

THE THIRTEENTH ANNUAL

# Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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**THE PHARMACEUTICAL COMPLIANCE FORUM**

**A Hybrid Conference & Internet Event**

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## November 5 – 7, 2012

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### KEYNOTE SPEAKERS



**Thomas W. Abrams, RPh, MBA,** Director, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research (CDER), US Food and Drug Administration



**Lanny A. Breuer, Esq.,** Head, Criminal Division, US Department of Justice



**Deirdre Connelly,** President, North America Pharmaceuticals, GlaxoSmithKline; Former President of US Operations, Eli Lilly and Company



**Gregory E. Demske, Esq.,** Chief Counsel to the Inspector General, DHHS Office of Inspector General



**Susan Dentzer,** Editor-in-Chief, *Health Affairs*; Health Policy Analyst, *The News Hour with Jim Lehrer*



**Louis Joseph Freeh, JD, LLM,** Founder and Chairman, Freeh Group International Solutions, Former Director, Federal Bureau of Investigation



**Carmen M. Ortiz, Esq.,** United States Attorney, District of Massachusetts



**Mary E. Riordan, Esq.,** Senior Counsel, Office of Counsel to the Inspector General, DHHS Office of Inspector General

### CO CHAIRS



**Gary Del Vecchio,** Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company



**Margaret K. Feltz, Esq.,** Director, Corporate Compliance, Purdue Pharma LP



**Kelly B. Freeman, PhD,** Ethics and Compliance Officer, Eli Lilly and Company



**Michael L. Shaw, Esq.,** Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Senior Counsel, DHHS Office of Inspector General

[www.PharmaCongress.com](http://www.PharmaCongress.com)

## AGENDA AT A GLANCE

### Featuring Preconferences:

Precon I: Compliance 101

Precon II: Auditing and Monitoring Boot Camp

Precon III: A Comprehensive Overview of Pharma and Medical Device Corporate Integrity Agreements (CIAs)

Precon IV: The New Era of Scrutiny: FCPA Compliance in Pharma Operations

### Plenary Sessions:

OIG Update

DOJ Criminal Division Update

Prosecuting Pharma and Device Fraud

FDA-DDMAC Update

AUSA Panel

Qui Tam Panel

State Enforcement Panel

Best Practices in Negotiating and Implementing CIAs

State Disclosure, Federal Sunshine Act and Global Transparency

Life Sciences in America the Morning after the Election

Managing Internal and External Investigations

PhRMA's New Compliance Work Group Update

Global Pharma and Device Compliance Issues and Strategies

### And Mini Summits:

Mini Summit I: Co-pay Coupon Litigation Update

Mini Summit II: What Enhanced Obligations in CIAs and DPAs say about Agency Expectations for Compliance Programs

Mini Summit III: Compliance Issues in Global R&D and Medical Affairs

Mini Summit IV: US Disclosure Implementation Update

Mini Summit V: Medical Device Compliance Issues Update

Mini Summit VI: Global Pharma and Device Compliance Issues

Mini Summit VII: Anticorruption, Including FCPA and UK Bribery Act Update

Mini Summit VIII: Fair Market Value Update

Mini Summit IX: Enforcement Threat Against Individuals

Mini Summit X: Global Transparency Update

Mini Summit XI: Special Compliance Issues and of Small Pharma and Medical Device Companies

Mini Summit XII: Integrating a Culture of Ethics into Your Compliance Program

Mini Summit XIII: Government Price Reporting Update

Mini Summit XIV: Clinical Trial Disclosure and Results Reporting Liability under FDAAA, Section 801

Mini Summit XV: Board and Management Certifications and Working with an IRO

Mini Summit XVI: Drug Samples Disclosure: The Next Horizon?

Mini Summit XVII: Professional Responsibilities for Compliance Officers and In-house Counsel in the Pharmaceutical, Biotech and Medical Device Industries

Mini Summit XVIII: Compliance Program Innovation

### SAVE THESE DATES! Hybrid Conferences & Internet Events

#### Fifth Annual Summit on Disclosure, Transparency and Aggregate Spend for Drug, Device and Biotech Companies

Media Partners: *Harvard Health Policy Review*, *Health Affairs*, and *RxCompliance Report*

**February 19 – 21, 2013, Washington, DC**

**[www.DisclosureSummit.com](http://www.DisclosureSummit.com)**

#### Sixth International Pharmaceutical Compliance Congress

Sponsored by International Society of Healthcare Compliance Professionals

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Media Partners: *Life Science Compliance* and *RX Compliance Report*

**May 21 – 23, 2013, Madrid, Spain**

**[www.InternationalPharmaCongress.com](http://www.InternationalPharmaCongress.com)**

## Who Should Attend:

- Pharmaceutical and Health Care Executives and Board Members
- Compliance Executives
- Health Plan, Health System and Physician Organizations
- Medical Directors
- Physicians
- Pharmacists and Pharmacy Technicians
- Purchasers, including Private Employers and Public Purchasers
- Pharmaceutical Manufacturers
- Generic Pharmaceutical Manufacturers
- Site Management Organizations
- Clinical Research Organizations
- Pharmacy Benefit Management Companies
- Nurses
- Health Plans and Health Insurers
- Wholesale, Retail, Mail Order and Internet Pharmacies
- Health Care Attorneys and In-house Counsel
- Compliance Officers
- Privacy Officers
- Ethics Officers
- Food and Drug Law Attorneys
- Pharmaceutical Consultants
- Investment Bankers
- Venture Capitalists
- Health Care Regulators and Policy Makers
- Health Services Researchers and Academics
- Auditors

## About the Congress Sponsor



The Pharmaceutical Compliance Forum (PCF) is a coalition of senior compliance professionals and legal counsel from more than 50 of the largest research-based pharmaceutical manufacturers. The PCF was founded in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The members meet twice a year, for two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field, and sponsors a three-day compliance congress each Fall. For membership information, contact Tim Bower at 215-599-6617 or via email at [info@PharmaComplianceForum.org](mailto:info@PharmaComplianceForum.org). Please visit their website at [www.PharmaComplianceForum.org](http://www.PharmaComplianceForum.org).

