THE TWELFTH ANNUAL Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Transformational Learning – Effective Knowledge Exchange

November 2–4, 2011

Mandarin Oriental • Washington, DC

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Media Partners: Harvard Health Policy Review, Health Affairs, RX Compliance Report

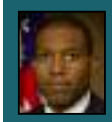
Keynote Speakers:

- Ariel Kaminer, The Ethicist, New York Times Magazine

- John C. Lechleiter, PhD, Chairman, President and Chief Executive Officer, Eli Lilly and Company; Chairman-elect, PhRMA Board of Directors

- Richard M. Mullane (Colonel, USAF, Ret.), Former NASA Astronaut

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

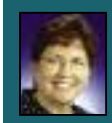


- Tony West, Esq., Head, Civil Division, US Department of Justice

Co chairs:

- Gary DelVecchio, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company

- Margaret K. Feltz, Director, Corporate Compliance, Purdue Pharma LP



- Kelly B. Freeman, PhD, Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company

- Michael L. Shaw, Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals

Featuring Preconferences:

- Compliance Basics
- Practical Approaches to Implementing an Aggregate Spend Program

Plenary Sessions:

- OIG Update
- DOJ Civil Division Update
- Coordinating Pharma Prosecutions
- FDA-DDMAC Update
- Pharma 2020
- Sunshine Act Regulations
- FCPA and UK Bribery Act Enforcement and Compliance Update
- Lessons of the Stevens Case
- Lessons of the Forrest and Purdue
- Best Practices to Avoid Individual Liability and Exclusion
- Compliance Professional Responsibilities in the Pharma, Biotech & Device Industries
- Board and Executive Responsibilities and Certifications

And the Following Tracks:

- Taking Your Compliance Program to a New Level
- Internal and External Investigations Update
- Fair Market Value Update
- FCPA and UK Bribery Act Compliance Update
- Compliance Lessons Learned from Medical Devices
- Advanced Issues in Auditing and Monitoring
- The Hottest Emerging Issues in Industry/HCP Relationships
- Government Payment and Price Reporting Update
- Research & Development and Clinical Trials
- Global Pharma and Device Compliance Issues

Co chairs:

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Kelly B. Freeman, PhD, *Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company*

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- Government Payment and Price Reporting Update
- Research & Development and Clinical Trials
- Global Pharma and Device Compliance Issues

And a Pharma Company Best Practices Poster Board Reception

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

THE PHARMACEUTICAL COMPLIANCE FORUM

About 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 215-599-6617or via email at info@PharmaComplianceForum.org. Please visit their website at www.pharmacomplianceforum.org.

Wednesday, November 2, 2011

Preconference Symposia (Optional, choose one)

7:00 am **Congress Registration**

8:00 am **Preconferences Commence (Choose one)**

PRECONFERENCE I: COMPLIANCE BASICS

8:00 am Welcome and Introductions
Kelly B. Freeman, PhD, *Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN (Co chair)*

Sean P. Fahey, Esq., *Partner, Pepper Hamilton LLP, Philadelphia, PA (Co chair)*

8:15 am The Legal Framework: Laws and Regulations, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the Federal Sentencing Guidelines, and Important Settlements with the Government
Sean P. Fahey, Esq., *Partner, Pepper Hamilton LLP, Philadelphia, PA*

10:00 am Break

10:15 am Implementing the Seven Elements of a Compliance Program: Practical Advice and Best Practices for Policy Development, Training, Communications, Monitoring, Auditing, and Corrective Actions
Kelly B. Freeman, PhD, *Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN*

Noon Preconference Adjournment and Lunch on your Own

PRECONFERENCE II: PRACTICAL APPROACHES TO IMPLEMENTING AN AGGREGATE SPEND PROGRAM

8:00 am Welcome and Introductions
Eve M. Brunts, Esq., *Partner, Ropes & Gray, Boston, MA (Co chair)*

Melanie Gross, JD, MPH, *Corporate Counsel, Genentech, Inc., South San Francisco, CA (Co chair)*

