens**

...as well as 9 government enforcers and regulators and leading outside counsel will help you:

- REASSESS your compliance program as a result of the Deferred Prosecution Agreements
- DISSEMINATE peer-reviewed studies of **off-label** uses and AVOID FCA/FFDCA scrutiny of off-label promotion
- AVOID **anti-kickback** red flags when handling activities involving prescribers and purchasers, including **grants, gifts, entertainment, and free goods**
- DESIGN compliant policies and procedures for **consulting arrangements**, including FMV determination and **needs assessments**
- RESPOND to government inquiries and NEGOTIATE and IMPLEMENT **Corporate Integrity Agreements**
- REDUCE the risk of FCPA investigations and violations
- OVERCOME the current coverage, coding, and payment challenges with device **reimbursement**
- EXAMINE the appropriate circumstances for discounting, bundling and price concessions
- IDENTIFY legal parameters of **DTC marketing**, including "new media"
- TRACK state legislative initiatives on device promotion and HARMONIZE inconsistent state obligations

Plus, register for the Master Class on Compliance Process Management:
**IMPLEMENTING AND EXPANDING EFFECTIVE MONITORING AND AUDITING
CONTROLS AS PART OF YOUR OVERALL COMPLIANCE PROGRAM**
NOV. 19, 2008 – 9 A.M.-12 P.M.

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Congress is focusing on disclosure and transparency in the device industry like never before and enforcement authorities are stepping up the number and aggressiveness of investigations of device companies' doctor relationships.

There has never been a more important time to attend the industry's best forum on enhancing sale and marketing compliance functions.

Increased focus on the sale and marketing activities of device manufacturers is here:

DPA/CIA/NPA, monitors, and consulting arrangements...

The Senate bill on disclosure to patients of doctors' financial ties to device companies...

Huge settlements as a result of improper gifts and giveaways...

Federal prosecutors targeting medical device companies in FCPA investigations...

New guidance on the dissemination of peer-reviewed studies of off-label uses...

And these developments are in addition to the uncertainty device companies already face in creating effective compliance programs (in areas such as **grants, entertainment, and free goods**), as well as the continuing obligation to keep tabs on the traditional sales and marketing activities that have triggered enforcement in the past, *i.e.* off-label promotion, direct-to-consumer marketing.

As device companies continue to adapt to the "new world order" of scrutiny in their attempt to stay on the right side of law, *it's not enough to just have a compliance program in place.* In response, ACI is proud to introduce its **8th National Conference on Reducing Legal Risks in the Sale and Marketing of Medical Devices**. Through a faculty of 17 distinguished in-house counsel and compliance officers, 9 government enforcers and regulators, and leading outside counsel, this conference will provide attendees with the strategies needed to not only develop an ethical compliance infrastructure, but also the ability to show commitment to compliance through intensive training, supervision, and monitoring, as well as the skills needed to remediate before the prosecutors come knocking and the knowledge on when and how to cooperate if they do.

PLUS, add value to your attendance by also registering for the Master Class on Compliance Process Management:

Implementing and Expanding Effective Monitoring and Auditing Controls as Part of Your Overall Compliance Program

Nov. 19, 2008 – 9 a.m. – 12 p.m.

Register now by calling 888-224-2480, faxing your registration form to 877-927-1563 or registering online at www.AmericanConference.com/MedicalDevices

Who You Will Meet

- In-house counsel, VPs of Sales and Marketing and compliance officers for the medical device industry
- Attorneys who specialize in the following practice areas:
 - Fraud & Abuse
 - Medical Device Regulation
 - Advertising & Marketing
 - Healthcare Compliance
 - Food & Drug
 - Medicare & Medicaid Reimbursement

Continuing Legal Education Credits



Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as **nontransitional** for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board in the amount of 18.0 hours. An additional 3.5 credit hours will apply to workshop participation.

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Medical Industry Week



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Day One: Monday, November 17, 2008

7:20 Registration and Continental Breakfast

8:00 Co-Chairs' Opening Remarks

Neal R. Roach, Jr.

