Industry Perspectives:

Minnie Baylor Henry, Vice President, Medical and Regulatory Affairs, **McNeil Consumer & Specialty Pharmaceuticals**

Ann Beasley Bacon, Senior Corporate Counsel, **Sepracor Inc.**

Rick Cassino, Vice President, HCC, **Johnson & Johnson Pharmaceuticals Group**

Gordon M. Chapman, Senior Director, Asia Pacific Compliance, **Bristol-Myers Squibb Company**

Colleen M. Craven, Vice President, Ethics and Corporate Compliance, **Endo Pharmaceuticals**

Kris Curry, Director, HCC Operations, **Ortho McNeil Janssen**

Kim Elting, General Counsel, **ANS Medical (subsidiary of St. Jude Medical)**

Margaret K. Feltz, Associate Director, Corporate Compliance, **Purdue Pharma L.P.**

Indrani M. Franchini, Deputy Compliance Officer, Worldwide Programs, Senior Corporate Counsel, **Pfizer Inc**

Robert Freeman, U.S. Compliance Officer and Compliance Counsel, **Serono, Inc.**

Roy Galan, Assistant Director of Sales Training, **Astellas**

Daniel Garen, Chief Compliance Officer, **Siemens Medical Solutions Diagnostics**

Gary Giampetruzzi, Senior Corporate Counsel, **Pfizer Inc**

Tom Glavin, Deputy Compliance Officer, **Shire**

Jeffrey Greenman, Vice President, Compliance, **Bayer**

Monica Jonhart, Director, Compliance and Auditing, **Bristol-Myers Squibb**

Stephen Kanovsky, U.S. Compliance Officer, **sanofi-aventis**

Fabiana Lacerca, Legal Compliance Director, **Bristol-Myers Squibb**

Ed Miller, Chief Compliance Officer, **Boehringer Ingelheim Pharmaceuticals**

Anne Nobles, Vice President, Compliance and Enterprise Risk Management, **Eli Lilly**

Lori Queisser, Senior Vice President, Global Compliance and Business Practices, **Schering-Plough Corporation**

Michael Shaw, Global Head, Ethics & Compliance, **Novartis Oncology**

Jim Shehan, Vice President and General Counsel, **Novo Nordisk**

Jon Sprole, Chief Compliance Officer, **Bristol-Myers Squibb**

Marc Stanislawczyk, Counsel, **AstraZeneca Pharmaceuticals LP**

Scot Steinheiser, Assistant Director, Corporate Compliance, **Astellas**

Michael P. Swiatocha, Vice President and SPRI Compliance Officer, **Schering-Plough Research**

David Vance, J.D., Senior Director, Business Conduct, **Gilead Sciences, Inc.**

L. Stephan Vincze, J.D., L.L.M., MBA, Vice President, Ethics and Compliance Officer, Privacy Officer, **TAP Pharmaceutical Products Inc.**

Government Officials:

Julie Brill, Assistant Attorney General, **Office of Attorney General, Vermont**

Brian J. Laliberte, Deputy First Assistant Attorney General, Chief Deputy Attorney General, Criminal Division, **Office of Ohio Attorney General**

Michael Loucks, First Assistant, **U.S. Attorney**

Thomas L. Storm, Assistant Attorney General, Director, **Wisconsin Department of Justice**

Cody Wiberg, Pharm.D., R.Ph., Executive Director, **Minnesota Board of Pharmacy**

Lawrence G. Wasden, **Idaho Attorney General;** President, **National Association of Attorneys General**

Marcia B. Wooden, Executive Director, Board of Pharmacy and Pharmaceutical Control, **District of Columbia**

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Keynote Speaker

"Industry Changes and Complexity Call for Reinventing the Traditional Pharmaceutical Company Model"

Geno Germano, President, U.S. and General Manager, **Wyeth Pharmaceuticals**

Keynote Panel Discussions

"Perceptions Pre and Post Investigations Settled in 2007"

Carol Gamble, J.D., Senior Vice President, General Counsel and Corporate Secretary, **Jazz Pharmaceuticals**

James Bianco, M.D., President and CEO, **Cell Therapeutics**

Jason Hanson, Executive Vice President and General Counsel, **Medicis Pharmaceutical Corporation**

"Law Enforcement Panel"

James Stansel, Deputy General Counsel, **HHS**

Lewis Morris, Deputy Inspector General and Chief Counsel to the Inspector General, **OIG**

Douglas F. Gansler, Attorney General, **Maryland**

Stephen Cha, M.D., MHS, Committee on Oversight and Government Reform, **U.S. House of Representatives**

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A

A Primer!

Fundamentals of Marketing Compliance

Understanding the evolving world of compliance is still a complex issue for the industry, added to this is the ever increasing pressure of heightened government regulations and increased regulatory scrutiny. This in-depth workshop provides attendees with a thorough understanding of the key areas in marketing compliance and the tools needed for developing an effective compliance program.