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

8:30 am PwC Benchmarking Survey on Aggregate Spend Programs
David J. Wysocky, *Director, Pharmaceutical and Life Sciences Practice, PricewaterhouseCoopers LLP, Florham Park, NJ*

9:30 am Break

9:45 am Roundtable on Getting Ready for Sunshine: Helping You Assess Readiness Across:
- **Business Policies and Procedures that Manage HCP Spend**
- **Data Flow, Collection, Aggregation and Reporting**
- **Information Systems to Support all Spend Activities**
- **Anticipating and Managing External Reaction (e.g. HCPs, government, media, etc.) to Posted Data**

Melanie Gross, JD, MPH, *Corporate Counsel, Genentech, Inc., South San Francisco, CA*

Timothy J. Nugent, CPA, CCEP, *Managing Director, KPMG, LLP, Short Hills, NJ*

John Poulin, *Director, Life Sciences Practice, Huron Consulting Group, New York, NY*

Laura Sciarrino, Esq., *Chief Legal Officer, Tercica, Inc., A Subsidiary of the Ipsen Group, Brisbane, CA*

Jack T. Tanselle, *Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Chicago, IL*

11:45 am Wrap-up
Eve M. Brunts, Esq., *Partner, Ropes & Gray, Boston, MA (Co chair)*

Melanie Gross, JD, MPH, *Corporate Counsel, Genentech, Inc., South San Francisco, CA (Co chair)*

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

Noon Preconference Adjournment and Lunch on your Own

Wednesday, November 2, 2011

Pharma Congress Agenda Day 1 • Opening Plenary Session—Government Enforcement

1:00 pm Welcome and Introduction
Margaret K. Feltz, PhD, *Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)*

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

1:15 pm Keynote
John C. Lechleiter, PhD, *Chairman, President and Chief Executive Officer, Eli Lilly and Company, Chairman-elect, PhRMA Board of Directors, Indianapolis, IN*

1:45 pm Keynote: OIG Update
Mary E. Riordan, Esq., *Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, US Department of Health and Human Services, Washington, DC*

2:30 pm Keynote: DOJ Civil Division Update
Tony West, Esq., *Head, Civil Division, US Department of Justice; Former California Special Assistant Attorney General; Former Assistant US Attorney, Northern California, Washington, DC*

3:00 pm Break

3:30 pm Coordinating Pharma Prosecutions
Michael Blume, Esq., *Director, Office of Consumer Litigation, US Department of Justice, Washington, DC*

Joyce R. Branda, Esq., *Director, Commercial Litigation Branch, US Department of Justice; Recipient, Presidential Meritorious Executive Award and Attorney General's Award for Exceptional Service, Washington, DC*

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

4:15 pm Keynote: FDA-DDMAC Update
Thomas W. Abrams, RPh, MBA, *Director, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Silver Spring, MD*

4:45 pm **Keynote Panel: Pharma 2020**

Jonathan Kellerman, *Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP, Newark, NJ*

5:30 pm **Adjournment and Networking Reception and Best Practices Poster Board Session**

Kathryn A. Fillenwarth, *Advisor, LRL Ethics and Compliance, Lilly Research Laboratories, Eli Lilly & Company, Indianapolis, IN (Poster Board Session Chair)*

Thursday, November 3, 2011

Pharma Congress Agenda Day II • Morning Plenary Session

7:00 am **Registration Opens: Continental Breakfast in Exhibit Hall**

8:00 am **Welcome and Introduction to Day II Morning**

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

8:15 am **The New SEC Whistleblower Office**

Sean McKessy, Esq. (Invited), *Whistleblower Office, Division of Enforcement, Securities and Exchange Commission, Washington, DC*

8:45 am **FCPA and UK Bribery Act Enforcement and Compliance Update**

Charles E. Cain, Esq. *(Invited) Assistant Director, FCPA Unit, Director of the Division of Enforcement, Securities and Exchange Commission, Washington, DC*

Nathaniel Edmonds, Esq., *Assistant Chief, Foreign Corrupt Practices Act Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC*

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*

Ted Acosta, Esq., *Principal, Ernst & Young LLP; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, New York, NY and Paris, France (Moderator)*