### EXHIBIT AND SPONSORSHIP OPPORTUNITIES

Take advantage of this unique opportunity to expand your reach! The Congress is attended by highly influential and experienced professionals. Sponsorship offers you strategic positioning as an industry leader. For more information call 206-673-4815 or email [exhibits@hconferences.com](mailto:exhibits@hconferences.com).

Monday, November 5, 2012

## PRECONFERENCE SYMPOSIA

**7:30 am Congress Registration Opens**

**8:30 am Preconferences Commence** (Choose one)

### Preconference I: Compliance 101

- Overview of Pharma Compliance Programs
- Key Laws, Regulations, and Guidance:
  - OIG Compliance Program Guidance for Pharmaceutical Manufacturers
  - Federal Sentencing Guidelines
  - PhRMA Code
  - FDA Regulations
  - Important Settlements with the Government
- Implementing the Seven Elements of a Compliance Program
- Practical Advice and Best Practices for Policy Development, Training, Communications, Monitoring, Auditing, and Corrective Actions
- Sales and Marketing Compliance
- Med Affairs and Clinical Compliance
- International Compliance
- Interactive Group Discussion of Hypothetical Scenarios

**8:30 am Welcome and Introduction**

**Gary Del Vecchio**, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ

**Margaret K. Feltz**, Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT

**Michael Kendall, Esq.**, Partner and Head, White-Collar Defense Group, McDermott Will & Emery LLP; Former Deputy Associate Attorney General and Counselor, United States Department of Justice; Former Assistant United States Attorney, United States Attorney's Office, District of Massachusetts, Boston, MA

**Janet L. "Lucy" Rose**, President, Lucy Rose and Associates, LLC; Former Director, Division of Drug Marketing, Advertising, and Communications (DDMAC); Former Director, Office of Training and Communications, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Washington, DC

**Kelly B. Freeman, PhD**, Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN (Co chair)

**11:30 am Preconference Adjournment;  
Lunch on your Own**

### Preconference II: Auditing and Monitoring Boot Camp

- Compliance Auditing Best Practices
  - Drivers for Renewed Focus on Compliance Auditing — Data Collection, Analysis and Reporting, etc.
  - Sample Compliance Auditing Cycle/Approach
  - The Use of Risk Assessments to Guide Audit Planning
  - Compliance Audit Focus Areas — Where are we seeing the highest risks?
  - Legal Considerations — When should an audit be privileged, if ever?
- Compliance Monitoring Best Practices
  - Drivers for Increased Importance of Compliance Monitoring — CIA's, Commercial, R&D, etc.
  - Types of Monitoring — Physical, Electronic, Risk-Based Targeting and Scoring Process
  - Legal Considerations
  - Panel/Audience Discussion on Different Approaches, Perspectives and Practices
- A Look to the Future: What's Needed, What's Wanted, and What Do We Need to Get There in the Next 2-5 Years?

**8:30 am Welcome and Introduction**

**Thomas C. Frongillo, Esq.**, Partner, Head of Litigation (Boston Office) and Co-Chair of the White Collar Criminal Practice, Weil Gotshal & Manges, Boston, MA

**Noor Haq, MS, MBA**, Director, Compliance, Healthcare Compliance Internal Audit, Amgen, Inc., Los Angeles, CA

**Jeffrey L. Handwerker, Esq.**, Partner, Arnold & Porter LLP, Washington, DC

**Michael Hercz, Esq.**, Director, Audit and Enterprise Risk Services, Deloitte & Touche LLP; Former Vice President and Chief Compliance Officer, Victory Pharmaceuticals, Inc., Costa Mesa, CA

**Jeff Rosenbaum**, Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Global Head, Ethics & Compliance, Novartis Oncology, Boston, MA

**Vickie L. McCormick**, Vice President, Health Care Compliance, DePuy, Inc.; Chief Compliance Officer, DePuy Orthopaedics, Inc.; Former Chief Compliance Officer, St. Jude Medical, Warsaw, IN

**L. Stephan Vincze, JD, LL M, MBA**, Director, Audit and Enterprise Risk Services, Deloitte & Touche LLP; Former Vice President, Ethics and Compliance Officer/Privacy Officer, TAP Pharmaceutical Products Inc., Boston, MA (Co chair)

**11:30 am Preconference Adjournment;  
Lunch on your Own**

### Preconference III: A Comprehensive Overview of Pharma and Medical Device Corporate Integrity Agreements (CIAs)

- Lessons Learned from the New and Sunsetting CIAs
- CIA Implementation — The First 120 Days and Organizational Challenges
- Key Considerations Relating to the "Evolved" CIA

All attendees of this session receive a comprehensive compendium of Pharma and Device CIAs.

