

THE FOURTEENTH ANNUAL

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING -
EFFECTIVE KNOWLEDGE EXCHANGE



GHC LIFE SCIENCES
Global Health Care, LLC

CO CHAIRS:



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



Kelly B. Freeman, PhD,
Senior Director, Ethics and
Compliance, Eli Lilly and
Company



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



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

KEYNOTE SPEAKERS:



Thomas W. Abrams,
RPh, MBA, Director,
Division of Drug Marketing,
Advertising, and Com-
munications, Center for Drug Evaluation
and Research (CDER), Food and Drug
Administration



Zane David Memeger,
Esq., United States
Attorney, Eastern District
of Pennsylvania



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



Brent L. Saunders,
JD, MBA, Former Chief
Executive Officer, Bausch
+ Lomb; Former President,
Global Consumer Health
Care and Former Senior Vice President,
Global Compliance and Business Practices,
Schering-Plough



Mit Spears, Esq.,
Executive Vice President
and General Counsel,
Pharmaceutical Research
and Manufacturers of
America (PhRMA); Former General Counsel,
Federal Trade Commission; Former
Principal Deputy Assistant Attorney
General, Civil and Environmental and
Natural Resources Divisions, United States
Department of Justice

**KEYNOTE CHIEF COMPLIANCE
OFFICER AND AUSA ROUNDTABLES,
4 PRECONFERENCES AND
26 IN-DEPTH MINI SUMMITS**



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In your own
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October 28 – 30, 2013

Washington, DC Hyatt Regency
on Capitol Hill

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SPECIAL PCF REGISTRATION DISCOUNTS — See page 11.

MEDIA PARTNERS:

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CONTINUING EDUCATION CREDITS:

Compliance Professionals: The
Congress is currently pending approval
to offer Compliance Certification Board
CCB Credits.

Accounting Professionals:
up to 26 NASBE CPE credits

Attorneys: The Congress is currently
pending approval to offer California,
Pennsylvania and Texas MCLE Credit.

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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. PCF also sponsors a three-day compliance congress each Fall. For membership information, contact Kelly Freeman via email at kbfreeman@lilly.com. Please visit their website at www.PharmaComplianceForum.org.

2013 PHARMA CONGRESS PLANNING COMMITTEE

Gary DelVecchio, 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)

Elizabeth V. Jobs, Esq., Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc. (Co chair)

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

Karen Anderson, Chief Compliance Officer, Cubist Pharmaceuticals Inc.

Timothy Ayers, Esq., Compliance Consulting

Wayne Baker, Senior Vice President and Chief Sales Officer, AHM

Valli Baldassano, President and Chief Executive Officer, VFB Associates, PC

Scott Bass, Esq., Partner, Sidley Austin LLP

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

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

Eve Costopoulos, Vice President, Chief Ethics and Compliance Officer, Eisai Inc.

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

Michael B. Dusseau, Divisional Compliance Officer, Merck Consumer Care

Keary Dunn, Esq., Global Head, Ethics and Compliance, Novartis Oncology

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., Partner and Chair, White Collar and Corporate Investigations Practice Group, Pepper Hamilton LLP

Steven N. Gersten, Esq., Vice President, Ethics and Compliance Officer, AbbVie

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

Wendy C. Goldstein, Esq., Partner, Cooley, LLP

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

Jonathon L. Kellerman, Principal, Pharmaceutical & Life Sciences Advisory, 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

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

Lynn Robson, Esq., Executive Director, Legal and Compliance, LEO Pharma Inc.

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

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

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

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

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

Paul J. Silver, Managing Director, Huron Consulting Group

Jon Smollen, Executive Vice President and Chief Compliance Officer, Endo Pharmaceuticals Inc.

Don Soong, Vice President of Strategic Solutions, Cegedim Relationship Management, Richmond, VA

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

Mike Wagner, Esq., Partner and Chair, Global and North America Pharma Industry Groups, Baker & McKenzie

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 and Privacy, Johnson & Johnson

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

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 over the Internet and at your convenience at any time 24/7 for six months immediately following the event.