9:30 am **Personal Accountability and Individual Liability of In-house Counsel and Chief Compliance Officers and Exclusions from Federal Health Programs**

Lessons of the Stevens Case

Colleen A. Conry, Esq., *Partner and Co-Chair, Government Enforcement Practice Group, Ropes & Gray; Former Senior Litigation Counsel, Criminal Division, Fraud Section, US Department of Justice, Washington, DC*

Lessons of the Forrest and Purdue

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

10:00 am **Break**

10:30 am **Personal Accountability and Individual Liability of In-house Counsel and Chief Compliance Officers and Exclusions from Federal Health Programs**

Best Practices to Avoid Individual Liability and Exclusion

Colleen A. Conry, Esq., *Partner and Co-Chair, Government Enforcement Practice Group, Ropes & Gray; Former Senior Litigation Counsel, Criminal Division, Fraud Section, US Department of Justice, Washington, DC*

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

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

Arjun Rajaratnam, Esq., *Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Durham, NC*

Thomas M. Gallagher, Esq., *Partner and Chair, White Collar and Corporate Investigations Practice Group, Pepper Hamilton LLP; Former Prosecutor, Criminal Division, US Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA (Moderator)*

11:15 am **Compliance Professional Responsibilities in the Pharmaceutical, Biotech & Medical Device Industries**

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

11:45 am **Board and Executive Responsibilities and Certifications**

12:15 pm **Networking Lunch**

DAY II AFTERNOON TRACK SESSIONS I

TRACK I: Taking Your Compliance Program to a New Level: Building a Culture of Compliance; Compliance Program Branding; Making Policies and Procedures Relevant to Internal Constituencies; Envisioning the Compliance Professional of the Future; Recruitment and Retention

Timothy Ayers, Esq., *Associate General Counsel, Executive Director of Compliance, Seattle Genetics, Bothell, WA (Co chair)*

Elizabeth V. Jobes, Esq., *Vice President and Chief Compliance Officer, Adolor; Former Assistant District Attorney, Philadelphia, PA, Exton, PA (Co chair)*

1:15 pm **PwC Annual Compliance Organization and Administration Survey**

1:45 pm **Responding to Health Reform: How Pharma and Device Manufacturers can Participate in Delivery System and Payment Reform—Strategic, Legal and Compliance Implications**

Constance A. Wilkinson, Esq., *Member, Epstein Becker & Green, PC, Washington, DC*

2:15 pm Taking your Compliance Program to the Next Level: Building a Culture of Compliance; Compliance Program Branding; Making Policies and Procedures Relevant to Internal Constituencies; Envisioning the Compliance Professional of the Future; Recruitment and Retention
Lori Alarimo, Esq. *(Invited), Vice President, Deputy Compliance Officer, Allergan; Former Assistant General Counsel, Pfizer, Irvine, CA*

David Gaffin, Esq. *(Invited), Deputy General Counsel and Senior Director Government Affairs, Alkermes, Boston, MA*

Heather Reilly Powell, Esq., *Director, Compliance Training and Reporting, Daiichi Sankyo, Inc.; Former Associate Director, Global Compliance, Cephalon, Inc., Parsippany, NJ*

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

Timothy Ayers, Esq., *Associate General Counsel, Executive Director of Compliance, Seattle Genetics, Bothell, WA (Co chair)*

Elizabeth V. Jobes, Esq., *Vice President and Chief Compliance Officer, Adolor; Former Assistant District Attorney, Philadelphia, PA, Exton, PA (Co chair)*

3:15 pm Break

TRACK II: Internal and External Investigations Update

Jonathan L. Diesenhaus, Esq., *Partner, Hogan Lovells US LLP; Former Senior Trial Counsel, Civil Division of the US Department of Justice, Washington, DC (Co chair)*

Constance A. Wilkinson, Esq., *Partner, Epstein Becker & Green, Washington, DC (Co chair)*

1:15 pm Defending Government Pharmaceutical/ Device Investigations and Qui Tam Litigation
Mark A. Jensen, Esq., *Partner, King & Spalding LLP, Washington, DC*