**8:30 am Welcome and Introduction**

**Clive Davis, Esq.** (Invited), Vice President and Chief Compliance Officer, Corporate Compliance, UCB Inc.; Former Senior Corporate Counsel, Pfizer, Atlanta, GA

**Tracy Mastro, MPH**, Senior Director, Life Sciences Advisory Services, Huron Consulting Group, Washington, DC

**Bert Weinstein, Esq.**, Vice President, Corporate Compliance, Purdue Pharma LLP; Former Member, PCF Executive Committee, Stamford, CT

**Wendy C. Goldstein, Esq.**, Partner, Epstein Becker & Green, New York, NY (Co chair)

**Paul J. Silver**, Practice Leader, Life Sciences Advisory Services, Huron Consulting Group, Atlanta, GA (Co chair)

**11:30 am Preconference Adjournment;  
Lunch on your Own**

### Preconference IV: The New Era of Scrutiny: FCPA Compliance in Pharma Operations

An Overview of Compliance Risks Facing Pharma Companies, Drawn from:

- Recent FCPA Enforcement Actions
- Historical Study of Pharma Companies Involved in the Iraq Oil-for-Food Scandal
- Risk Awareness for Trends in Pharma International Operations
- Emerging Compensation Issues
- Emerging Distribution Channel Issues
- Managing and Prioritizing Risk

**8:30 am Welcome and Introduction**

**Gregory Paw, Esq.**, Partner, Pepper Hamilton LLP; Former Director, Division of Criminal Justice, Office of the New Jersey Attorney General; Former Deputy US Attorney, Eastern District of Pennsylvania; Former Deputy Chief, Regime Crimes Liaison Office in Iraq, Philadelphia, PA

**Jim Bucknam, Esq.** (Invited), Chief Executive Officer, Freeh Group International Solutions; Former Executive Vice President for Risk Management and Compliance, Kroll; Former Senior Advisor, FBI Director Louis J. Freeh; Former Assistant US Attorney, Southern District of New York, Washington, DC

**11:30 am Preconference Adjournment;  
Lunch on your Own**

Monday, November 5, 2012

**PHARMA CONGRESS: AGENDA DAY I**

**12:00 pm Meet and Greet in Exhibit Hall**

**1:00 pm Welcome and Introduction**

**Kelly B. Freeman, PhD**, Senior Director, Ethics and Compliance, Eli Lilly and Company; Executive Committee Member, Pharmaceutical Compliance Forum, Indianapolis, IN (Co chair)

**Michael L. Shaw, Esq.**, Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals, Philadelphia, PA (Co chair)

**1:15 pm Keynote**

**Deirdre Connelly**, President - North America Pharmaceuticals, GlaxoSmithKline; Former President of US Operations, Eli Lilly and Company, Philadelphia, PA

**1:45 pm Keynote: OIG Update**

**Gregory E. Demske, Esq.**, Chief Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services, Washington, DC

**Mary E. Riordan, Esq.**, Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services, Washington, DC

**2:45 pm Keynote: DOJ Criminal Division Update**

**Lanny A. Breuer, Esq.**, Head, Criminal Division, US Department of Justice; Former Special White House Counsel; Former Assistant District Attorney, New York City, Washington, DC

**3:15 pm Break**

**3:45 pm Keynote: Prosecuting Pharma and Device Fraud**

**Carmen M. Ortiz, Esq.**, United States Attorney, District of Massachusetts, Boston, MA

**4:15 pm AUSA Panel**

**Paul Kaufman, Esq.**, Assistant US Attorney and Chief, Civil Health Care Fraud, United States Attorney's Office, Eastern District of New York, Brooklyn, NY

**Marilyn May, Esq.**, Assistant US Attorney, United States Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA

**Maureen Ruane, Esq.**, Assistant US Attorney and Chief, Health Care and Government Fraud Unit, Criminal Division, United States Attorney's Office, District of New Jersey, Newark, NJ

**Susan Winkler, Esq.**, Assistant US Attorney, United States Attorney's Office, District of Massachusetts, Boston, MA

**John T. Bentivoglio, Esq.**, Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, US Department of Justice, Washington, DC (Moderator)

**5:00 pm Keynote: FDA-DDMAC Update**

**Thomas W. Abrams, RPh, MBA**, Director, Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD

**5:30 pm Adjournment and Networking Reception**

Tuesday, November 6, 2012

**PHARMA CONGRESS: AGENDA DAY II**

**7:00 am Registration Opens**

**7:30 am Continental Breakfast and Optional Table Discussion Topics in Exhibit Hall**

Discussion topics will be identified onsite.