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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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. . . or home

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

PRECONFERENCE SYMPOSIA

7:30 am Congress Registration

8:30 am PRECONFERENCES COMMENCE *(Choose one)*

Preconference I: Compliance Basics

8:30 am Introduction, Panel Discussion and Q&A

Wendy C. Goldstein, Esq., *Partner, Health Care and Life Sciences Regulatory Practice, Cooley, LLP, New York, NY*

Retta M. Riordan, JD, *President, Riordan Compliance LLC; Former Business Ethics and Compliance Officer, Organon Biosciences, Apex, NC*

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*

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

Noon Preconference Adjournment; Lunch on your Own

Preconference II: Auditing and Monitoring Boot Camp

8:30 am Welcome and Introduction

Paul J. Silver, *Managing Director, Huron Consulting Group, Atlanta, GA*

8:45 am Conducting Impact and Maturity Risk Assessments to Prioritize Areas for Auditing and Monitoring

Mark Scallon, *Partner, Polaris, San Francisco, CA*

9:30 am How to Implement a Monitoring Program to Increase Business Value

Ron Cook, *Compliance Program Manager, EMD Serono, Boston, MA*

Lori Greene, *Manager, Huron Consulting Group, Atlanta, GA*

Lynne Inman, *Compliance Director, Abbvie, Chicago, IL*

Jay Patel, *Life Sciences Advisory Services, Huron Consulting Group, Atlanta, GA*

10:15 am Break

10:30 am Planning and Executing an Effective Records Review

Elaina Filauo, *Associate, Huron Consulting Group, New York, NY*

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

11:15 am Making Change Stick: The Importance of Driving Follow Ups and Results from Monitoring Activities

BJ D'Avella, MBA, *Manager, Huron Consulting Group, New York, NY*

Leanne DiDomenico, MA, *Manager, Huron Consulting Group, Philadelphia, PA*

Rashad Kirby, *Compliance Senior Manager, Endo Pharmaceuticals, Malvern, PA*

Jon Smollen, *Chief Compliance Officer, Endo Pharmaceuticals, Malvern, PA*

Noon Preconference Adjournment; Lunch on your Own

Preconference III: Ethical Decision Making Workshop

- Introduction of basic concepts of Values Based Leadership and the ethical lenses
- Values Based Leadership: Tasks of Leadership
- Ethics: Understanding and broadening our own view
- Integration of Values Based Leadership within the Ethics/Values of your organization

8:30 am Introduction, Panel Discussion and Q&A

Jan Byars, PhD, *Founder and President, LeadSync, LLC; Co-Chair, Ethics Forum Learning Community, Vandalia, OH*

Paula J. Presnoples, MPA, SPHR, *Consultant, LeadSync, LLC, Vandalia, OH*

Noon Preconference Adjournment; Lunch on your Own

Preconference IV: Chief Compliance Officer (or designee) Summit *(No charge; Invitation Only)*

Persons interested in attending may contact

Kelly B. Freeman, PhD, *Senior Director, Ethics and Compliance, Eli Lilly and Company at freeman_kelly_b@lilly.com.*

8:30 am Introduction, Panel Discussion and Q&A

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

Margaret K. Feltz, Esq., *Director, Corporate Compliance, Purdue Pharma LP; Member, PCF Executive Committee, Stamford, CT (Co chair)*

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

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc.; Member, PCF Executive Committee, Philadelphia, PA (Co chair)*

Noon Preconference Adjournment; Lunch on your Own

HOTEL INFORMATION/RESERVATIONS

The Hyatt Regency Washington on Capitol Hill is the official hotel for the Fourteenth Pharmaceutical Regulatory and Compliance Congress. A special group rate of \$289.00 single/double per night (plus tax) has been arranged for Congress Attendees.

Please go to <http://www.PharmaCongress.com/travel.html> for instructions on how to make your reservation and obtain the group rate.

You may also make a reservation by calling Central Reservations toll free at 1-888-421-1442 or 202-737-1234 to reach the hotel directly. Please refer to 14TH PHARMA CONGRESS in order to obtain the group rate. Reservations at the group rate will be accepted while rooms are available or until the cut-off date of Friday, October 4th, 2013. After this, reservations will be accepted on a space-available basis at the prevailing rate.