7:30 *Registration and Continental Breakfast*

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

I. Implementing a Compliance Program — Changing Management Mindset

- How to work with senior management to set appropriate expectations for compliance — Help your organization change how they've done it "forever", particularly if they feel they've been successful

II. Effective Internal Communication for Successful Compliance Program Development

- Resources for questions and guidance
- Developing opportunities for dialogue within departments

III. Monitoring and Assessment

- Assess effectiveness of training to promote compliance
- Establish an effective monitoring program
- Document and investigate any findings

IV. Compliance Program Development

- Tailoring compliance programs to fit specific needs
- Incorporating flexibility to respond to change

12:00 *Close of Workshop A*

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

— WORKSHOP LEADERS —

Robert Merrill, J.D.,
Senior Manager,
Ernst & Young

Kip Ebel,
Senior Manager,
Ernst & Young

B

Strategies for Effective Compliance Training

Training is an important aspect of compliance and needs to be continually updated to ensure the new and changing issues are addressed without overburdening sales marketing and medical affairs professionals with too much training. The effectiveness of any compliance program can not be audited unless the standard of behavior has been communicated appropriately. Therefore, it is important for companies to ensure that the dollars invested in training return value in reducing risks and ensuring compliance. In this workshop, learn how to improve compliance training and its overall value.

7:30 *Registration and Continental Breakfast*

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

I. Innovative Training Techniques

- Understand what types of new training tools are available
- Develop the right mix of online and live interactive training

II. Verify Compliance Training Programs Are Having a Positive Impact

- Highlight positive compliance practices
  - * do you incentivize field professionals to complete required training — pros and cons
- Compliance contributing to the bottom line — How do we move from minimally required training to effective training
- Test the effectiveness and value of compliance training
- Conducting ongoing analysis

III. Partnering for Success

- Utilize in-house corporate training departments
- When to outsource training
- What to look for in a training partner

12:00 *Close of Workshop B*

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

— WORKSHOP LEADERS —

Scot Steinheiser,
Assistant Director,
Corporate Compliance, **Astellas**

Roy Galan,
Assistant Director of Sales Training,
Astellas

8:30-12:00 INVITATION-ONLY CHIEF COMPLIANCE OFFICER SUMMIT:

HOSTED BY: ERNST & YOUNG *Quality In Everything We Do*

CBI is proud to announce the 4th Annual Invitation-Only Chief Compliance Officer Summit, to be held Monday morning, January 28, 2008 in Washington, DC, in conjunction with the 5th Annual Pharmaceutical Marketing Compliance Congress. Because we recognize the complex role of the Chief Compliance Officer in this changing economic, political and regulatory climate, CBI has created a forum to convene those in this critical role to openly discuss their challenges, both present and future. If you would like to be a part of this exclusive forum, please contact Roberts Apse at 781-939-2590 or Roberts.apse@cbinet.com for complete information and a separate agenda.

C Tools to Conduct an Effective Risk Assessment

The need to conduct periodic assessments to measure the effectiveness of the compliance function remains a key focus area for most pharmaceutical and medical device companies. The effectiveness of monitoring and auditing controls used by the compliance and ethics function is underscored by numerous regulatory enforcement agencies, the U.S. Sentencing Guidelines (§8B2.1) and for publicly traded companies Section 404 of the Sarbanes-Oxley Act. Attendees of this workshop obtain the tools to conduct an effective risk assessment and strategies to use those tools to measure risk in three key areas of company operations: sales & marketing, commercial contracting and government price reporting and medical affairs.

7:30 *Registration and Continental Breakfast*

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

I. The Tools to Measure and Stratify Compliance Risk

- Develop a systematic method to consider inherent risk
- Design a monitoring and auditing process where the activities are reasonably risk-weighted toward preventing and detecting weaknesses in compliance controls and company risk

II. Measuring Risk in Sales & Marketing

III. Measuring Risk in Commercial Contracting and Government Price Reporting

IV. Measuring Risk in Medical Affairs

12:00 *Close of Workshop C*

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

— WORKSHOP LEADERS —

Paul Silver, Managing Director, Life Sciences Advisory Services, **Huron Consulting Group**

Timothy J. Nugent, Managing Director, Life Sciences Advisory Services, **Huron Consulting Group**

Debjit A. Ghosh, Director, Life Sciences Advisory Services, **Huron Consulting Group**

Pamela DePierre, Director Life Sciences Advisory Services, **Huron Consulting Group**

D Ensuring Compliance in Clinical Research

Companies are continuing to see sales and marketing activities scrutinized by the government and public. However, the next area that is now receiving focused attention is in clinical research. Given the heightened level of oversight, it has become a necessity for companies to ensure that they are remaining in compliance with their clinical and post-marketing studies. This workshop addresses the current climate for clinical and post-marketing studies and how to ensure programs and processes are in place to ensure compliance.

7:30 *Registration and Continental Breakfast*

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

I. Clinical Research Hot Buttons

- Continuing evolution of GCP regulations in different global jurisdictions
- Posting of programs and results

II. Protection of Privacy

- Data privacy directive
- Implementing appropriate controls
- Blind record keeping

III. Bridging the Communication Gap Between Commercial and Clinical

- Potential issues and proposed solutions
- Compliance tips

12:00 *Close of Workshop D*

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

— WORKSHOP LEADER —

Michael P. Swiatocha, Vice President and SPRI Compliance Officer, **Schering-Plough Research**

8:30-12:00 INVITATION-ONLY CHIEF COMPLIANCE OFFICER SUMMIT:

HOSTED BY: ERNST & YOUNG *Quality In Everything We Do*

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MAIN CONFERENCE

Day One — Monday, January 28, 2008

12:00 *Main Conference Registration and Luncheon*

1:10 *Lead Sponsor's Welcome and Opening Remarks*

Ted Acosta, J.D.,
Principal,
Ernst & Young

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

Michael Shaw, Global Head, Ethics & Compliance, **Novartis Oncology**

Mr. Shaw joined Novartis in 2004 as a Deputy Compliance Officer in the Company's U.S. General Medicines business. Prior to joining Novartis, Mr. Shaw was a Director in ***PricewaterhouseCoopers'*** *Global Pharmaceutical and Health Sciences Practice where he assisted large and mid-sized pharmaceuticals, medical products and biotechnology companies to develop their compliance programs and assess key operational and regulatory controls. Mr. Shaw is also a former Senior Counsel with the* ***Office of Inspector General (OIG)*** *of the U.S. Department of Health & Human Services where he developed compliance program guidance for the healthcare industry, monitored and developed corporate integrity agreements, reviewed compliance programs from dozens of healthcare companies and coordinated the OIG self disclosure program. Mr. Shaw started his career in compliance as in-house counsel for* ***Olsten Health Services*** *where his responsibilities included designing and maintaining corporate compliance program initiatives for an organization of 30 pharmacies and 400 home health agencies. Mr. Shaw is a national speaker on healthcare fraud/compliance and has been quoted in numerous healthcare industry publications.*

President's Address

1:30 **Industry Changes and Complexity Call for Reinventing the Traditional Pharmaceutical Company Model**

In the last decade, the complexity of issues and challenges faced by pharmaceutical companies has grown dramatically. Mr. Germano speaks about industry changes and why pharmaceutical companies must reinvent their business model. To succeed in this market, companies must be less brand focused, more customer-focused and more engaged in the public debate about the future of healthcare and the valuable role of pharmaceuticals.

- Payers are increasing efforts to control costs and demanding more evidence of the value of new treatments, in terms of both safety and efficacy
- Competition in many therapeutic areas has intensified while at the same time patent life for products are being shortened with generics coming faster to market
- Physician clinical decisions are now driven more often by payers and government regulators
- Government and media continue to call into question industry sales and marketing practices
- Consumers are being required to pay higher out-of-pocket costs, especially for innovator medicines

Geno Germano,
President, U.S. and General Manager,
Wyeth Pharmaceuticals

In this role, Mr. Germano has responsibility for Wyeth Pharmaceuticals' U.S. commercial organization, which encompasses marketing, sales and new product development, accounting for approximately $10 billion in sales and approximately 3,600 employees. In addition, Mr. Germano directs the global commercialization of products falling into the following therapeutic categories: Neuroscience, Gastroenterology, Infectious Diseases and Transplantation. Mr. Germano serves on the Wyeth Operations Committee and is a member of Wyeth Pharmaceuticals Executive Management Team. Mr. Germano also is Wyeth's executive lead for four major partnership alliances, with Nycomed GbmH, Solvay Pharmaceuticals, Cordis and Progenics Pharmaceuticals, Inc. These alliances include co-marketing agreements for currently available medicines and co-development agreements for investigational medical compounds. Throughout his nearly 20 years with Wyeth, Mr. Germano has held a diversity of positions across the Company and globe, including Executive Vice President and General Manager for Wyeth Global Vaccines; Managing Director, Wyeth Australia and New Zealand; and Vice President of Diversified Marketing for the United States. Through these experiences Mr. Germano has managed businesses across all five Wyeth Pharmaceuticals' Business Units: Pharma, BioPharma, Women's Health Care, Vaccines and Nutrition. Mr. Germano is a pharmacist who completed his Bachelor of Science in Pharmacy from the Albany College of Pharmacy in 1983.

Investigation Keynote Panel Discussion

2:15 **Perceptions Pre and Post Investigations Settled in 2007**

- How do you continue to relationship sell post investigation?
- Managing customer expectations under a CIA
- Retaining key talent
- Create a strong commitment to compliance, from the top down, embodied in all company collateral (internal and external)

Moderator:

Paul Kalb, M.D., Partner, **Sidley Austin**

Dr. Kalb heads the firm's national Healthcare group and is a member of the firm's Executive Committee. He principally represents drug and device manufacturers and institutional healthcare providers in criminal, civil and administrative enforcement actions and related civil litigation involving healthcare fraud and abuse and off-label promotion. In that capacity, he has negotiated a number of ground-breaking settlement agreements and corporate integrity agreements. Dr. Kalb is a graduate of Yale Law School, where he was an editor of the Yale Law Journal. Prior to attending law school, he received his M.D. degree, magna cum laude from the Boston University School of Medicine, completed his residency in Internal Medicine at the New York Hospital-Cornell Medical Center and served as an attending physician at the Memorial Sloan-Kettering Cancer Center. He also was a visiting lecturer at Yale College in Medicine, Law and Public Policy.

Panelists:

Carol Gamble, J.D., Senior Vice President, General Counsel and Corporate Secretary, **Jazz Pharmaceuticals**

Ms. Gamble was appointed as Jazz Pharmaceuticals' Senior Vice President in 2004 and has served as Jazz Pharmaceuticals' General Counsel and Corporate Secretary since 2003. From 2000 to 2002, she served as General Counsel and Corporate Secretary of ***Aerogen, Inc.****, a biopharmaceutical company acquired by* ***Nektar Therapeutics****. From 1988 to 2000, she held various positions with* ***ALZA Corporation****, most recently as its Senior Vice President and Chief Corporate Counsel. Ms. Gamble received a B.S. from Syracuse University and a J.D. from the University of California, Berkeley, Boalt Hall.*