Partner

Taft Stettinius & Hollister LLP (Indianapolis, IN)

Tracy Palmer Berns

Associate General Counsel

Covidien (Mansfield, MA)

8:05 The Enforcers Speak: Providing Clarity and Guidance on the DPAs and the Legality of Sale and Marketing Practices and Relationships Specific to the Device Industry

Virginia A. Gibson

Assistant U.S. Attorney and Chief, Civil Division

U.S. Attorney's Office, Eastern District of Pennsylvania

Laura G. Hoey

Assistant U.S. Attorney, Criminal Division, Health Care

Fraud Coordinator

U.S. Attorney's Office, Eastern District of Arkansas

Ana Maria Martinez

Assistant U.S. Attorney

U.S. Attorney's Office, Southern District of Florida

Sean R. McKenna

Assistant U.S. Attorney

U.S. Attorney's Office, Northern District of Texas

Jeremy M. Sternberg

Assistant U.S. Attorney

U.S. Attorney's Office, District of Massachusetts

Hank Bond Walther

Trial Attorney, Criminal Division's Fraud Section

U.S. Department of Justice

Linda A. Wawzenski

Assistant U.S. Attorney and Deputy Chief, Civil Division

U.S. Attorney's Office, Northern District of Illinois

Moderator:

Nicholas C. Theodorou

Partner

Foley Hoag LLP (Boston, MA)

former Assistant U.S. Attorney in the U.S. Attorney's Office for the District of Massachusetts

- The DPAs: Reassessing your compliance programs in light of new requirements defined in the agreements
 - examining whether they signal a trend toward increasing use of DPAs in health care investigations and/or an effort to achieve industry-wide reform
- What types of practices/violations in the device industry are currently attracting government scrutiny?
 - activities susceptible to investigation and/or prosecution and business practices that raise red flags
 - how does the government decide whether it should proceed on a civil vs criminal basis?
- Concrete strategies to implement to minimize the risk of prosecution
- The benefits of self-disclosure and how to provide disclosure protections
- What device manufacturers should expect once the government has served a subpoena and how to effectively respond to a government investigation

- examining new attorney-client privilege issues during federal investigations, including the latest on the Attorney-Client Privilege Protection Act of 2007
- How to get the enforcers to notice your company's strong compliance program
- What should medical device companies expect to see in 2009 and in the next 5 years?

10:20 Morning Coffee Break

10:35 Providing Information About Devices to Doctors, Disseminating Peer-Reviewed Studies of Off-Label Uses and Avoiding FCA/FFDCA Scrutiny of Off-Label Promotion

Laurie A. Clarke

Partner

King & Spalding LLP (Washington, DC)

Sharon Post

Manager General Legal Compliance

GE Healthcare (Wauwatosa, WI)

SanDee I. Priser

Partner, Fraud Investigation & Dispute Services

Ernst & Young LLP (Chicago, IL)

Processes and Controls for the Dissemination of Information

- The current role of the FDA on dissemination issues and the FDA's current thinking regarding the distribution of medical journal articles and scientific or medical reference publications that discuss unapproved new uses of approved or cleared medical devices
- Clarification of the issues left open by the FDA's proposed "principles of Good Reprint Practices" that would allow device companies to distribute articles from medical and scientific journals that discuss unapproved uses of medical devices
 - how the guidance can be both more and less restrictive
- Going forward, how do device manufacturers distribute reprints on off-label uses?
 - carefully reviewing your practices against the draft guidance (or the final version)
 - determining whether to modify your procedures with regard to:
 - limitation on the types of acceptable publications (abstracts; sponsored pubs)
 - the materials and information expected to accompany a reprint
 - separation between science and sales/marketing
- Examining off-label claims regarding dissemination of white papers (as distinguished from peer-reviewed published papers)
- Overcoming the difficulty of citing learned journal articles that might mention something in passing about a potential off-label use of a device

Minimizing Exposure to Liability from Off-Label Use

- Knowing what factors the government considers when conducting off-label investigations
- Understanding the legal liability associated with off-label promotion: FFDCA, FCA, and beyond
- Designing successful, cost-effective in-house programs to communicate the dangers of off-label marketing throughout your company
- Learning from mistakes: an examination of recent off-label prosecutions and settlements, including the Seventh Circuit *Caputo* decision finding a device company CEO and CCO criminally liable for off-label marketing

THE ANTI-KICKBACK STATUTE (INCLUDING ADVANCED CODE ISSUES): AVOIDING RED FLAGS WHEN HANDLING ACTIVITIES INVOLVING PRESCRIBERS AND PURCHASERS

11:45 Critically Reviewing Your Existing Arrangements With Physicians

Mark N. Bonaguro
Chief Compliance Counsel
Covidien (Mansfield, MA)

