THE THIRTEENTH ANNUAL

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING — EFFECTIVE KNOWLEDGE EXCHANGE

November 5 – 7, 2012

Washington, DC • Grand Hyatt

DIAMOND GRANTORS

Ernst & Young — Quality In Everything We Do

pwc

SILVER GRANTORS

Deloitte.

KPMG

Huron Life Sciences

NAVIGANT

BRONZE GRANTORS

AHM

Davis Wright Tremaine LLP — Defining Success Together

McDermott Will & Emery

PORZIO Life Sciences

ROPES & GRAY

ARNOLD & PORTER LLP

EPSTEIN BECKER GREEN

Pepper Hamilton LLP — Attorneys at Law

BAKER & MCKENZIE

SIDLEY AUSTIN LLP — SIDLEY

cegedim — Relationship Management

Hogan Lovells

KING & SPALDING

Polaris

Skadden

MEDIA PARTNERS

HARVARD health policy REVIEW

HealthAffairs

LIFE SCIENCE COMPLIANCE

Rx COMPLIANCE REPORT

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

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

Sixth International Pharmaceutical Compliance Congress

Sponsored by International Society of Healthcare Compliance Professionals

Cosponsored by Pharmaceutical Compliance Forum

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

May 21 – 23, 2013, Madrid, Spain

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

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. Please visit their website at 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@hcconferences.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*

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

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

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.

At your office . . .

. . . or home

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)*

Session continued next page

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. DeWyngaert, 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. Jobes, 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)

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

Ted Acosta, Esq., Principal, Ernst & Young LLP

Timothy Ayers, Esq., Associate General Counsel, Executive Director of Compliance, Seattle Genetics

Wayne Baker, Senior Vice President and Chief Sales Officer, Advanced Health Media LLC

Scott Bass, Esq., Partner, Sidley Austin LLP

John T. Bentivoglio, Esq., Partner, Skadden Arps LLP

Eve M. Brunts, Esq., Partner, Ropes & Gray

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

Sujata T. Dayal, Corporate Vice President and Chief Compliance Officer, Global Operations, Biomet, Inc.

Sue Egan, Director and Principal Consultant, Sue Egan Associates

Thomas Forrester, Esq., Vice President, US Legal Affairs and General Counsel, Lundbeck Inc.

Thomas M. Gallagher, Esq., Chair, White Collar Investigations and Defense, Pepper Hamilton LLP

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

Wendy C. Goldstein, Esq., Partner, Epstein Becker & Green

Alessandra N. Hawthorne, Vice President, Chief Ethics and Compliance Officer, Boehringer Ingelheim USA, Inc.

Michael Hercz, Esq., Director, Audit and Enterprise Risk Services, Deloitte & Touche LLP

Elizabeth V. Jobes, Esq., Senior Vice President and Chief Compliance Officer, Auxilium Pharmaceuticals Inc.

Jonathon Kellerman, Partner, Global Pharmaceutical Advisory Services Group, PwC

Daniel Kracov, Esq., Partner, Arnold & Porter LLP

Maxine Nogard, Senior Director, Global Corporate Compliance, Biogen Idec, Inc.

John Patrick Oroho, Esq., Executive Vice President and Chief Strategy Officer, Porzio Pharmaceutical Services, LLC; Principal, Porzio, Bromberg & Newman

Neena M. Patil, Esq., Senior Corporate Counsel, Novo Nordisk Inc.

Lawrence P. Platkin, Vice President and Compliance Officer, Bayer Healthcare LLC

Arjun Rajaratnam, Chief Compliance Officer, Smith & Nephew

Kelly N. "Nikki" Reeves, MPA, JD, Partner, King & Spalding LLP

Susan Romanus, Vice President, Chief Ethics and Compliance Officer, Daiichi Sankyo

Jeff Rosenbaum, Vice President, Chief Compliance Officer, Vertex Pharmaceuticals

Karen Patruno Sheehy, Esq., Vice President, US Corporate Compliance Officer, Sanofi

Eric Siegel, Esq., Executive Vice President & General Counsel, Incyte Corporation

Paul J. Silver, Managing Director, Huron Consulting Group

Jack T. Tanselle, Managing Director, Navigant Consulting, Inc.