James Bianco, M.D., President and CEO, **Cell Therapeutics**

Dr. Bianco is the principal founder of Cell Therapeutics, Inc. and has been the Company's President and Chief Executive Officer and Director since February 1992. Dr. Bianco has been responsible for securing nearly $1 billion in operating capital. He introduced the model of vertical integration as a cornerstone in the Company's business strategy, providing a platform for developing commercially successful solutions for the management of cancer and side effects of cancer therapy. He was also the chief architect of the company's portfolio strategy leading to the acquisition of its PG drug delivery technology in 1998, TRISENOX® in 2000, Novuspharma's pixantrone in 2003, as well as a worldwide license and co-development agreement for development and commercialization of XYOTAX™ with Novartis in 2006. Prior to joining CTI, Dr. Bianco was an Assistant Member in the clinical research division of the ***Fred Hutchinson Cancer Research Center (FHCRC)*** *and an Assistant Professor of Medicine at the* ***University of Washington****. From 1990*

*to 1992, Dr. Bianco was the director of the Bone Marrow Transplant Program at the **Veterans Administration Medical Center** in Seattle. He received his B.S. in Biology and Physics from New York University and his M.D. from Mount Sinai School of Medicine in New York.*

Jason Hanson, Executive Vice President and General Counsel,
Medicis Pharmaceutical Corporation
*From May 2004 to July 2006, Mr. Hanson served as General Counsel for **GE Healthcare Technologies**, a $12 billion global business, where he was responsible for the global legal affairs of GE Healthcare Technologies and a member of the company's senior management team. From 2001 to 2004, Mr. Hanson served as General Counsel for the Americas, GE Medical Systems. Mr. Hanson joined GE in 1999 serving as Senior Counsel for Litigation and Compliance for GE Medical Systems. Mr. Hanson began his legal career with **Arnold & Porter** in Washington, D.C. concentrating his practice in litigation, intellectual property and commercial disputes. From 1997 to 1999, Mr. Hanson served with the **United States Department of Justice, Antitrust Division** in Washington D.C. as a prosecutor and trial attorney in what is now known as the National Criminal Enforcement Section. Mr. Hanson earned his law degree at Duke University, where he was an editor of the law review and earned his undergraduate degree in Economics from Cornell University.*

3:15 *Networking & Refreshment Break*

Regulatory Keynote Panel Discussion

3:45 **Law Enforcement Panel**

A panel of leading law enforcement officials discuss key trends surrounding current regulations and future initiatives. Attendees also have the opportunity to pose questions to this elite panel of experts.

Moderator:

Lynn Shapiro Snyder, Senior Member, **Epstein Becker & Green P.C.**
*Ms. Snyder has almost thirty years of experience advising clients about federal, state and international health law issues, including Medicare, Medicaid, TRICARE, compliance and managed care issues. In August 2002, Modern Healthcare magazine named Ms. Snyder as one of the "100 Most Powerful People in Healthcare" in its inaugural list. In April 2005, Modern Healthcare magazine named Ms. Snyder as one of the "Top 25 Women in Healthcare." In the May 2006 issue of Nightingale's Healthcare News, Ms. Snyder was named one of the "Outstanding Fraud & Compliance Lawyers for 2006." In 2007, Ms. Snyder was listed as one of the "Top 50 Women Lawyers in Washington, DC" according to Super Lawyers. Ms. Snyder was outside General Counsel for over a decade to the **American Managed Care and Review Association**, one of the national trade associations for HMOs, PPOs and UROs. Ms. Snyder is Founder and board member of the Women Business Leaders of the U.S. Health Care Industry Foundation.™ Ms. Snyder joined the firm in 1979 and is admitted to practice law in the District of Columbia, the State of Florida and before the United States Supreme Court. She earned a B.A. in Economics from Franklin & Marshall College in 1976 and her J.D. from the George Washington University National Law Center in 1979.*

Panelists:

James Stansel, Deputy General Counsel,
United States Department of Health & Human Services, HHS
*In that capacity, he is responsible for all legal issues, including litigation, fraud and abuse, the promulgation of regulations and program review issues, arising out of programs administered by the Centers for Medicare & Medicaid Services. Previously, Mr. Stansel was a partner in the healthcare and food and drug groups at the Washington, D.C. office of **Sidley Austin LLP**. Before joining Sidley Austin, Mr. Stansel was a clerk with the Honorable Stephen H. Anderson of the **United States Court of Appeals for the Tenth Circuit**. Mr. Stansel is a graduate of Yale Law School and Brigham Young University.*

Lewis Morris, Deputy Inspector General and Chief Counsel in the Office of Inspector General, **OIG**, *Department of Health and Human Services*
*In that capacity, Mr. Morris is responsible for coordinating the OIG's role in the investigation and resolution of healthcare fraud cases, including cases brought under the civil False Claims Act. He also is responsible for deciding whether to exclude a healthcare provider from participation in the Federal and State Healthcare programs, as well as negotiating the imposition of corporate integrity agreements in cases where the decision has been made not to seek exclusion. As part of the OIG's effort to promote compliance with program requirements, Mr. Morris oversaw the issuance of the compliance program guidance for the pharmaceutical industry. Prior to serving as the Chief Counsel to the Inspector General, Mr. Morris served in a variety of capacities within the OIG and the Office of General Counsel, including the Inspector General's Special Prosecutor. He has been a Special Assistant **United States Attorney for the Middle District of Florida**, the **Eastern District of Pennsylvania** and the **District of Columbia**.*