Christina F. Rich
Principal Legal Counsel
Medtronic, Inc. (Minneapolis, MN)

Moderator:

Neal R. Roach, Jr.
Partner
Taft Stettinius & Hollister LLP (Indianapolis, IN)

It has never been more important to critically review and document all terms of arrangements with physicians to avoid unlawfully inducing the prescribing or purchasing of products. This panel of experts will help you reduce the risk that your business practices offer the appearance of impropriety and raise red flags. They will focus on:

- Educational and research grants and funding
- Product education and training
- Travel expenses for training
- Promotional meetings with physician participation
- Support for third-party educational conferences
- Gifts, meals, recreation and entertainment
- Charitable contributions and donations
- Physician investments in and joint ventures with manufacturers, distributors, and GPOs

The panel will also focus on transparency efforts including the Senate Bill on disclosure to patients of doctors' financial ties to device companies.

12:55 Networking Luncheon Sponsored by:

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Special Address:
Richard F. Kingham
Partner
Covington & Burling LLP

2:05 Spotlight on Consulting Arrangements: Designing Compliant Policies and Procedures — and then Managing the Process

Cynthia M. Arndt
Senior Legal Director
Medtronic, Inc. (Minneapolis, MN)

David A. Hile
Senior Managing Director – Forensic & Litigation Consulting
FTI Consulting, Inc. (Nashville, TN)

Brian J. Leddin
Associate General Counsel, Compliance and Litigation
C.R. Bard, Inc. (Murray Hill, NJ)

Moderator:

Brien T. O'Connor
Partner
Ropes & Gray LLP (Boston, MA)
former Chief of Public Corruption and Special Prosecutions in the U.S. Attorney's Office for the Dist. of Mass.

The Business Need and the Needs Assessment for Consulting Agreements

- Identifying the need
- Performing a needs assessment before entering into a consulting arrangement, to show evidence that the doctor will be performing services that will benefit the company
- Developing, presenting, and defending these plans in light of federal scrutiny

Identifying the Consultant

- Conducting a selection process with objective criteria aligning potential consultants' qualifications with business need
- Verifying a consultant's credentials, and implementing an effective policy in this regard

Drafting and Executing a Fair and Thorough Contract that Reflects Fair Market Value for Services

- Defining the parameters of the agreements to minimize inspection: factoring in the industry standards and the red flags to watch out for
- Determining accepted methodologies for the determination of FMV even with limited regulatory guidance
- Determining FMV for marketing and development activities such as focus groups and design validation of new products

Monitoring the Arrangement

- Maintaining accurate and appropriate records to adequately defend partnerships and payments for consulting services
- Documenting deliverables and how a consultant's work product is being used by the company
- Requiring time sheets
- Creating and monitoring electronic databases to document arrangements and interactions with physicians and other potential sources of business or referrals
- Closely tracking remuneration, as well as service and activity logs to ensure that doctors are doing the work they're being paid for
- Showing evidence that the arrangement is still needed come renewal time
- Adequately training the consultant and ensuring regular interaction with him/her

3:20 Afternoon Refreshment Break

3:30 Examining Ongoing Monitoring in the Industry and the Evolving Role of the Independent Corporate Monitor in Light of Enhanced Scrutiny

David N. Kelley

Partner
Cahill Gordon & Reindel LLP (New York, NY)
former U.S. Attorney for the Southern District of New York

David Samson

Partner
Wolff & Samson PC (West Orange, NJ)
former New Jersey Attorney General

- Determining whether the DPAs reflect a trend toward or against increasing use of monitors at the federal level - how their role and authority is currently being defined
- Critical information on what monitors will be looking at when evaluating a needs assessment
- What factors are to be considered in determining whether a monitor (as opposed to an IRO) is needed?
- Enlisting and cooperating with an in-house compliance monitor
- Assessing the impact of a monitor on your day-to-day business operations
- Developing a plan of action: what to expect if your company faces federal monitoring
- Costs: Evaluating the costs of having a monitor and the costs of failing to have one

4:30 **Device Companies Under Investigation:
Seamlessly Responding to Government Inquiries
and Negotiating and Implementing Corporate
Integrity Agreements**

Peter Henderson

Americas Compliance Manager
GE Healthcare (Wauwatosa, WI)

Karen F. Green

Partner

Wilmer Cutler Pickering Hale and Dorr LLP (Boston, MA)
former First Assistant U.S. Attorney for the U.S. Attorney's
Office for the District of Massachusetts