1:40 pm Responding to State Attorneys General Investigations
Barry H. Boise, Esq., *Partner, Pepper Hamilton LLP, Philadelphia, PA*

2:05 pm Analyzing Data in Off Label and Other Cases—From Production to Damages
Thomas A. Gregory, CFA, MBA, *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP, Atlanta, GA*

Kathleen Meriwether, Esq., *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA*

2:30 pm Working with the Board of Directors in Responding to an Investigation
Constance A. Wilkinson, Esq., *Partner, Epstein Becker & Green, Washington, DC*

2:55 pm Ethical Challenges of Internal Investigations and the Representation of Individuals in Light of the Government's New Focus on Individuals
Jonathan L. Diesenhaus, Esq., *Partner, Hogan Lovells US LLP; Former Senior Trial Counsel, Civil Division of the US Department of Justice, Washington, DC*

3:15 pm Break

TRACK III: Fair Market Value Update

Eric Siegel, JD, MBA, *Chief Compliance Officer, Incyte Corporation, Philadelphia, PA (Co chair)*

Paul J. Silver, *Managing Director and Practice Leader, Life Sciences Practice, Huron Consulting Group, Atlanta, GA (Co chair)*

1:15 pm International FMV: Growing Trends
Mark A. DeWyngaert, PhD, *Managing Director, Life Sciences Practice, Huron Consulting Group, New York, NY*

Jeff Rosenbaum, *Global Head, Ethics & Compliance, Novartis Oncology, Florham Park, NJ*

1:45 pm Developing a Global FMV Methodology
Bridget Bourgeois, *Partner, Ernst & Young LLC, Atlanta, GA*

2:15 pm Fair Market Value and the Emerging Company
Eric Siegel, Esq., *Chief Compliance Officer, Incyte Corporation, Philadelphia, PA*

2:45 pm Operationalizing Fair Market Value
Dieter Peise, *Associate Director Ethics & Compliance, Novartis, New York, NY*

3:15 pm Break

TRACK IV: FCPA and UK Bribery Act Compliance Update

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

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

1:15 pm Focus on China: Assessing Your FCPA Risk Exposure in R&D and Manufacturing Operations, and Bracing for a New Era of Local Enforcement
Hui Chen, Esq., *Senior Corporate Counsel, Asia-Pacific Regional Lead, International Compliance Investigations, Pfizer Inc., New York, NY*

Peter S. Spivack, Esq., *Partner, and Co-Leader, Investigations, White Collar and Fraud Practice Area, Hogan Lovells US LLP, Washington, DC*

2:00 pm Maintaining Research Integrity While Minimizing Bribery Risks in Foreign Clinical Trials: Effective Due Diligence and Oversight Strategies for your Doctors, CROs, and HCPs

2:45 pm UK Bribery Act Update
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*

3:15 pm Break

TRACK V: Compliance Lessons Learned from Medical Devices

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)*

Arjun Rajaratnam, Esq. *Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Durham, NC (Co chair)*

1:15 pm Compliance Lessons Learned from Medical Devices:
- **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**

Scott Bass, Esq., *Partner and Co-Head, Global Life Sciences Practice, Sidley Austin LLP, Washington, DC*

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*

Stephen J. Immelt, Esq., *Partner, Hogan Lovells; Former Assistant U.S. Attorney, District of Maryland, US Department of Justice, Baltimore, MD*

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

David E. Matyas, Esq., *Member, Epstein Becker & Green, Washington, DC*

Arjun Rajaratnam, Esq., *Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Durham, NC*

Tom Schumacher, Esq., *Vice President, Chief Ethics and Compliance Officer, Medtronic, Minneapolis, MN*

3:15 pm Break

DAY II AFTERNOON TRACK SESSIONS II

TRACK VI: Advanced Issues in Auditing and Monitoring

Joseph J. Skupen, CPA, *Senior Director, US Corporate Compliance, sanofi-aventis US, Bridgewater, NJ (Co chair)*

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

3:45 pm Monitoring Medical Affairs (MSLs, IIS, Medical Information)
Eileen Erdos, *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP, Chicago, IL*