Hyatt Regency Washington on Capitol Hill

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**PHARMA CONGRESS: AGENDA DAY I —
CHIEF COMPLIANCE OFFICER ROUNDTABLE
AND GOVERNMENT ENFORCEMENT**

12:45 pm Co-chair's Introduction to Day One

1:00 pm Chief Compliance Officer Roundtable



Alessandra Hawthorne, Esq., Vice President, Chief Ethics and Compliance Officer, Boehringer Ingelheim Pharmaceuticals, Inc., New York, NY



Eve Costopoulos, Esq., Vice President, Chief Ethics and Compliance Officer, Eisai Inc., Woodcliff Lake, NJ



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



Caroline West, Esq., Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc.; Former Vice President, Global Legal Compliance, Aventis, Philadelphia, PA



Thomas M. Gallagher, Esq., Partner and Chair, White Collar and Corporate Investigations Practice Group, Pepper Hamilton LLP, Philadelphia, PA (Moderator)

2:00 pm OIG Update



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

3:00 pm Break

3:30 pm AUSA Roundtable



Margaret (Peg) Hutchinson, Esq., Assistant US Attorney and Chief, Civil Division, United States Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA



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



Richard Robinson, Esq. (Invited), Section Chief-Major Frauds, Criminal Division, United States Attorney's Office, Central District of California, Los Angeles, CA



Susan Winkler, Esq. (Invited), Assistant US Attorney and Chief, Health Care Fraud Unit, 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)

4:30 pm FDA-OPDP 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

5:00 pm Keynote



Mit Spears, Esq., Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA); Former General Counsel, Federal Trade Commission; Former Principal Deputy Assistant Attorney General, Civil and Environmental and Natural Resources Divisions, United States Department of Justice, Washington, DC

5:30 pm ADJOURNMENT AND NETWORKING RECEPTION

GHC, LLC LIFE SCIENCES GLOBAL CONGRESSES



PHARMA CONGRESS: AGENDA DAY II



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



Optional Breakfast Table Discussion Topics

• Compliance Issues in Medical Affairs including grants, investigator-sponsored studies, MSL activities, health economics and outcomes research (HEOR) –
Facilitator: Cliff Saffron, Principal, Pharmaceuticals, KPMG LLP



• Health Reform and Compliance Considerations –
Facilitator: Kathleen Peterson, Esq., Partner, Cooley, LLP, and Lawrence P. Platkin, Vice President and Compliance Officer, Bayer HealthCare LLC



• Managing Post-settlement Compliance Obligations –
Facilitators: Joshua S. Levy, Esq., and Brien T. O'Connor, Esq., Partners, Ropes and Gray



• UK Bribery Act –
Facilitator: Vivian Robinson, Esq., QC, Partner, McGuireWoods



• US Sunshine and Transparency –
Facilitator: John Patrick Oroho, Esq., Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC



• Inside the New Chinese Enforcement Initiatives –
Facilitators: Ames Gross, MBA, President and Founder, Pacific Bridge Medical and Yuet-Ming Tham, Esq., Partner, Sidley Austin LLP



• Monitoring in a World of Abundant Data –
Facilitator: Saul B. Helman, MD, Managing Director, Healthcare & Life Sciences Disputes, Navigant Consulting



MORNING PLENARY SESSION

8:00 am Interactive Dialogue on Compliance Issues via Discussion and Audience Response System



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



Margaret K. Feltz, Esq., Director, Corporate Compliance, Purdue Pharma LP; Member, PCF Executive Committee, Stamford, CT (Co chair)



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



Elizabeth V. Jobes, Esq., Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc.; Member, PCF Executive Committee, Philadelphia, PA (Co chair)



Kris Curry, Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Former Vice President, Health Care Compliance, Pharmaceuticals Group, Johnson & Johnson, Philadelphia, PA (Moderator)

9:00 am



Views from the C-suite: The Role of Compliance in HR, R&D and Sales & Marketing

Andrew M. Dahlem, PhD, Vice President, Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN



Mark Glickman, MBA, Executive Vice President, Sales and Marketing, Auxilium Pharmaceuticals; Former Vice President-Medical Device Division, Otsuka America Pharmaceutical, Inc.; Former Senior Vice President Sales and Marketing, Oscient Pharmaceuticals, New York, NY



Zachary B. Ward, Esq. (Invited), Assistant General Counsel, GlaxoSmithKline, Research Triangle Park, NC