Teresa I. Ford

Law Offices of Teresa Ford, PC (Houston, TX)

Moderator:

Lynn Shapiro Snyder

Senior Member

Epstein Becker & Green, P.C. (Washington, DC)

Responding to Government Inquiry, Including Subpoenas

- Internal remediation from the start: Finding out what the facts really are, and if you find something wrong, fixing it before the prosecutor tells you to fix it
- To cooperate or not to cooperate?: Educating and working with prosecutors but ensuring your company doesn't say too much too soon
- How can a company best initiate resolution discussions with the government?: Effectively responding to government investigations and subpoenas
 - the documents you are and are not required to submit
 - instituting effective document holds
 - complying with mandatory reporting obligations
 - ensuring accuracy/completeness of information provided to maintain company credibility
 - avoiding conduct that could give rise to further investigation, such as obstruction
- What you now need to know about the attorney-client privilege during federal investigations
- Controlling collateral damage: What steps can a company take to ensure that any resolution is a global one and will not merely lead to follow-on litigation?

*Life Under a CIA and How to Exert Your Influence
When Negotiating One*

- Lessons learned from the recent CIAs
 - rigorous compliance programs, codes of conduct, employee training and beyond
 - the latest on creating and monitor electronic databases to document arrangements and interactions with physicians and other potential sources of business or referrals
 - examining the extended reach of CIAs to independent distributors of company's products
- Defining the scope of the alleged violation and agreement as narrowly as possible in terms of geographic location, business unit or business process
- Limiting which employees must undergo the most extensive level of compliance training under the agreement
- Negotiating the ability to internally monitor adherence to integrity agreements with a third party that reviews your audit process, as opposed to hiring an IRO for all oversight

5:45 **Conference Adjourns**

5:45 **Networking Cocktail Reception Hosted by:**



Day Two: Tuesday, November 18, 2008

7:30 Continental Breakfast

8:00 Co-Chairs' Remarks

8:00 **CDRH/FDA Spotlight Address**

Bryan H. Benesch

Special Assistant to the Director, Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration (Rockville, MD)

Mr. Benesch will discuss the overriding philosophy, goals, and priorities within CDRH at this juncture, help you structure your compliance program to reflect current priorities on domestic and international promotion and advertising (including FDA warning letters and FDA untitled letters), and tell you what to expect to be high on the Center's agenda for the future.

THE GLOBAL COMPLIANCE RISK

8:35 **Reducing the Risk of FCPA Investigations
and Violations**

Thomas J. Meier

Branch Chief

Securities and Exchange Commission (Chicago, IL)

Daniel Garen

Chief Compliance Officer

Siemens Medical Solutions USA (Tarrytown, NY)

Donald J. Ridings Jr.

Attorney

Covington & Burling LLP (Washington, DC)

Lawrence T. Weiss

Vice President – Chief International Counsel

Covidien (Mansfield, MA)

Moderator:

Michael C. Theis

Partner

Hogan & Hartson LLP (Denver, CO)

former Assistant U.S. Attorney and Criminal Health Care
Fraud Coordinator for the District of Colorado

- Identifying the industry-specific FCPA issues for medical device companies
- Defining "anything of value": what activities by your sales people are considered a bribe?
- Conducting an internal assessment to identify potential areas of risk under the FCPA
 - examining the various aspects of foreign operations such as relationships with distributors, joint venture partners, customers, resellers, agents, and reps, etc.
 - everything you need to know about liability for the actions of your agents and contractors operating on foreign soil
- Review your existing compliance policies and procedures to ensure that they address bribes and other improper payments to non-U.S. officials
- Analyzing financial relationships with physicians in nations with large public health systems
- Identifying the point when a business activity becomes an SEC violation and adjusting your practices accordingly
- Ongoing FCPA training and educating employees about the risks of FCPA
- China and other emerging markets: Managing the risks presented by established cultural norms which present compliance challenges for US-based multinational companies and developing training methods to overcome these challenges

10:10 Factoring in Unique International Ethics Codes and Legal Requirements

Grant H. Castle

Partner

Covington & Burling LLP (London)

Kris Rapp

Vice President, Global Ethics & Compliance

Hospira, Inc. (Lake Forest, IL)

- The current landscape on non-U.S. trade associations' codes of ethics – how do the codes differ from the PhRMA and AdvaMed Codes and what changes have occurred recently?
- Complying with other unique local legal standards around the globe
- Examining the consequences of decisions outside of the U.S. that put companies in conflict with U.S. legal requirements for whistleblowers/reporting requirements and other code provisions
- Additional steps to take to reduce compliance risks (and penalties) related to sale and marketing practices outside the U.S.