Douglas F. Gansler, Attorney General, **Maryland**
*For eight years prior to becoming Maryland Attorney General, Mr. Gansler had been **Montgomery County's chief prosecutor**. He has an unparalleled record of experience as a State's Attorney, former Assistant **United States Attorney** and private litigator. Mr. Gansler was elected to be Montgomery County State's Attorney in 1998. Prior to being elected State's Attorney, Mr. Gansler was an Assistant United States Attorney from 1992 to 1998. In addition to his prosecutorial experience, Mr. Gansler has practiced civil litigation as a counsel in the law firm of **Coburn & Schertler**, and worked for two years as an associate at **Howrey & Simon**. Mr. Gansler graduated from Yale cum laude. He received his law degree from the University of Virginia School of Law, and is a member of the Bar Association in both Maryland and the District of Columbia.*

Stephen Cha, M.D., MHS, Committee on Oversight and Government Reform,
U.S. House of Representatives
Dr. Cha is a board-certified internist and currently serves as professional staff for the Committee on Oversight and Government Reform under Chairman Henry A. Waxman. He earned his medical degree from Brown University and subsequently completed his internal medicine residency at the Montefiore Medical Center in New York City, where he also served as chief resident. Dr. Cha received a degree in health services research as part of the Robert Wood Johnson Clinical Scholars Program at Yale University, and continues to serve as an adjunct faculty member at Yale.

5:15 *Close of Day One*

5:15-6:15 ***Networking Cocktail Reception***

Hosted by: Huron CONSULTING GROUP

CHOOSE FROM ONE OF FIVE BREAKOUT SESSIONS

Day Two — Tuesday, January 29, 2008

7:30 *Continental Breakfast*

8:15 Breakout A Compliance 101 (A Continuation from Workshop A)

This breakout continues the theme of the pre-conference workshop regarding the fundamentals of marketing compliance. In this breakout, you have the opportunity to discuss with and hear from your peers about the fundamental principles and important considerations in establishing and maintaining an effective compliance program. Each of the elements of a successful compliance program as described in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers are addressed and practical tips are provided to help implement these requirements. The breakout leaders facilitate conversation around the following topics and also discuss specific issues raised by the attendees.

- Defining the role of the compliance officer
- The makeup and role of the compliance committee
- The role of the compliance function in drafting and implementing policies and procedures
- The form and frequency of compliance training
- How do you use auditing and monitoring to make sure your policies and procedures are being followed and your training is effective?
- What do you do when you uncover compliance violations (remedial action)?

Tom Glavin,
Deputy Compliance Officer,
Shire

Stephen Kanovsky,
U.S. Corporate Compliance Officer,
sanofi aventis

8:15 Breakout B Benchmarking Strategies – Bio/Pharmaceutical Compliance Professionals in the Trenches

This is a closed-door summit for bio/pharmaceutical compliance professionals. In order to register for this breakout, you must be from a bio/pharmaceutical company working in the area of legal, regulatory and/or compliance.

This exclusive breakout gives you the opportunity to engage in an open, informal dialogue about solutions for the challenges you face daily with other in-house professionals while observing anti-trust.

This breakout is limited to the first 80 people to register.

- Provide training and education that sticks
- Conduct internal investigations
- Treat violations and take corrective action

Colleen Craven,
Chief Compliance Officer,
Endo Pharmaceuticals

8:15 Breakout C Benchmarking Strategies — Medical Technology Professionals in the Trenches

This is a closed-door summit for medical technology compliance professionals. In order to register for this breakout, you must be from a medical technology company working in the area of legal, regulatory and/or compliance.

This exclusive breakout gives you the opportunity to engage in an open, informal dialogue about solutions for the challenges you face daily with other in-house professionals while observing anti-trust.

This breakout is limited to the first 80 people to register.

- Investigational best practices
- Credentialing/vendor access issues
- Policy challenges in a global organization
- Privilege issues in internal investigations
- Complying with CIAs

Daniel Garen,
Chief Compliance Officer,
Siemens Medical Solutions Diagnostics

Kim Elting,
General Counsel,
ANS Medical (subsidiary of St. Jude Medical)

8:15 Breakout D Mergers and Co-Promotions

Mergers have become common place in the pharmaceutical industry and seem to be a way of survival. However, similar to co-promotions, there is a lot of pre-merger and acquisition homework that needs to be done. Also, once the merger takes place the difficulty becomes determining how to blend different cultures and strategies for the conduct of sales and marketing activities, not to mention the challenges that companies face with a U.S. and EU merger. In this breakout, hear how to survive a merger and strategies for building a new and improved compliance department. In this breakout discuss:

- Pre-merger compliance due diligence
- Understanding liabilities
- Handling a CIA from an acquired company
- Developing compliance standards that blend both cultures
- Ensuring compliance with language in contracts

Indrani M. Franchini, Deputy Compliance Officer,
Worldwide Programs, Senior Corporate Counsel,
Pfizer Inc

8:15 Breakout E Global Compliance Program Development

Every company aims to "Think Global and Act Local", but the fact is that laws, regulations, ethical standards and business culture differ around the world. People in headquarters who don't have hands-on experience outside the home country often don't understand why the markets don't "get" the company's global compliance culture. Also, on the other side, people in the markets who don't have hands-on experience in headquarters often don't understand why they are being subjected to so many restrictive "foreign" rules. What's more, resources are often an issue, certainly for small companies, but also for large ones, because some markets present compliance risks that are out of proportion to their sales numbers. This breakout gives you the opportunity to engage in an open, informal dialogue about the challenges you face including:

- The obstacles surrounding a global organization — Small company versus large company perspectives
- "Tensions" between local practices and global standards — How real are they?
- "Changes in Latitudes, Changes in Attitudes" — Being an advocate for headquarters in the region and being an advocate for the region at headquarters
- Doing more with less — Setting priorities and begging and borrowing resources

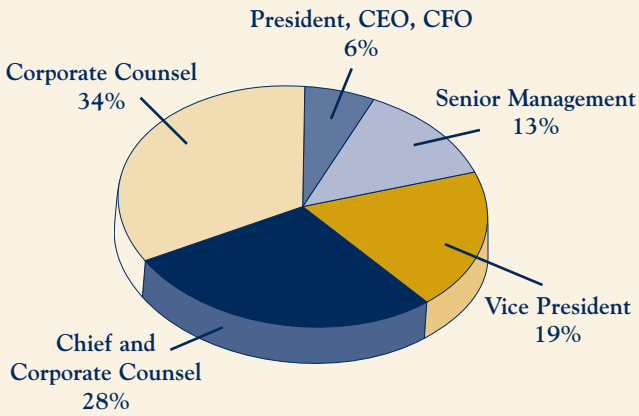
Eileen Erdos,
Principal,
Investigative & Dispute Services,
Ernst & Young

Gordon M. Chapman,
Senior Director,
Asia Pacific Compliance,
Bristol-Myers Squibb Company

Fabiana Lacerca,
Legal Compliance Director,
Bristol-Myers Squibb

9:45 *Close of Breakouts and Networking and Refreshment Break*

2007 ATTENDEE PROFILE



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We would like to thank our advisory board for their time and dedication in preparing for the 2008 PMCC.

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Partner,
Sidley Austin

Indrani M. Franchini,
Deputy Compliance Officer, Worldwide Programs, Senior Corporate Counsel,
Pfizer Inc

Michael Shaw,
Global Head, Ethics & Compliance
Novartis

Colleen Craven,
Chief Compliance Officer,
Endo Pharmaceuticals

William C. Bertrand, Jr., J.D.,
Senior Vice President, Legal Affairs, General Counsel and Corporate Compliance Officer,
MedImmune

Natasha Nelson,
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TRACK A — FRAUD & ABUSE

10:15 *Moderator's Welcome Remarks*

Kathleen Meriwether, Principal,
Ernst & Young

10:30 **University of Chicago/ECOA Ground-Breaking Research Project — Determining the Economic Effects of Ethics, Compliance and Corporate Governance Programs**

Ethics and compliance programs are not without controversy. Critics see such programs as merely window dressing, an attempt to improve a firm's public, investor or employee relations efforts. Others are concerned that such programs may be costly efforts to pursue management or outside objectives at the expense of shareholder value. Two years ago in a keynote speech to the PMCC, Steve Vincze referenced an idea to conduct research into the economic effects of ethics and compliance programs. Hear how that idea has now materialized into reality.

- Kicking off the research — How can you and your organization participate
- What the research is going to address, e.g., the factors that correlate to the creation or destruction of economic value and sustainable competitive advantage in highly regulated industries

L. Stephan Vincze, J.D., LL.M., MBA, Vice President, Ethics & Compliance Officer, Privacy Officer,
TAP Pharmaceutical Products

Michael Gibbs, Ph.D., Clinical Professor of Economics,
University of Chicago GSB

11:15 **Creating a Culture of Compliance**

Most individuals are law abiding; yet within the corporate context, otherwise law abiding employees can and do engage in crimes. These crimes can run the gamut from sales and marketing crimes — cheating on pricing agreements with government agencies — to regulatory violations — cheating on required manufacturing processes or cheating on the approvals for a drug or a device — to crimes of inducement — the payment of kickbacks to particular customers to assure they purchase your product. Corporate culture can and does play an important role, both with respect to encouraging and discouraging such conduct. Mr. Loucks reviews significant recent prosecutions with an eye on how corporate culture and tolerance by executives fostered a culture of compliance with, or disregard for, the rules.

Michael Loucks, First Assistant,
U.S. Attorney

12:00 **Ensure Compliance with the FCPA**

The industry continues to struggle with FCPA. In different parts of the world hospitals and clinics are government-owned which would make the medical staff and other employees government officials. This makes it extremely difficult to conduct traditional sales activities while remaining in compliance with FCPA. In this interactive session, analyze the scope and components of FCPA.

Jim Shehan, Vice President and General Counsel,
Novo Nordisk

Ted Acosta, Principal,
Ernst & Young

Thomas H. Suddath, Jr., Partner,
Reed Smith

12:45 *Luncheon Hosted by:* ERNST & YOUNG Quality In Everything We Do

2:00 **Implementation of Corporate Integrity Agreements**

PANEL

CIA's have been getting much more burdensome since the first one was established. This session reviews the first corporate integrity agreements as well as more recent ones, which are much more complex. Dissect what has changed over the past 5-10 years and how to work effectively internally as well as externally in implementing CIAs.

- Overcome internal challenges with implementing CIAs

Moderator:
Wendy C. Goldstein, Member, Chairperson of the Pharma Industry,
Epstein Becker & Green P.C.