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 (Moderator)

10:30 am

Break

11:00 am

The Compliance Function of the Future — Forecasting the Impact of New Integrated Healthcare Delivery Models



Todd Evans, Director, Pharmaceutical and Life Sciences Advisory Services, PwC, Chicago, IL



Brian Riewerts, Principal, Global Pharmaceuticals and Life Sciences, PwC, Baltimore, MD, USA

11:45 am

Prosecuting Pharma and Device Fraud



Zane David Memeger, Esq., United States Attorney, Eastern District of Pennsylvania, Philadelphia, PA

12:15 pm

NETWORKING LUNCHEON

PHARMA CONGRESS MINI SUMMITS

1:15 pm – 2:30 pm MINI SUMMITS BLOCK A

Mini Summit I: Adult Learning and Leading as a Compliance Professional

1:15 pm Introduction, Panel Discussion and Q&A

Stephen Celestini, Esq., Consultant, Aquinas Leadership Group; Former Senior Vice President, Chief Compliance Officer, Inspire Pharmaceuticals, a subsidiary of Merck, Inc., Raleigh, NC

Matthew Yesko, CPLP, Senior Consultant, Aquinas Leadership Group, Raleigh-Durham, NC (Moderator)

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

1:15 pm Introduction, Panel Discussion and Q&A

Lina A. Braude, Esq., Partner, Baker & McKenzie LLP, Washington, DC

Nathaniel B. Edmonds, Esq., Partner, Paul Hastings; Former Assistant Chief, Foreign Corrupt Practices Act Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC

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

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

Mark Scallon, Partner, Polaris, San Francisco, CA

Jeremy Perisho, Partner and National Life Sciences & Health Care Industry Leader, Deloitte Financial Advisory Services LLP, Boston, MA (Moderator)

Mini Summit III: Handling Parallel Criminal, Civil and Administrative Investigations

1:15 pm Introduction, Panel Discussion and Q&A

Zane David Memeger, Esq., *United States Attorney, Eastern District of Pennsylvania, Philadelphia, PA*

Scott A. Coffina, Esq., *Partner, Drinker Biddle & Reath LLP; Former Associate Counsel to President George W. Bush; Former Assistant US Attorney, Philadelphia, PA (Moderator)*

Mini Summit IV: Aggregate Spend 2.0: The Rest of the World is Catching onto the Open Payments Trend. This is a Primer for What the Rest of World is Looking for as Compared to the US Version. Will your Current Aggregate Spend System be a Global Solution?

1:15 pm Introduction, Panel Discussion and Q&A

Thomas W. Beimers, Esq., *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*

Diane E. Bieri, Esq., *Partner, FDA and Healthcare and Antitrust Practice Groups, Arnold & Porter, Washington, DC*

Katherine Norris, *Compliance Consultant, The Spectranetics Corporation, Atlanta, GA*

J. Mark Farrar, CPA, CFE, CFF, *Director, Healthcare & Life Sciences Disputes, Compliance and Investigations, Navigant Consulting, Inc., Atlanta, GA (Moderator)*

Mini Summit V: How to Grow a Chief Compliance Officer

1:15 pm Introduction, Panel Discussion and Q&A

Mary Bennett, *Vice President, Advisory Services, Ethical Leadership Group™, The Advisory Services Practice of NAVEX Global; Former Vice President, Compliance and Integrity Group, Caremark. Mundelein, IL*

Donna Phelps, *Product Specialist, Advisory Service, Navex Global; Former Senior Director, Corporate Compliance, Biogen Idec, Lake Oswega, OR*

Maxine Nogard, MBA, *Senior Director, Corporate Compliance, Biogen Idec, Inc., Weston, MA (Moderator)*

Mini Summit VI: Managing Third Party Relationship Risks

1:15 pm Introduction, Panel Discussion and Q&A

Kip Ebel, MBA, *Partner, Ernst & Young, New York, NY (Moderator)*

Mini Summit VII: Government Pricing Update

1:15 pm Introduction, Panel Discussion and Q&A

Rebecca Chan, *Associate Director, Government Analytics and Compliance, Genentech, Inc., South San Francisco, CA*