**MORNING PLENARY SESSION**

**8:30 am Welcome and Introduction to Day II Morning Plenary Session**

**Gary Del Vecchio**, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ (Co chair)

**8:45 am Qui Tam Panel**

**Erika A. Kelton, Esq.**, Partner, Phillips & Cohen LLP, Washington, DC

**Daniel R. Miller, Esq.**, Partner, Berger & Montague, PC; Former Deputy Attorney General, Delaware Department of Justice, Philadelphia, PA

**Michael A. Morse, Esq.**, Partner, Pietragallo Gordon Alfano Bosick & Raspanti, LLP; Former Assistant District Attorney, Philadelphia District Attorney's Office, Philadelphia, PA

**Joseph E. B. "Jeb" White, Esq.**, Partner, Nolan & Auerbach, PA, Philadelphia, PA

**Kirk Ogrosky, Esq.**, Partner, Arnold & Porter; Former Deputy Chief, Fraud Section, US Department of Justice Washington, DC (Moderator)

**9:30 am State Enforcement Panel**

**Jacob Bergman, Esq.** (Invited), Special Assistant Attorney General, Medicaid Fraud Control Unit, NY Office of the Attorney General, New York, NY

**Keesha Mitchell, Esq.**, Chief, Health Care Fraud Section, Director, Medicaid Fraud Control Unit, Ohio Attorney General's Office, Columbus, OH

**Cynthia O'Keeffe**, Deputy Chief, Civil Medicaid Fraud Division, Texas Office of the Attorney General, Austin, TX

**Nicholas N. Paul, Esq.** (Invited), Supervising Deputy Attorney General, Bureau of Medi-Cal Fraud and Elder Abuse, Office of the Attorney General, California Department of Justice San Diego, CA

**Virginia "Ginny" A. Gibson, Esq.**, Partner, Hogan Lovells US LLP; Former Executive Assistant US Attorney, United States Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA (Moderator)

**10:15 am Break**

## 10:45 am Best Practices in Negotiating and Implementing CIAs

**Cynthia Cetani**, Vice President, Ethics and Compliance, Chief Compliance Officer, Novartis Pharmaceuticals Corporation, New York, NY

**Kris Curry**, Vice President, Health Care Compliance, Johnson & Johnson Pharmaceuticals, Titusville, NJ

**Lauran S. D'Alessio**, Vice President and Compliance Officer, Merck & Co., Whitehouse Station, NJ

**Michael L. Shaw, Esq.**, Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Senior Counsel, Office of Inspector General, Philadelphia, PA

**Thomas A. Gregory, CFA, MBA**, Partner, Fraud Investigation and Dispute Services, Ernst & Young LLP, Atlanta, GA (Moderator)

## 11:30 am Panel: State Disclosure Laws, Federal Sunshine Act and Global Transparency Initiatives

- US Sunshine Act

**Niall Brennan, MPP** (Invited), Acting Director, Policy and Data Analysis Group, Centers for Medicare and Medicaid Services, Washington, DC

- State Disclosure Laws

**Trudy J. Seeley**, Senior Manager, Transparency Operations, Sanofi US, Bridgewater, NJ

- Global Transparency

**Katrina S. Cahill**, Senior Manager, Corporate Compliance - Global Transparency Lead, Biogen Idec, Weston, MA

- Global Transparency Industry Surveys US, EMEA, APAC

**William E. Buzzeo, MS**, Vice President and General Manager, Compliance Solutions Division, Cegedim Relationship Management, Richmond, VA

**Jonathon Kellerman**, Principal, Pharmaceutical and Life Sciences Advisory Services, PwC, Florham Park, NJ (Moderator)

## 12:15 pm NETWORKING LUNCHEON

### Optional Luncheon Presentation: Mandatory Exclusion: Making Better Use of the Double-Edged Sword

Attendance limited to 150 due to limitations in meeting room capacity.

**Paul E. Kalb, JD, MD**, Partner and Global Coordinator, Life Sciences Practice, Sidley Austin LLP, Washington, DC

## PARTICIPATION OPTIONS

### Traditional Onsite Attendance

Simply register, travel to the conference city and attend in person.

PROS: subject matter immersion; professional networking opportunities; faculty interaction.



Onsite

## MINI SUMMITS BLOCK A — 1:15 pm to 2:30 pm

### Mini Summit I: Co-pay Coupon Litigation Update

- Allegations that Pharma Co-pay Programs Constitute Violations of RICO, Robinson-Patman, and/or State Insurance Fraud Prohibitions
- Overview of Related Litigation, the Evolution in the Underlying Theories, and their Procedural Posture
- Damage Calculation Models Pre- and Post-Discovery
- Data that may support key defense arguments
- Compliance Approaches Taken by Companies both Pre- and Post-Litigation
- Survey Results Related to Pharmaceutical Companies' Responses to the Litigation
- The Recent Legislative Changes in Massachusetts and the Ambiguities in the Language
- Survey Results Related to Key Massachusetts Interpretive Issues

### 1:15 pm Panel Discussion

**Perry Goldman, Esq.**, Vice President and Deputy General Counsel, Onyx Pharmaceuticals, San Francisco, CA

**Jennifer Lee-Crist, Esq.**, Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN

**William A. Sarraille, Esq.**, Partner, Sidley Austin LLP, Washington, DC (Co chair)

**Richard L. Zimmerer**, Partner, Forensic Advisory Services, KPMG LLP, Los Angeles, CA (Co chair)

### 2:30 pm Transition Break

### Mini Summit II: Great Expectations: What Enhanced Obligations in Corporate Integrity Agreements (CIAs) and Deferred Prosecution Agreements (DPAs) say about Agency Expectations for Compliance Programs

- Using CIAs and DPAs to Reduce Fraudulent Activity
- How To Document Board and Management Certifications
- The Role of Compliance Experts and Monitors
- Field Force Monitoring Best Practices
- Current Risk Areas