Caroline West, Esq., Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc.

Ronald L. Wisor, Jr., Esq., Partner, Hogan Lovells US LLP

Christopher D. Zalesky, Executive Director, World Wide Office of Health Care Compliance & Privacy, Johnson & Johnson

Richard L. Zimmerer, Partner, Forensic Advisory Services, KPMG LLP

THE FOLLOWING REGISTRATION TERMS AND CONDITIONS APPLY

REGARDING INTERNET REGISTRATIONS

1. Individuals or groups may register for Internet access. Conference plenary sessions are broadcast in video. Conference preconference and mini summits are broadcast in audio only. From time to time individuals decline to sign the waiver permitting Internet broadcast. In those instances their presentations are not included in the broadcast.

2.Organizations may register for group access without presenting specific registrant names. In such instances the registering organization will be presented a series of user names and passwords to distribute to participants.

3. Each registrant will receive a user name and password for access. Registrants will be able to change their user names and passwords and manage their accounts.

4. Internet registrants will enjoy six (6) months of access from the date of issuance of a user name and password.

5. Only one user (per user name and password) may access the archived conference. It is not permissible to share the user name and password with third parties. Should Internet registrants choose to access post conference content via alternative media (Flash Drive), this individual use limitation applies. It is not permissible to share alternative media with third parties.

6. User name and password use will be monitored to assure compliance.

7. Each Internet registration is subject to a "bandwidth" or capacity use cap of 5 gb per user per month. When this capacity use cap is hit, the registration lapses. Said registration will be again made available at the start of the next month so long as the registration period has not lapsed and is subject to the same capacity cap.

8. For online registrants there will be no refunds for cancellations. Please call the Conference Office at 800-503-7419 or 206-452-5662 for further information.

REGARDING ONSITE REGISTRATION, CANCELLATIONS AND SUBSTITUTIONS

1. For onsite group registrations, full registration and credit card information is required for each registrant. List all members of groups registering concurrently on fax or scanned cover sheet.

2. For onsite registrants there will be no refunds for "no-shows" or for cancellations. You may send a substitute or switch to the online option. Please call the Conference Office at 800-503-7419 or 206-452-5662 for further information.

METHOD OF PAYMENT FOR TUITION

Make payment to Health Care Conference Administrators LLC by check, MasterCard, Visa or American Express. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC. Checks or money orders should be made payable to Health Care Conference Administrators LLC. A $30 fee will be charged on any returned checks.

REGISTRATION OPTIONS

Registration may be made online or via mail, fax or scan.

You may register through either of the following:

• Online at 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. 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.

For registrants awaiting company check or money order, a credit card number must be given to hold registration. If payment is not received by seven days prior to the Congress, credit card payment will be processed.

TAX DEDUCTIBILITY

Expenses of training including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor. Federal Tax ID: 91-1892021.

HOTEL INFORMATION/RESERVATIONS

The Grand Hyatt Washington is the official hotel for the Thirteenth Pharmaceutical Regulatory and Compliance Congress. A special group rate of $289.00 single/double per night (plus tax) has been arranged for Congress Attendees. Information on how to make your reservation online is available on the travel page of the conference website, www.PharmaCongress.com. To make a phone reservation, please call Hyatt Reservations directly at 1-888-421-1442 or 402-592-6464 and refer to the group name "Pharma Congress" in order to receive the group rate. Reservations at the group rate will be accepted while rooms are available or until the cut-off date of **Monday, October 8, 2012**. After this, reservations will be accepted on a space-available basis at the prevailing rate.

Grand Hyatt Washington

1000 H Street NW • Washington, DC 20001 US

CONTINUING EDUCATION UNITS (CEUs)

The Congress does not offer pre-approved Continuing Education Credits (CEUs) directly. However, onsite attendees can request a Certificate of Attendance which they can file with appropriate entities for credit, and online attendees can request an Online Certificate of Attendance on which they can certify the number of hours they watched and can file with appropriate entities for credit.