Alice Valder Curran, Esq., *Partner, Hogan Lovells LLP, Washington, DC*

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

Mini Summit VIII: Changes to the Commercial Business Model and the Implications to the Compliance Office Function of the Future Part I: Defining and Measuring Value to the Patient

1:15 pm Introduction, Panel Discussion and Q&A

Joshua Pagliaro, *Director, Pharmaceutical and Life Sciences Advisory Services, PwC, Chicago, IL*

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

2:30 pm Break

3:00 pm – 4:15 pm MINI SUMMITS BLOCK B

Mini Summit IX: OIG Increases Auditing of Pharmaceutical Manufacturers: Coupons, Part D Remuneration and Medicaid Rebate Administration

3:00 pm Introduction, Panel Discussion and Q&A

Katherine Chaurette, Esq., *Senior Corporate Counsel, Healthcare, Sanofi, Cambridge, MA*

S. Todd LaMastres, *Partner, Ernst & Young LLP, Dallas, TX*

Josh O'Harra, Esq., *Assistant General Counsel, Eli Lilly and Company, Washington DC*

William A. Sarraile, Esq., *Partner, Sidley Austin LLP, Washington, DC (Moderator)*

Mini Summit X: Fair Market Value Update

3:00 pm Introduction, Panel Discussion and Q&A

Beth Krewson, Esq., *Senior Director, Regulatory Counsel, Incyte Corporation, Wilmington, DE*

John Moose, *Manager, Huron Consulting Group, Chicago, IL*

Troy Morgan, Esq., *Senior Counsel, Biogen Idec, Boston, MA*

Rahsaan Thompson, Esq., *Senior Counsel, Actellion, San Francisco, CA*

Mark A. DeWyngaert, PhD, *Managing Director, Huron Consulting Group, New York, NY (Moderator)*

Mini Summit XI: Emerging Pharma Compliance Issues in the Technology Space, including Apps, Tech Platforms, Social Media, etc.

3:00 pm Introduction, Panel Discussion and Q&A

Chris Bergstrom, MBA, *Chief Strategy and Commercial Officer, WellDOC, Baltimore, MD*

Wain Fishburn, Jr., Esq., *Partner, Cooley, LLP, San Diego, CA*

Stephanie Wisdo, Esq., *Corporate Counsel, Otsuka Pharmaceuticals, Rockville, MD*

Wendy C. Goldstein, Esq., *Partner, Health Care and Life Sciences Regulatory Practice, Cooley, LLP, New York, NY (Moderator)*

Mini Summit XII: Off-label Promotion: Will the Government Take the First Amendment Seriously?

3:00 pm Introduction, Panel Discussion and Q&A

Jeffrey S. Bucholtz, Esq., *Partner, King & Spalding LLP; Former Acting Assistant Attorney General, Civil Division of the US Department of Justice, Washington, DC*

Damon Burrows, Esq., *Vice President and Assistant General Counsel – Regulatory, Allergan; Former Senior Counsel, Roche Pharmaceuticals, Irvine, CA*

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

Mini Summit XIII: Life Sciences Privacy and Data Protection Issues Update, Including the New Challenges and Opportunities Presented by Big Data

3:00 pm Introduction, Panel Discussion and Q&A

John Poulin, *Director, Huron Consulting Group, New York, NY*

Hilary M. Wandall, JD, MBA, *Global Privacy Leader, Merck & Co, Inc., Whitehouse Station, NJ*

Brian L. Hengesbaugh, Esq., *Partner and Global Co-Leader, Privacy and Data Protection Practice, Baker & McKenzie LLP, Chicago, IL (Moderator)*

Mini Summit XIV: Ethics and Compliance: Laughter is Still the Best Medicine

3:00 pm Introduction, Panel Discussion and Q&A

Ronnie Feldman, MBA, *Director, Second City Communications, Chicago, IL (Moderator)*

Mini Summit XV: The Interplay between Company Culture and Compliance

3:00 pm Introduction, Panel Discussion and Q&A

Leslie Altizer, Director, Corporate Executive Board, Director, Compliance and Ethics Leadership Council, Arlington, VA

Thomas Costa, Vice President, US Pharmaceuticals Compliance, Bristol-Myers Squibb, Princeton, NJ

Gina Dunsmuir, Health Care Compliance Officer, Ortho Clinical Diagnostics, Inc., Red Bank, NJ