### 1:15 pm Panel Discussion

**Steve Guymon** (Invited), US Medical Compliance Officer, Eli Lilly and Company, Indianapolis, IN

**Steven J. Tave, Esq.**, Counsel, Gibson, Dunn & Crutcher LLP; Former Associate Chief Counsel for Enforcement, Office of Chief Counsel, US Food and Drug Administration, Washington, DC

**Thomas W. Beimers, Esq.**, Special Counsel, Faegre Baker Daniels; Former Senior Counsel for Administrative and Civil Remedies, Office of the Inspector General, US Department of Health and Human Services, Minneapolis, MN (Co chair)

**Edward Nowicki, Esq.**, Vice President and Assistant General Counsel, Pfizer Inc., New York, NY (Co chair)

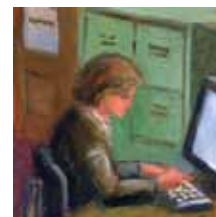
### 2:30 pm Transition Break

### Live and Archived Internet Attendance

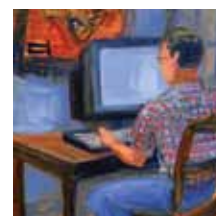
Watch the conference in live streaming video of plenary sessions and listen to audio of preconference and mini summits over the Internet and at your convenience at any time 24/7 for six months following the event.

The archived conference includes speaker video and audio and coordinated PowerPoint presentations.

PROS: Live digital feed and 24/7 Internet access for the next six months; accessible in the office, at home or anywhere worldwide with Internet access; avoid travel expense and hassle; no time away from the office.



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## Mini Summit III: Compliance Issues in Global R&D and Medical Affairs

- Regulatory Enforcement Environment: Has the Bar Moved?
- Applying Quality Management Principles to R&D
- Managing Global Trials — Special Considerations
- Publication of Clinical Trial Results
- Support of Medical Education Globally
- Compliance Challenges with Investigator-Sponsored Research

### 1:15 pm Panel Discussion

**Leslie Ball, MD** (Invited), *Director, Office of Scientific Investigations, Center for Drug Evaluation and Research, US Food and Drug Administration, Washington, DC*

**Gerald “Jerry” Kuncio, PhD**, *Deputy Compliance Officer for NA Medical Affairs, GlaxoSmithKline; Former Medical/Scientific Compliance and Ethics Director, AstraZeneca, Philadelphia, PA*

**Mary Newman** (Invited), *Vice President, Quality and Compliance, Bristol-Myers Squibb, New York, NY*

**Annalisa Pizzarello, Esq.**, *Vice President, Commercialization and R&D Compliance, Amgen, Thousand Oaks, CA*

**Gregory H. Levine, Esq.**, *Partner and Co chair, Life Sciences Practice Group, Ropes & Gray, Washington, DC (Co chair)*

**Kathleen Meriwether, Esq.**, *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Philadelphia, PA (Co chair)*

### 2:30 pm Transition Break

## Mini Summit IV: US Disclosure Implementation Update

- Legal Update (Including Final Rule if Issued)
- Lessons Learned on Disclosure from Living under a CIA
- Pharmaceutical Company Perspective
- Medical Device Company Perspective
- Global Context and Other Disclosure Topics
- Conclusions and Current Operational Priorities

### 1:15 pm Panel Discussion

**Daniel Char, Esq.**, *Associate General Counsel - Commercial, Smith & Nephew; Former Vice President, General Counsel and Secretary, Targanta Therapeutics Corporation, Boston, MA*

**Diane Cruz-Burke, Esq.**, *Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN*

**Gus Papandrikos, MBA**, *Director Transparency Operations, Sanofi, New York, NY*

**Eve M. Brunts, JD, LLM**, *Partner, Ropes & Gray, Boston, MA (Co chair)*

**Jack T. Tanselle**, *Managing Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Indianapolis, IN (Co chair)*

### 2:30 pm Transition Break

## Mini Summit V: Medical Device Compliance Issues Update

- Building Global Compliance Organizations
- Operating Under Deferred Prosecution Agreements (DPAs)
- Collaborating with HCPs-Physician Inventors
- Managing Distributors and Sales Agents
- Sales Reps in the Operating Room
- Emerging GMP/QSR Issues
- Global Monitoring Programs

### 1:15 pm Panel Discussion

**Eileen Erdos**, *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP, Chicago, IL, USA*

**Daniel J. Garen, Esq.**, *Senior Vice President/Chief Compliance Officer, Wright Medical; Former Chief Compliance Officer and Senior Counsel, Siemens Healthcare Sector, USA, Malvern, PA*

**Thomas J. Schumacher, Esq.** (Invited), *Vice President, Chief Ethics and Compliance Officer, Medtronic, Inc., Mounds View, MN*

**Sujata T. Dayal, Esq.**, *Corporate Vice President and Chief Compliance Officer, Biomet; Former Counsel, Domestic Legal Operations, Abbott Laboratories; Former Member, PCF Executive Committee, Warsaw, IN (Co chair)*

**Ronald L. Wisor, Jr., Esq.**, *Partner, Hogan Lovells US LLP, Washington, DC (Co chair)*

### 2:30 pm Transition Break

## Mini Summit VI: Global Pharma and Device Compliance Issues

- Recognizing Local Cultural Diversity within Global Policies
- Translating Global Policies into Local Practices
- Global Transparency Requirements
- When Things go Wrong Internationally