Kathleen Meriwether, Esq., *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA*

4:15 pm Using Data and Analysis to Advance Your Monitoring Efforts
Manny Tzavlakis, *Managing Director, Life Sciences Practice, Huron Consulting Group, New York, NY*

Suj Patel, *Director, Life Sciences Practice, Huron Consulting Group, New York, NY*

4:45 pm Field Force Monitoring
Dennis K. Barnes, JD, CPA, *Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Philadelphia, PA*

5:15 pm Use of Outside Vendors in Monitoring Compliance Programs
Fred Eaton, MBA, *Partner and Chair, Market Value Practice, Polaris Management Partners, New York, NY*

5:45 pm Adjournment

TRACK VII: Healthcare Professionals Compliance Update—the Hottest Emerging Issues in Industry/HCP Relationships

Maureen Doyle-Scharff, MBA, FACME, *Senior Director, Team Lead, Medical Education Group, Pfizer, Columbus, OH (Co chair)*

Seth H. Lundy, Esq., *Partner, King & Spalding LLP, Washington, DC (Co chair)*

3:45 pm Challenges Implementing Recent CIA Requirements — Lessons Learned
Seth H. Lundy, Esq., *Partner, King & Spalding LLP, Washington, DC*

Daniel Moynihan, Esq., *Chief Compliance Officer and Former Associate General Counsel, EMD Serono, Rockland, MA*

Scott A. Memott, Esq., *Partner, Morgan Lewis; Former Trial Attorney, Civil Division, US Department of Justice; Former Special Assistant US Attorney in Norfolk, Virginia, Washington, DC*

Tracy Mastro, MBA, *Director, Life Sciences Practice, Huron Consulting Group, Washington, DC*

4:45 pm Risk Stratification and Monitoring of Industry-funded Third Party Educational Activities, Grants and Charitable Contributions
Maureen Doyle-Scharff, MBA, FACME, *Senior Director, Team Lead, Medical Education Group, Pfizer, Columbus, OH*

Edmund Greenidge, Esq., *Director, Grants and Charitable Contributions, Janssen Biotech, Inc., Philadelphia, PA*

Hilary J. Schmidt, PhD, *Vice President Independent Grants and Learning, sanofi-aventis US, Bridgewater, NJ*

5:45 pm Adjournment

TRACK VIII: Government Payment and Price Reporting Update

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

Jerry Wolf, *Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Philadelphia, PA (Co chair)*

3:45 pm Government Price Reporting Update
Jeffrey L. Handwerker, Esq., *Partner, Arnold & Porter, Washington, DC*

4:15 pm Quick Diagnostics for the Compliance Officer: Process and System
Susan Dunne, *Director, Life Sciences Practice, Huron Consulting Group, Washington, DC*

Mark Linver, *Managing Director, Life Sciences Practice, Huron Consulting Group, New York, NY*

5:00 pm 340B Expansion and Diversion issues
Commander Krista Pedley, PharmD, MS, *Director, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), Washington, DC*

William A. Sarraille, Esq., *Partner, Sidley Austin LLP, Washington, DC*

5:45 pm Adjournment

TRACK IX: Research & Development and Clinical Trials

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

Daniel A. Kracov, Esq., *Partner and Chair, FDA and Healthcare Practice, Arnold & Porter LLC, Washington, DC (Co chair)*

3:45 pm Updating the Common Rule Governing Human Subjects Research Protections
Jerry A. Menikoff, MD, JD, *Director, Office for Human Research Protections, Office of Public Health and Science, US Department of Health and Human Services; Former Director, Office of Human Subjects Research, National Institutes of Health, Rockville, MD*

4:15 pm Risk Management in Clinical Development
Jeffrey S. Kasher, PhD, *Vice President Global Clinical Development, Eli Lilly and Company, Indianapolis, IN*

Andy Lee, *Senior Vice President, Head Global Clinical Operations, Genzyme, Boston, MA*

Winifred (Ann) Meeker-O'Connell, MS, *Acting Associate Director of Risk Science, Intelligence and Prioritization, Office of Scientific Investigation (OSI), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Silver Spring, MD*