Sue Egan, Director and Principal Consultant, Sue Egan Associates; Former Vice President, Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK

Jeffrey Klimaski, MBA, CPA, Compliance Officer, BTG International; Former Vice President, Global Compliance Officer, Stiefel, a GSK company, Philadelphia, PA

Christopher D. Zalesky, Executive Director, World Wide Office of Health Care Compliance and Privacy, Johnson & Johnson, New Brunswick, NJ (Moderator)

Mini Summit XVI: Changes to the Commercial Business Model and the Implications to the Compliance Function of the Future Part II: Defining the Customer & Influencer

3:00 pm Introduction, Panel Discussion and Q&A

Joshua Pagliaro, Director, Pharmaceutical and Life Sciences Advisory Services, PwC, Chicago, IL

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

4:15 pm Transition Break

4:30 pm – 5:45 pm MINI SUMMITS BLOCK C

Mini Summit XVII: Compliance in Commercial Operations Update: Review of Legal Developments and Best Practices Performance-based Discounts, Copay Coupons and Reimbursement Support

4:30 pm Introduction, Panel Discussion and Q&A

Debra Bromson, JD, LLM, Senior Corporate Counsel, Jazz Pharmaceuticals, Philadelphia, PA

Robert Malkin, Esq. (Invited), Associate General Counsel at Biogen Idec., Boston, MA

Kevin G. McAnaney, Esq. (Invited), Law Office of Kevin G. McAnaney; Former Chief, Industry Guidance Branch Office of Counsel to the Inspector General, Washington, DC

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

Mini Summit XVIII: Update on Data Sharing/Data Transparency in Clinical Trials

4:30 pm Introduction, Panel Discussion and Q&A

Barbara E. Bierer, MD, Senior Vice President Research, Brigham and Women's Hospital; Professor of Medicine and Pediatrics, Harvard Medical School, Faculty Co-Chair, Multi-Regional Clinical Trials Center, Harvard University (Harvard MRCT), Boston, MA

Caroline Stockwell, Assistant General Counsel, R&D, Pfizer; Solicitor (England and Wales), Walton on the Hill, Surrey, United Kingdom

Mark Barnes, Esq., Partner, Ropes and Gray LLP; Faculty Co-Chair, Multi-Regional Clinical Trials Center, Harvard University (Harvard MRCT); Former Senior Associate Provost for Research and Chief University Research Compliance Officer, Harvard University, Boston, MA (Moderator)

Mini Summit XIX: How to Build a Robust and Sustainable Compliance Organization

4:30 pm Introduction, Panel Discussion and Q&A

Valli Baldassano, Esq., President and Chief Executive Officer, VFB Associates, PC; Former Executive Vice President and Chief Compliance Officer, Cephalon; Former Vice President, Global Compliance, Schering-Plough; Former Senior Director, Global Compliance, Pfizer, Ottsville, PA

Steven N. Gersten, Esq., Divisional Vice President, Ethics and Compliance Officer, International and Global Marketing, Abbvie, Chicago, IL

Jack T. Tanselle, Managing Director, Healthcare Dispute Compliance and Investigation Practice, Navigant Consulting, Inc., Indianapolis, IN

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

Mini Summit XX: Medical Device Compliance Issues Update

4:30 pm Introduction, Panel Discussion and Q&A

Paul E. Kalb, JD, MD, Partner and Global Coordinator, Life Sciences Practice, Sidley Austin LLP, Washington, DC (Co-moderator)

Seth Whitelaw, JD, LLM, SJD, Director, Life Sciences Regulatory Compliance Practice, Deloitte & Touche LLP; Former R&D Compliance Officer, GlaxoSmithKline; Former Legal Compliance Officer, SmithKline Beecham Pharmaceuticals, Philadelphia, PA (Co-moderator)

Mini Summit XXI: Developing Appropriate Target Lists for Sampling, Detailing and Speaker Meeting Invitees

4:30 pm Introduction, Panel Discussion and Q&A

Gregory W. Beeman, Ethics and Compliance Officer, Lilly USA, Eli Lilly and Company, Indianapolis, IN

Scot Steinheiser, CHC, CCEP, Director, Steinheiser Consulting Services LLC; Former Associate Director, Compliance, Astellas; Former Training Manager, Fujisawa, Mundelein, IL