Panelists:

Stephen Kanovsky, U.S. Corporate Compliance Officer,
sanofi-aventis

Margaret K. Feltz, Associate Director, Corporate Compliance,
Purdue Pharma L.P.

Robert A. Freeman, U.S. Compliance Officer and Compliance Counsel, **Serono, Inc.**

2:45 **Determine Fair Market Value**

This session focuses on establishing the *fair market value* of payments to physicians in order to remain in compliance with applicable regulatory guidance. The session deals with methods and resources for establishing supportable payment rates, as well many common pitfalls to be avoided during the process. For example, the session addresses potential drawbacks of using "opportunity cost" as a valuation methodology and the risks of placing reliance upon market data which itself may be in excess of fair market value.

Daryl P. Johnson, AVA, Principal,
HealthCare Appraisers, Inc.

Ann Brandt, Ph.D., Senior Associate,
HealthCare Appraisers, Inc.

3:30 **EXECUTIVE EXCHANGE**

(Choose between three topics)

Topic 1: How to Respond to an Internal Report of Fraud and Abuse Misconduct

- Prioritizing investigations — Prompt response strategies
- Corrective action and the need for documentation

Moderator: Marc Stanislawczyk, Counsel,
AstraZeneca Pharmaceuticals LP

Topic 2: Responding to Enforcers

- Decision on the making of a voluntary disclosure
- Defining the scope of an investigation
- Meeting with the government and reporting on results

Moderator: Gary Giampetruzzi, Deputy Compliance Officer,
Pfizer Inc

Topic 3: Managing Whistleblowers During Investigations

- Conflicts of interest and how to manage a workforce
- What constitutes retaliation?

Moderator: Jon Sprole, Chief Compliance Officer,
Bristol-Myers Squibb

4:15 *Close of Track and Main Conference Resumes*

TRACK B — MEDICAL COMMUNICATION EXCHANGE

10:15 *Moderator's Welcome Remarks*

Natasha Nelson, Esq.,
Executive Director, Chief Ethics and Compliance Officer,
Daiichi-Sankyo, Inc.

10:30 **EXECUTIVE EXCHANGE**
(Choose between three topics)

Topic 1: Understand Key Issues Involved with Managing MSLs

- Trends and regulatory developments
- Describing roles and defining processes
- Monitoring requests for medical information

Moderator:
Monica Jonhart, Director, Compliance and Auditing,
Bristol-Myers Squibb

Topic 2: Legal Considerations Surrounding Communication with MCOs

Moderator:
Isabel P. Dunst, Partner,
Hogan & Hartson

Topic 3: Good Practices at Conventions

- The do's and don'ts
- Discussion of various gray area situations

Moderator:
David Vance, J.D., Senior Director, Business Conduct,
Gilead Sciences, Inc.

11:15 **Auditing Off-Label Controls**

Recent CIAs are including off-label promotion. Therefore, companies need to be pro-active in incorporating auditing and monitoring activities for off-label communication before it becomes required. Learn strategies for how to track and monitor these activities and the roles of sales, marketing and medical science liaisons.

- Understand what auditing is required under a CIA
- Techniques for auditing promotional practices, detailing, grants, sponsorship and research funding

Tom Gregory,
Partner,
Ernst & Young

12:00 **Implementation Strategies for a Compliant Grant Process**

The conclusion of a recent senate finance report on grant concerns is that no one is minding the store. Grants as a kickback is old news and companies are really doing well in policing that, but recently subtle nuances about the grant process are coming to light especially in reaction to off-label use. In this session, hear strategies for developing an effective and compliant grant process.

Mark DeWyngaert, Managing Director,
Life Sciences Advisory Services,
Huron Consulting Group

Tracy Mastro, Director,
Life Sciences Advisory Services,
Huron Consulting Group

12:45 *Luncheon Hosted by:* **ERNST & YOUNG** *Quality In Everything We Do*

2:00 **Publication Considerations — The Balancing Act**

This must-attend, highly-interactive, session explores the sensitive considerations surrounding publications. Join us to explore such issues as: compliance issues surrounding a "strategy", ghost written articles, payment considerations and conflicts of interest. Please bring your questions and prepare to participate!

Janet L. "Lucy" Rose,
President,
Lucy Rose and Associates

2:45 **Development of Advisory Boards**

Advisory boards continue to be developed in both clinical and post-marketing settings. However, these boards have come under increased scrutiny regarding the structure and nature of these meetings. In this session, learn how to successfully structure these boards to ensure compliance.

- Strategies companies need to be aware of in order to ensure a successful partnership of advisory board members
- Selection of advisory board members and appropriate outcomes

Minnie Baylor Henry,
Vice President, Medical and Regulatory Affairs,
McNeil Consumer & Specialty Pharmaceuticals

3:30 **Oversight Monitoring — Art of Analysis, Not Science**

Case Studies

As compliance programs mature, companies are spending a lot more time on data analysis. However, as multitudes of data continue to flow, there are two main areas in terms of increasing transparency. First, is how we spend money which there is already significant information out there on and solutions to tracking it. The second is the interaction between our employees and customers. Which is an area that needs much further investigation? How do you know what actually goes on in a sales call? You don't know, but there are signals and pieces of data that you can compile to create a picture. This interactive session discusses the struggles with data and how to collectively look at it to get a better understanding of areas to be concerned with. Walk through multiple cases discussing how to analyze data and address areas where flags should be raised. Audience polling is used to benchmark and gain further insight into how companies are analyzing data. Case examples are discussed.