CANCELLATIONS/SUBSTITUTIONS

No refunds will be given for "no-shows" or for cancellations of either online or onsite registrations. You may send a substitute or transfer your onsite registration to an online registration. For more information, please call the Conference Office at 800-503-7419 or 206-452-5662.

INTELLECTUAL PROPERTY POLICY

Unauthorized sharing of Congress content via Internet access through the sharing of user names and passwords or via alternative media (Flash Drive) through the sharing of said media is restricted by law and may subject the copyright infringer to substantial civil damages. The Congress aggressively pursues copyright infringers. If a registrant needs the ability to share Congress content within his or her organization, multiple Congress registrations are available at discounted rates.

The Congress will pay a reward for information regarding unauthorized sharing of Congress content. The reward will be one quarter (25%) of any recovery resulting from a copyright infringement (less legal fees and other expenses related to the recovery) up to a maximum reward payment of $25,000. The payment will be made to the individual or individuals who in the opinion of our legal counsel first provided the factual information, which was necessary for the recovery. If you have knowledge regarding the unauthorized Congress content sharing, contact the Congress registration office.

REGISTRATION BINDING AGREEMENT

Registration (whether online or by this form) constitutes a contract and all of these terms and conditions are binding on the parties. In particular, these terms and conditions shall apply in the case of any credit/debit card dispute.

GENERAL TERMS AND CONDITIONS

Program subject to cancellation or change. If the program is cancelled the only liability of the Congress will be to refund the registration fee paid. The Congress shall have no liability regarding travel or other costs. Registration form submitted via fax, mail, email or online constitutes binding agreement between the parties.

FOR FURTHER INFORMATION

Call 800-503-7419 (Continental US, Alaska and Hawaii only) or 206-452-5662, send e-mail to registration@hcconferences.com, or visit our website at www.PharmaCongress.com.

Pharmaceutical Congress

HOW TO REGISTER: Fully complete the form below (one form per registrant, photocopies acceptable). Payment must accompany each registration (U.S. funds, payable to Health Care Conference Administrators, LLC).

ONLINE: Secure online registration at www.PharmaCongress.com.

FAX: 206-319-5303 (include credit card information with registration)

MAIL: Conference Office, 22529 39th Ave SE, Bothell, WA 98021

FOR REGISTRATION QUESTIONS:

PHONE: 800-503-7419 (Continental US, Alaska and Hawaii only) or 206-452-5662, Monday-Friday, 7 AM - 5 PM PST

E-MAIL: registration@hcconferences.com

COMPLETE THE FOLLOWING. PLEASE PRINT CLEARLY:

NAME

SIGNATURE OF REGISTRANT - REQUIRED

JOB TITLE

ORGANIZATION

ADDRESS

CITY/STATE/ZIP

TELEPHONE

E-MAIL

❑ Special Needs (Dietary or Physical)

ONSITE CONFERENCE ATTENDANCE

Onsite conference registration includes onsite attendance, professional networking, and live interaction with the faculty, plus a conference materials CD.

PRECONFERENCE:

❑ Precon I: Compliance 101 $ 495

❑ Precon II: Auditing and Monitoring Boot Camp $ 495

❑ Precon III: A Comprehensive Overview of Pharma and Medical Device Corporate Integrity Agreements (CIAs) $ 495

❑ Precon IV: The New Era of Scrutiny: FCPA Compliance in Pharma Operations $ 495

STANDARD CONFERENCE REGISTRATION (Does not include Preconference):

❑ Through Friday, September 7, 2012* $1,995
❑ Through Friday, October 5, 2012** $2,195
❑ After Friday, October 5, 2012 $2,395

PCF* CONFERENCE REGISTRATION** (Does not include Preconference):

❑ Through Friday, September 7, 2012* $1,695
❑ Through Friday, October 5, 2012** $1,895
❑ After Friday, October 5, 2012 $2,095

PCF* GROUP REGISTRATION DISCOUNT** (Does not include Preconference):

Registrations from the same organization submitted at the same time receive the following discounted rates for conference registration only:

❑ 5 or more — each attendee $1,595 ❑ 10 or more — each attendee $1,495

CONFERENCE ELECTRONIC MEDIA:

Onsite Attendees — Following the Congress, the audio/video and Powerpoint presentations are made available in the following formats. To take advantage of the discounted prices below, you must reserve media WITH your Congress registration:

❑ Flash Drive ($129 + $30 shipping) $ 159 ❑ 6 months' access on Web $ 129

SELECT YOUR MINI SUMMITS (Tues. Nov.6; one from each group):

Block A: 1:15 pm	❑ I	❑ II	❑ III	❑ IV	❑ V	❑ VI
Block B: 2:45 pm	❑ VII	❑ VIII	❑ IX	❑ X	❑ XI	❑ XII
Block C: 4:15 pm	❑ XIII	❑ XIV	❑ XV	❑ XVI	❑ XVII	❑ XVIII

ONLINE CONFERENCE ATTENDANCE

Online conference registration includes the live Internet feed from the Conference, plus six months of continued archived Internet access, available 24/7.

STANDARD RATE (Includes preconferences):

❑ Through Friday, September 7, 2012* $ 795
❑ Through Friday, October 5, 2012** $ 995
❑ After Friday, October 5, 2012 $1,195

PCF INDIVIDUAL REGISTRATION* ** (Includes preconferences):

❑ Through Friday, September 7, 2012* $ 595
❑ Through Friday, October 5, 2012** $ 795
❑ After Friday, October 5, 2012 $ 995

GROUP REGISTRATION:

Group registration offers the substantial volume discounts set forth below.

All group registrants are enrolled in the full Pharma Congress.

Group registration offers the possibility of implementing a pharma online training program. Group registration permits the organizational knowledge coordinator either to share conference access with colleagues or to assign and track employee conference participation.

Conference Access: ❑ 5 or more $595 each ❑ 10 or more $495 each ❑ 20 or more $395 each ❑ 40 or more $295 each

See INTELLECTUAL PROPERTY POLICY, page 10.

CONFERENCE ELECTRONIC MEDIA:

Online attendees — Following the Congress, the audio/video and Powerpoint presentations are made available on a flash drive. To take advantage of the discounted price below, you must reserve media WITH your Congress registration:

❑ Flash Drive ($129 + $30 shipping) $159

(All online attendees automatically receive 6 months access on web.)

* This price reflects a discount for registration and payment received through Friday, 9/7/12.

** This price reflects a discount for registration and payment received through Friday, 10/5/12.

*** To qualify for the PCF member rate an individual must be an employee of a member company of the Pharmaceutical Compliance Forum (PCF).

PAYMENT

Discount Code:

TOTAL FOR ALL OPTIONS, ONSITE OR ONLINE:

Please enclose payment with your registration and return it to the Registrar at Pharma Congress, 22529 39th Ave SE, Bothell, WA 98021, or fax your credit card payment to 206-319-5303.

You may also register online at www.PharmaCongress.com.

❑ Check/money order enclosed (payable to Health Care Conference Administrators LLC)

❑ Payment by credit card: ❑ American Express ❑ Visa ❑ Mastercard

If a credit card number is being given to hold registration only until such time as a check is received it must be so noted. If payment is not received by seven days prior to the Congress, the credit card payment will be processed. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC.

REGISTRATION BINDING AGREEMENT

Registration (whether online or by this form) constitutes a contract and all of these terms and conditions are binding on the parties. In particular, these terms and conditions shall apply in the case of any credit/debit card dispute. For online and onsite registrants there will be no refunds for "no-shows" or cancellations.

ACCOUNT #

EXPIRATION DATE SECURITY CODE

NAME OF CARDHOLDER

SIGNATURE OF CARDHOLDER

Pharmaceutical Congress
Publications Printing Dept.
41651 Corporate Way
Palm Desert, CA 92260
USA
(Address for Return Mail Only)

www.PharmaCongress.com

THE THIRTEENTH ANNUAL

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING — EFFECTIVE KNOWLEDGE EXCHANGE

A Hybrid Conference & Internet Event

See page 5

SPONSOR

THE PHARMACEUTICAL COMPLIANCE FORUM

November 5 – 7, 2012

Washington, DC • Grand Hyatt

www.PharmaCongress.com