### 1:15 pm Keynote: EU Update

**Vincenzo Salvatore, Esq.**, *Senior Counsel, Sidley Austin LLP, Professor of International Law, University of Insubria; Former Head of Legal Service, European Medicines Agency, Varese, Italy*

### 1:35 pm Panel Discussion of Global Compliance Issues

**Michael K. Volz, LLM**, *Group Compliance Officer, Merck KgaA, Frankfurt Am Main, Germany*

**Sue Egan**, *Director and Principal Consultant, Sue Egan Associates; Editor, Life Science Compliance; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK (Co chair)*

**Keith M. Korenchuk, JD, MPH**, *Partner, Arnold & Porter LLP, Washington, DC (Co chair)*

### 2:30 pm Transition Break

## MINI SUMMITS BLOCK B — 2:45 pm to 4:00 pm

### Mini Summit VII: Anticorruption, Including FCPA and UK Bribery Act Update

- Lessons from recent FCPA Prosecutions and Settlements
- Expectations from the SEC on Cooperation and Self-disclosure
- Interactions Overseas Most Likely to Generate Problems
- Expectations from the UKBA thus far
- Prospects for the UKBA
- The Impact of Recent Change at the Serious Fraud Office
- Self-reporting under the UKBA
- The UK Initiative for DPAs

### 2:45 pm Panel Discussion

**Gary F. Giampetruzzi, Esq.**, *Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY*

**Michael Kendall, Esq.**, *Partner and Head, White-Collar Defense Group, McDermott Will & Emery LLP; Former Deputy Associate Attorney General and Counselor, United States Department of Justice; Former Assistant United States Attorney, United States Attorney's Office, District of Massachusetts, Boston, MA (Co chair)*

**Vivian Robinson, Esq.**, Partner, McGuireWoods; Former General Counsel of the UK Serious Fraud Office; Former Head, QEB Hollis Whiteman Chambers; Recorder of the Crown Court and Treasurer of Inner Temple, London, UK (Co chair)

**4:00 pm Transition Break**

### Mini Summit VIII: Fair Market Value Update

**Kelly B. Freeman, PhD**, Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN (Co chair)

**2:45 pm Fair Market Value at a Global Level: Challenges and Potential Solutions**

**Prateep Menon, CFA**, Principal, Deloitte Financial Advisory Services LLP, New York, NY

**3:10 pm Service Fee Fair Market Value**

**Mark A. DeWynngaert, PhD**, Managing Director, Huron Consulting Group, LLC, New York, NY

**John Moose, MBA, CPA, ABV**, Manager, Huron LifeSciences, Chicago, IL

**3:35 pm Methodology for Global Fair Market Value Calculations**

**Fred Eaton, MBA**, Partner, Polaris Management Partners, New York, NY

**4:00 pm Transition Break**

### Mini Summit IX: Enforcement Threat Against Individuals

- Prosecution of Individuals: Felony Theories and Responsible Corporate Officer Doctrine
- Exclusion of Individuals
- Current Enforcement Environment
- Best Practices

**2:45 pm Panel Discussion**

**Thomas M. Gallagher, Esq.**, Chair, White Collar Investigations and Defense, Pepper Hamilton LLP, Philadelphia, PA (Co chair)

**Lori Queisser**, Principal, Advisory Services, KPMG LLP; Former Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation; Former Member, PCF Executive Committee, Indianapolis, IN (Co chair)

**4:00 pm Transition Break**

### Mini Summit X: Global Transparency Update

- Overview of Global Transparency Laws and Codes
- Operational Challenges in Meeting Global Transparency Laws and Codes
- Data Privacy
- Cultural Impact of Transparency
- Technology Considerations
- Customer Master Data Considerations
- Impact of Potential EFPIA Transparency Initiatives

**2:45 pm Panel Discussion**

**Peter Burberry**, Senior Director, Global Practices, Business Practice Management, Allergan Inc., Irvine, CA

**Katrina S. Cahill**, Senior Manager, Corporate Compliance, Global Transparency Lead, Biogen Idec, Weston, MA

**Michael O'Connor, MS**, Executive Director, IS Business Consulting, Boehringer Ingelheim, New York, NY

**William E. Buzzeo, MS**, Vice President and General Manager, Compliance Solutions Division, Cegedim Relationship Management, Richmond, VA (Co chair)

**Kelly N. "Nikki" Reeves, MPA, JD**, Partner, King & Spalding LLP, Washington, DC (Co chair)

**4:00 pm Transition Break**

### Mini Summit XI: Special Compliance Issues and Strategies of Small Pharmaceutical and Medical Device Companies

**2:45 pm Panel Discussion**

**Justin A. Dillon**, Vice President, Chief Ethics and Compliance Officer, Ipsen Biopharmaceuticals, Inc.; Former Deputy Ethics and Compliance Officer, North America Pharma and Vaccines, GlaxoSmithKline, Basking Ridge, NJ

**Jeffrey Klimaski, MBA, CPA**, Vice President, Corporate Ethics and Compliance Officer, BTG International Inc.; Former Vice President, Global Ethics and Compliance Officer, Stiefel Laboratories, Inc., West Conshohocken, PA

**Daniel A. Kracov, Esq.**, Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC

**Timothy Ayers, JD, MPH**, Vice President and Chief Compliance Officer, Dendreon; Former Associate General Counsel and Executive Director of Compliance, Seattle Genetics, Bothell, WA (Co chair)