Briggs Morrison, MD, *Senior Vice President, Pfizer, New York, NY*

5:15 pm Mini Summit Faculty Discussion Panel: Maintaining Compliance and Quality with Increasing Outsourcing to Contract Research Organizations

5:45 pm Adjournment

TRACK X: Global Pharma and Device Compliance Issues

3:45 pm Introduction and Overview
- **Global Compliance Program Structure, Staffing and Decision Making**
- **Global Compliance Program Team Training and Development, Continuously Improving the Team**
- **Dealing with Centralized vs. Local Initiatives and Central Oversight; Balancing Local vs. Central Decision Making**
- **Escalation Strategies; When to Ask for Support**
- **Working within Different Cultures and Overcoming Barriers to Change**
- **Providing Training that Works on the Local Level**

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

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

Hui Chen, Esq., *Senior Corporate Counsel, Asia-Pacific Regional Lead, International Compliance Investigations, Pfizer Inc., New York, NY*

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*

Caroline West, Esq., *Senior Vice President, Chief Compliance and Risk Officer, Shire, Philadelphia, PA*

Richard L. Zimmerer, *Partner, Forensic Advisory Services, KPMG LLP, Los Angeles, CA*

5:45 pm Adjournment

Friday, November 4, 2011

Pharma Congress: Agenda Day III

Closing Plenary Session—Policy and Ethics

8:00 am

Introduction to Day Three
Michael L. Shaw, Esq., *Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Senior Counsel, Office of Inspector General, Philadelphia, PA (Co chair)*

8:15 am

Panel: OIG Monitors of CIAs and Independent Review Organizations (IROs) for CIAs and FCPA Settlements
Office of Inspector General *(Invited), US Department of Health and Human Services, Washington, DC*

Jayson Dukes, CPA, *Senior Managing Director, FTI Consulting, New York, NY*

Thomas A. Gregory, CFA, MBA, *Principal, Ernst & Young LLP, Atlanta, GA (Moderator)*

9:00 am

Panel: Interfacing between Third Party Vendors and Client Companies — Compliance Best Practices
Emma Boyev, *Director Regulatory Compliance, Commercial Enterprise Office, Quintiles, Parsippany, NJ*

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

2011 PCF Pharma Congress Planning Committee:

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

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Marc L. Miller, CPA, CFF, *Partner, Forensic Practice, KPMG, New York, NY (Moderator)*

9:45 am **Keynote: Ethics and Contemporary Society**

Ariel Kaminer, *The Ethicist, New York Times Magazine; Former Editor, Arts & Leisure Section, New York Times, New York, NY*

10:15 am **Break**

10:30 am **Reflections on My Transition from Government Service to Private Practice**

Michael K. Loucks, Esq., *Partner, Skadden Arps LLP; Former First Assistant US Attorney, U.S. Attorney's Office for the District of Massachusetts, Washington, DC*

11:00 am **Creating a Culture of Compliance and Transparency: Lessons from the Challenger Disaster**

Richard M. Mullane (Colonel, USAF, Ret.), *Former NASA Astronaut; Recipient, Air Force Distinguished Flying Cross, Legion of Merit and the NASA Space Flight Medal, Albuquerque, NM*

11:30 am **Facilitating Disclosure and Prohibiting Retaliation**

Michael L. Koon, Esq., *Partner, Shook Hardy, Washington, DC*

Shelley R. Slade, Esq., *Whistleblower Attorney, Partner, Vogel, Slade & Goldstein; Former Senior Counsel, Health Care Fraud, Civil Division, US Department of Justice, Washington, DC*

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

12:15 pm **Adjournment**

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○ **Track II:** Internal and External Investigations Update
○ **Track III:** Fair Market Value Update
○ **Track IV:** FCPA and UK Bribery Act Compliance Update
○ **Track V:** Compliance Lessons Learned from Medical Devices

DAY II AFTERNOON TRACK SESSIONS II

○ **Track VI:** Advanced Issues in Auditing and Monitoring
○ **Track VII:** The Hottest Emerging Issues in Industry/HCP Relationships
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