10:55 Morning Coffee Break

11:05 Examining the Appropriate Circumstances for Discounting, Bundling, and Price Concessions

Kevin G. McAnaney

The Law Offices of Kevin G. McAnaney (Washington, DC)
former Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General

Jody A. Gleason

Compliance Manager

GE Healthcare Integrated IT Solutions (Barrington, IL)

- How to protect the discount and alternative compliance strategies
- Examining the discount safe harbor
 - what is the same reimbursement methodology?
 - when is a discount properly disclosed and appropriately reflected on a cost report or a claim?
- Avoiding common problems and thorny issues associated with discounts:
 - free goods
 - bundled goods
 - rebates and prebates
 - changing out old inventory/conversion payments
 - GPOs and administrative fees
- Defining the discount: When is a discount not a discount?
 - determining whether meeting the competition's price is a discount or the fair market value price
- Documenting the discount and following the documentation

12:00 Device Reimbursement: Overcoming the Current Coverage, Coding, and Payment Challenges

Jeffrey Bush

Director, Corporate Reimbursement

BD (Franklin Lakes, NJ)

Allison Shuren

Partner

Arnold & Porter LLP (Washington, DC)

- FDA's current interaction with CMS on device coverage and reimbursement
- Analyzing the interplay between reimbursement and regulatory, clinical, sales and marketing, legal, and government affairs

- Examining potential Anti-Kickback and False Claims Act violations that could stem from your reimbursement policy, and the current OIG and DOJ enforcement priorities
- Ensuring improper reimbursement advice is not given to customers by the sales force
- Evaluating other risk areas for your reimbursement policies:
 - the timing of reimbursement actions
 - the appearance of price manipulation
 - marketing return on investment
 - off-label promotion
- New Technologies
 - examining the increasing burden of evidence and investment needed for reimbursement of new technologies
 - recent developments with regard to the transitional pass-through payment process for new technologies
- Using training and auditing programs to avoid headaches over improper billing and getting a handle on the device company's role in coding
- Avoiding fraud and abuse liability when seeking Medicare reimbursement for clinical costs

12:55 Networking Luncheon for Speakers and Delegates

2:00 Clinical Trials: The Current Fraud and Abuse Landscape on Pre- and Post-Market Device Human Subject Research Arrangements

Ralph F. Hall

Counsel, Baker & Daniels LLP (Indianapolis, IN)

Distinguished Visiting Practitioner and Professor,
University of Minnesota Law School (Minneapolis, MN)
former Senior Vice President and Deputy General Counsel-Litigation & Compliance at Guidant

David M. Ryan

Partner

Nixon Peabody LLP (Boston, MA)

- Promotional claims and FDAAA expanded registry and results databank requirements: what you now need to know and what you can and can't say when publishing study results
- Clinical trial impropriety and conflicts of interest when interacting with HCPs: avoiding improper payments and meeting disclosure requirements, including those associated with doctors who have financial stakes in the devices they help develop
- Post-marketing rigor: Minimizing fraud and abuse risks of post-market studies and policies
- The appropriate use of data from clinical trials and post-market studies without violating off-label promotion rules
- Examining and attempting to clarify the FDA's standard for "adequate and well controlled studies" in the context of off-label use
- Examining the use of a clinical issue to promote a device when the clinical issue is not exactly what the device is cleared for
- Educating the sales force on the use of clinical trial information
- Factoring in the enforcement environment
 - warning letter trends
 - Ortho settlements: lessons learned before beginning your next trial

3:00 Afternoon Refreshment Break

3:10 TV, Radio, Print and "New Media": Identifying Legal and Business Parameters for DTC Marketing of Medical Devices

Tracy Palmer Berns

Associate General Counsel
Covidien (Mansfield, MA)

Cathy Garrison
Litigation Specialist
Biomet, Inc. (Warsaw, IN)

Shirrell Gross
Senior Counsel
Bayer HealthCare, Diabetes Care (Tarrytown, NY)

Moderator:

Jeffrey K. Shapiro
Director

Hyman, Phelps & McNamara, P.C. (Washington, DC)