**Elizabeth V. Jobses, Esq.**, Senior Vice President and Chief Compliance Officer, Auxilium Pharmaceuticals Inc; Former Vice President and Chief Compliance Officer, Adolor, Philadelphia, PA (Co chair)

**4:00 pm Transition Break**

### Mini Summit XII: Integrating a Culture of Ethics into Your Compliance Program

**2:45 pm Panel Discussion**

**Paul J. McNulty, Esq.**, Partner and Chair, Global Corporate Compliance Steering Committee, Baker & McKenzie LLP; Former Deputy Attorney General, US Department of Justice, Washington, DC

**Matthew Pachman, Esq.**, Vice President and Chief Ethics Officer, FTI Consulting; Vice President, Chief Compliance Officer, Altegrity; Vice President, Compliance, Ethics and Business Practices, Freddie Mac; Director, Legal (and Ethics), MCI, Washington, DC

**Jeffrey S. Paden**, Deputy Compliance Officer, GlaxoSmithKline, Research Triangle Park, NC

**Caroline West, Esq.**, Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc., Philadelphia, PA (Co chair)

**4:00 pm Transition Break**

**MINI SUMMITS BLOCK C — 4:15 pm to 5:30 pm**  
(except Mini Summits XIII and XVIII, which end at 5:45 pm)

### Mini Summit XIII: Government Price Reporting Update

- The Streck Opinion and Bona Fide Service Fees
- 340B Integrity and Price Reporting
- The Proposed Expansion of "Bundled Sale" Definition
- Planning for AMP Final Rule, Due in early 2013.

**4:15 pm Panel Discussion**

**Marcy Imada**, Principal, Deloitte & Touche LLP, Los Angeles, CA (Co chair)

**John D. Shakow, Esq.**, Partner, FDA & Life Sciences Practice, King & Spalding, Washington, DC (Co chair)

**5:45 pm Adjournment and Best Practices Poster Board Reception**

## Mini Summit XIV: Clinical Trial Disclosure and Results Reporting Liability under FDAAA, Section 801

- FDA Update on FDAAA, Sec. 801 Activities
- Current Risk Areas in Clinical Trial Disclosure
- Monitoring Compliance with Global Clinical Trial Disclosure Requirements
- Specific Considerations for Investigator-initiated Research
- Trends in Research Transparency Policies and CIAs

### 4:15 pm Panel Discussion

**Jeffrey K. Francer, MPP, JD**, Assistant Legal Counsel, PhRMA; Former Associate Chief Counsel, US Food and Drug Administration, Washington, DC, USA

**Ann Meeker-O'Connell, MS, CCEP**, Office of Policy, Office of the Commissioner, US Food and Drug Administration, Silver Spring, MD

**Marc B. Wilenzick, Esq.**, Compliance Officer/Chief Compliance Counsel, R&D and Medical, Pfizer Inc., New York, NY

**Julie Finegan, Esq.**, Associate Chief Counsel, US Food and Drug Administration, Washington, DC (Chair)

### 5:30 pm Adjournment and Best Practices Poster Board Reception

## Mini Summit XV: Board and Management Certifications and Working with an IRO

### 4:15 pm Panel Discussion

**Meredith Manning, Esq.**, Co-director, Pharmaceutical and Biotechnology Practice Group, Hogan Lovells LLP; Former Assistant US Attorney, Civil Division, US Attorney's Office in Washington, DC; Former Associate Chief Counsel, Office of General Counsel, US Food and Drug Administration, Washington, DC (Co chair)

**Brian Riewerts**, Partner, Global Pharmaceuticals and Life Sciences, PwC, Baltimore, MD, USA (Co chair)

### 5:30 pm Adjournment and Best Practices Poster Board Reception

## Mini Summit XVI: Drug Samples Disclosure: The Next Horizon?

### 4:15 pm Panel Discussion

**Kendra Martello, Esq.**, Assistant General Counsel, PhRMA, Washington, DC

**Marilyn May, Esq.**, Senior Litigation Counsel, US Attorney's Office, Eastern District of Pennsylvania, United States Department of Justice, Philadelphia, PA

**Kate Whelley McCabe, Esq.** (Invited), Assistant Attorney General, Public Protection Division, Vermont Office of the Attorney General, Montpelier, VT

**Karen Rothschild, Esq.** (Invited), Regulatory Counsel, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, Washington, DC

**John Patrick Oroho, Esq.**, Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ (Chair)

### 5:30 pm Adjournment and Best Practices Poster Board Reception

## Mini Summit XVII: Professional Responsibilities for Compliance Officers and In-house Counsel in the Pharmaceutical, Biotech and Medical Device Industries

Many compliance officers are current or former lawyers and all work extensively with in-house legal counsel. Both are governed by standards of professional responsibility. It is important for both compliance officers and for in-house counsel to be mindful of where respective jobs and professional responsibilities overlap and where they are different — particularly where:

- Compliance and the Law Department are Separate Functions
- Compliance Reports to the Law Department
- Compliance and Legal are One Function

### 4:15 pm Panel Discussion

**Edward (Ed) Berg, Esq.**, Vice President, Associate General Counsel, Sanofi, New York, NY

**Robert Hoehn, Esq.**, Health Care Compliance Officer, Acclarent (a Johnson & Johnson company), San Francisco, CA

**Freddy Jimenez, Esq.**, Assistant General Counsel, Johnson & Johnson, New Brunswick, NJ

**Jeffrey Klimaski, MBA, CPA**, Vice President, Corporate Ethics and Compliance Officer, BTG International Inc.; Former Vice President, Global Ethics and Compliance Officer, Stiefel Laboratories, Inc., West Conshohocken, PA