Rick Cassino,
Vice President, HCC,
Johnson & Johnson Pharmaceuticals Group

Kris Curry,
Director, HCC Operations,
Ortho McNeil Janssen

4:15 *Close of Track and Main Conference Resumes*

TRACK C — STATE LAWS FOR SALES, MARKETING AND PRICING

10:15 *Moderator's Welcome Remarks*

John Patrick Oroho,
Principal,
Porzio, Bromberg & Newman P.C.

10:30 **State Laws for Sales and Marketing Compliance**

State laws have become a huge concern for the pharmaceutical industry in the area of sales and marketing compliance. Several states have proposed and/or adopted legislation that attempts to place upon pharmaceutical manufacturers certain requirements that in some instances are quite complex and in others overly broad. The compliance landscape has changed from a narrowly driven PDMA compliance strategy to a state by state approach. Some of the "Hot Topics" facing the industry today are:

- Compliance with state disclosure requirements
- State reports on company compliance
- Price reporting and false claims
- Codes of conduct • Interactions with healthcare providers
- Lobbyists • Pedigree

John Patrick Oroho,
Principal,
Porzio, Bromberg & Newman P.C.

11:15 **EXECUTIVE EXCHANGE**
(Choose between three topics)

Topic 1: State Ethics Laws

- Perfect storm — Discussion of Louisiana law
- What do you do from a state law reporting standpoint when reporting gifts to physicians?
- Areas of violations for state ethics laws

Jeffrey Greenman,
Vice President, Compliance,
Bayer

Topic 2: Overcoming Obstacles with Implementing State Tracking Systems

- Systems (legacy, integration, new platforms, validation, customer masters)
- Vocabulary/lexicon (similar to systems — Which is technical — but different in the sense that internal organizations use a different vocabulary to talk about the same people, roles and activities)
- Breaking down the organizational silos — How do you run a comprehensive project when your three major silos (R&D, Medical and Commercial) all use different systems, vocabulary and business processes?

Ann Beasley Bacon,
Senior Corporate Counsel,
Sepracor Inc.

Topic 3: Handling Challenges with Mid-Level Practitioners

- Interpretation of state laws
- What does it mean in terms of state law compliance?
- Determining cost breakout under statute

Keith Korenchuk,
Partner,
Covington & Burling

12:00 **Strategies for Tracking Aggregate Spend**

The industry has adopted voluntary guidelines that limit payments and gifts to physicians. However, states have determined that stricter laws need to be in place and several have developed laws requiring some form of disclosure. Senator Kohl and McCaskill are also in the process of pushing for a national registry that would force drug and medical device companies to report their gifts/payments to physicians. In this session, learn how to take pro-active approaches to tracking aggregate spend in order to remain in compliance with current as well as future requirements.

Greg Crouse,
Partner,
Ernst & Young

12:45 *Luncheon Hosted by:* ERNST & YOUNG *Quality In Everything We Do*

2:00 **State Perspectives on Existing and Future Regulations Surrounding Sales and Marketing**

PANEL

There is a great deal of money spent on sales and marketing efforts in each state and more and more laws are being developed in order to track this spending. Pharmaceutical companies need to ensure that they are keeping up to date with each states' regulations and understand the repercussions for non-compliance. Hear directly from states on current laws and strategies for how to work with state officials to ensure compliance.

Moderator:

Kathleen M. Sanzo,
Partner,
Morgan, Lewis & Bockius LLP

Panelists:

Julie Brill,
Assistant Attorney General,
Vermont

Cody Wiberg, Pharm.D., R.Ph.,
Executive Director,
Minnesota Board of Pharmacy

Brian J. Laliberte, Deputy First Assistant Attorney General, Chief Deputy Attorney General, Criminal Division, **Office of Ohio Attorney General**

Marcia B. Wooden, Executive Director, Board of Pharmacy and Pharmaceutical Control, **District of Columbia**

Thomas L. Storm, Assistant Attorney General Director,
Wisconsin Department of Justice

James D. Kole, Senior Assistant Attorney General, Special Lit.,
Office of Illinois Attorney General

Special Address

3:30 **State Attorney General Perspective**

Lawrence G. Wasden,
Idaho Attorney General;
President, **National Association of Attorneys General**

4:15 *Close of Track C and Main Conference Resumes*

Interactive Compliance Panel Discussion

4:15 **Interactive Compliance Officer Panel**

This interactive panel of experienced compliance officers synthesizes key issues uncovered and developed from the past two days and respond to Q&As. In addition, attendees get the benefit of audience benchmarking of compliance practices through the use of electornic Audience Response System (ARS). Topics include:

- How should compliance professionals prioritize limitless action items in light of limited resources?
- How can compliance professionals effectively interact with partners in Legal, Human Resources, Sales and Marketing?
- What can compliance professionals and companies do now to proactively prepare for future challenges?

Moderator:

Michael Shaw,
Global Head, Ethics & Compliance,
Novartis

Panelists:

Ed Miller,
Chief Compliance Officer,
Boehringer Ingelheim Pharmaceuticals

Anne Nobles,
Vice President, Compliance and Enterprise Risk Management,
Eli Lilly and Company

Colleen M. Craven,
Vice President, Ethics and Corporate Compliance,
Endo Pharmaceuticals

Lori Queisser,
Senior Vice President, Global Compliance and Business Practices,
Schering-Plough Corporation

5:00 *Close of Conference*

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