- Reviewing the rules and guidance from FDA, FTC, and other regulatory agencies
 - CDRH scrutiny and oversight of ads: in absence of concrete guidance, how to present balance between risk and benefit information
 - predicting issues the FDA will soon be examining
- Adequately conveying safety information about complex devices in DTC device ads
- Ensuring that physicians are not alienated by targeting the public through DTC
- Developing an effective method for reporting consumer complaints and tracking ad success
- Safeguarding against ads that veer into off label or false claims practices
- Reducing private litigation risks stemming from the Lanham Act and product liability and consumer fraud laws
- Applying lessons learned from actions against pharma companies to your DTC plan
- The Internet
 - presenting accurate and balanced information to millions of online consumers
 - the fine line between education and promotion in website ads
 - new media: the legal responsibilities associated with using blogs, social networking sites, and message boards for marketing purposes

4:25 Tracking State Legislative Initiatives and Harmonizing Inconsistent State Obligations Affecting the Sale and Marketing of Devices

Robert S. Salcido
Partner

Akin Gump Strauss Hauer & Feld LLP (Washington, DC)
former trial attorney with the U.S. DOJ in the Civil Fraud Unit

- Clarifying the confusion (and minimizing the potential for non-compliance) associated with the myriad state obligations that affect the sale of medical devices, including:
 - marketing initiatives, including California, Nevada, and Florida
 - gift registries
 - disclosure requirements
 - healthcare professional spending and price discount limits
 - sales representative restrictions
- The potential impact of developing state legal standards on your business practices and cost-effective implementation mechanisms
- Implementing procedures for staying on top of obligations under new state initiatives
- Practical solutions for aggregate spend tracking
- What legislation is pending? – monitoring the current proposals
- What does the future hold? – how federal preemption in the courts and/or the Senate Bill on disclosure to patients of doctors' financial ties to device companies may change the landscape

5:25 Conference Ends

Wednesday, November 19, 2008
9 a.m. – 12 p.m. (Registration Opens at 8:30 a.m.)

**MASTER CLASS ON
COMPLIANCE PROCESS MANAGEMENT**

**Implementing and Expanding Effective
Monitoring and Auditing Controls as Part
of Your Overall Compliance Program**

Brian Kelly

Director, Healthcare Compliance and Privacy
Animas Corporation, a Johnson & Johnson company
(West Chester, PA)

Karl H. Buch

Counsel

Chadbourne & Parke LLP (New York, NY)

former Assistant U.S. Attorney for the District of New Jersey

Teresa I. Ford

Law Offices of Teresa Ford, PC (Houston, TX)

Congress and state legislatures have never been more focused on disclosure and transparency in the device industry than they are now. Plus, government enforcers have gotten more aggressive in investigating and targeting device companies regarding questionable relationships with physicians.

As a result, it's not enough to just have a compliance program in place relating to doctor perks and payments. It's up to each company to show commitment to current law and demonstrate evidence that their compliance program works through effective monitoring and auditing. This master class will expand upon the legal risk developments presented in the conference to help you measure the effectiveness of your current compliance program and implement and expand innovative monitoring and auditing controls. Action points include:

Risk Management Techniques from the Start

- Managing and minimizing identified risks and safeguarding against unforeseen and unidentified risks
- Using innovative risk management principles to ensure effectiveness and success of your compliance program

Assessment

- Conducting a thorough compliance assessment and review of your current activities
- Identifying potential key areas for non-compliance and re-structuring your program to prevent fraud and abuse
- Developing and implementing processes for auditing and monitoring and then expanding upon them as the standard
- Benchmarking: Examples of the best auditing/monitoring measures of compliance for a sales organization

Company Training as a Whole

- Integrating and incorporating compliance training programs into your organization and assessing the effectiveness of this training
- Developing better training programs in alliance with government regulations and internal compliance programs
- Instilling a culture of ethical compliance from the top down and driving that message company-wide

Focus on Personnel/Employees/Sales Force

- Increasing the level and intensity of sophisticated training for sale and marketing staff
- Keeping your sales force current on legal and ethical rules and on the risks associated with basic marketing practices that may be fully acceptable in other lines of business
- Delivering adequate sophisticated education/training to employees on the AdvaMed Code
- Educating your sales force about common government triggers
- Techniques for policing violations and auditing salespeople
- Sales force compensation: ensuring compensation and evaluation strike the right balance between performance and compliance requirements

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Experienced faculty from:

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PROCESS MANAGEMENT

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Nov. 19, 2008 – 9 a.m. - 12 p.m.

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