**Thomas E. Costa**, Vice President, US Pharmaceuticals Compliance, Bristol-Myers Squibb Co., Princeton, NJ (Moderator)

**Christopher D. Zalesky, JD, CCEP, RAC**, Vice President Global Policy and Guidance, Health Care Compliance and Privacy, Johnson & Johnson, New Brunswick, NJ (Moderator)

### 5:30 pm Adjournment and Best Practices Poster Board Reception

## Mini Summit XVIII: Compliance Program Innovation

### 4:15 pm Compliance Program Excellence: Transforming/Rationalizing a Compliance Program

**Lori Queisser**, Principal, Advisory Services, KPMG LLP; Former Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation; Former Member, PCF Executive Committee, Indianapolis, IN (Co chair)

### 5:00 pm Compliance Effectiveness Reviews: Benefits to the Board of Directors and Beyond

**Joseph Cacciatore, MBA**, Executive Director, Ethics and Compliance, Novartis Pharmaceuticals Corporation; Former Director, US Compliance, Schering-Plough, East Hanover, NJ

**Saul B. Helman, MD, MBA**, Managing Director, Disputes and Investigations Practice, Navigant, Chicago, IL (Co chair)

### 5:45 pm Adjournment and Best Practices Poster Board Reception

### 5:30 pm BEST PRACTICES POSTER BOARD RECEPTION

**Danielle Bacco**, Manager Corporate Compliance, Purdue Pharma LP, Stamford, CT (Poster Board Session Chair)



Wednesday, November 7, 2012

## PHARMA CONGRESS: AGENDA DAY III

**7:30 am Registration Opens**

**7:30 am Continental Breakfast in Exhibit Hall**

**8:30 am Introduction to Day Three**

**Margaret K. Feltz**, Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)

**8:45 am Keynote Address: Life Sciences in America Following the Supreme Court ACA Decision and the Morning after the Election**

**Susan Dentzer**, Editor-in-Chief, Health Affairs; Health Policy Analyst, The News Hour with Jim Lehrer, Washington, DC

**9:15 am Keynote Address: Managing Internal and External Investigations**

**Louis Joseph Freeh, JD, LLM**, Founder and Chairman, Freeh Group International Solutions; Former Director, Federal Bureau of Investigation; Former Judge, United States District Court, Southern District of New York; Former Associate US Attorney and Chief, Organized Crime Unit, United States Attorney's Office, Southern District of New York, Wilmington, DE

**10:00 am Break**

**10:15 am PhRMA's New Compliance Work Group Update**

**Kendra Martello, Esq.**, Assistant General Counsel, PhRMA, Washington, DC

**Anne Nobles, MA, JD**, Chief Ethics and Compliance Officer and Senior Vice President Enterprise Risk Management, Eli Lilly and Company; Vice Chair, Ethics and Compliance Officers Association, Indianapolis, IN

**11:00 am Global Pharma and Device Compliance Issues and Strategies**

**Abdul Luheshi, MBA, PhD**, Vice President Health Care Compliance, Asia Pacific, Johnson & Johnson International, Inc.; Co chair, Asia Pacific American Pharma Congress, Singapore

**Clivetty Martinez, PhD**, Regional Vice President Latin America, Office of Healthcare Compliance and Privacy, Johnson & Johnson International, Inc.; Chair, Latin American Ethics and Compliance Network; Co chair, Latin American Pharma Congress, Miami, FL

**Roeland Van Aelst**, Vice President EMEA & Canada, Office of Health Care Compliance and Privacy, Johnson & Johnson International, Inc; Board Member, International Society of Healthcare Ethics and Compliance Professionals (ethics); Co chair, Latin American Pharma Congress, Brussels, Belgium

**Brian Riewerts**, Partner, Global Pharmaceuticals and Life Sciences, PwC, Baltimore, MD (Moderator)

**12:30 pm Congress Adjournment**

## PCF Planning Committee:

Gary Del Vecchio, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company (Co chair)

Margaret K. Feltz, Director, Corporate Compliance, Purdue Pharma LP (Co chair)

Kelly B. Freeman, PhD, Senior Director, Ethics and Compliance, Eli Lilly and Company (Co chair)

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## THE FOLLOWING REGISTRATION TERMS AND CONDITIONS APPLY

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- Online at [www.PharmaCongress.com](http://www.PharmaCongress.com).
- Fax/Mail/Email using this printed registration form. Mail the completed form with payment to the conference registrar at 22529 39th Ave. SE, Bothell, WA 98021, or fax the completed form to 206-319-5303, or scan and email the completed form to [registration@hcconferences.com](mailto:registration@hcconferences.com). Checks or money orders should be made payable to Health Care Conference Administrators LLC.

The following credit cards are accepted: American Express, Visa or MasterCard. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC.

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- Through Friday, October 5, 2012\*\* \$2,195
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- Flash Drive (\$129 + \$30 shipping) \$ 159
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### SELECT YOUR MINI SUMMITS (Tues. Nov.6; one from each group):

Block A: 1:15 pm  I  II  III  IV  V  VI

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