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

Mini Summit XXII: Blowing the Whistle on cGMPs: The Next Big Challenge for Compliance

4:30 pm Introduction, Panel Discussion and Q&A

Cheryl Eckard, Plaintiff/relator U.S. ex rel. Eckard v. GSK, et al.; Former Senior Manager of Global Quality Assurance, Glaxo SmithKline, New York, NY

Neil V. Getnick, Esq., Managing Partner, Getnick & Getnick LLP, New York, NY

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

Luis Moreno-Ocampo, Esq., Former First Chief Prosecutor, International Criminal Court; Former President, Latin America and Caribbean Office, Transparency International, New York, NY

Larry Spears, Director, Life Sciences Regulatory, Governance, Regulatory and Risk Strategies, Deloitte & Touche LLP, Washington, DC

Lesley Ann Skillen, Esq., Partner, Getnick & Getnick LLP, New York, NY (Moderator)

Mini Summit XXIII: Global Compliance Update

4:30 pm Introduction, Panel Discussion and Q&A

Yogesh Bahl, MBA, Partner, National Practice Leader - Life Sciences, Deloitte Financial Advisory Services LLP, New York, NY

Sue Egan, Director and Principal Consultant, Sue Egan Associates; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK

Ames Gross, MBA, President and Founder, Pacific Bridge Medical, Bethesda, MD

Joshua Holzer, Esq., Chief Counsel for Global Trade, Pfizer; Former Senior Special Agent and Special Assistant to the Assistant Secretary for Export Enforcement, US Department of Commerce; Former Special Agent, Office of Inspector General, US Department of Justice and US General Services Administration, New York, NY

Dominique Laymand, Esq., Vice President Compliance & Ethics, EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb; President, International Society of Healthcare, Ethics and Compliance Professionals (ethics), Paris, France

Yuet-Ming Tham, Esq., Partner, Sidley Austin LLP; Former, Asia-Pacific Regional Compliance Director, Pfizer; Former Deputy Public Prosecutor, Singapore, Hong Kong

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

Mini Summit XXIV: Changes to the Commercial Business Model and the Implications to the Compliance Function of the Future Part III: New Landscape of Disruptive Technology & Big Data

4:30 pm Introduction, Panel Discussion and Q&A

Peter Harries, MBA, Partner, Health Information and Privacy Services, PwC, Los Angeles, CA

Brian Williams, Director, PwC, Pharmaceutical and Life Sciences Advisory Services, Indianapolis, IN (Moderator)

5:45 pm ADJOURNMENT

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

PHARMA CONGRESS: AGENDA DAY III

8:30 am Co-chair's Introduction to Day Three

**8:45 am Keynote Address: Pharma Compliance:
A Global Business Perspective**



Brent L. Saunders, JD, MBA, Former Chief Executive Officer, *Bausch + Lomb*; Former President, *Global Consumer Health Care* and Former Senior Vice President, *Global Compliance and Business Practices*, *Schering-Plough*, Rochester, NY

9:15 am Ethics Keynote



James B. Stewart, JD (Invited), *Bloomberg Professor of Business Journalism*, *Columbia School of Journalism*; *Columnist*, *The New York Times*; *Pulitzer Prize Winner*; *Author*, *Tangled Webs: How False Statements Are Undermining America: From Martha Stewart to Bernie Madoff*, *New York, NY*

**9:45 am State Disclosure Laws, Federal Sunshine Act
and Global Transparency Initiatives**



- **US Sunshine Act**
Shantanu Agrawal, MPhil, MD (Invited), *Medical Director, Center for Program Integrity, Centers for Medicare & Medicaid Services*, Washington, DC



- **Global Transparency**
Dominique Laymand, Esq., *Vice President Compliance & Ethics, EMEA (Europe, Middle-East, Africa, Russia and Turkey)*, *Bristol-Myers Squibb*; *President, International Society of Healthcare, Ethics and Compliance Professionals (ethics)*, Paris, France



- **Global Transparency Industry Surveys US, EMEA, APAC**

Don Soong, *Vice President of Strategic Solutions, Cegedim Relationship Management*, Richmond, VA



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

10:30 am Break

10:45 am Lessons Learned from Public Service



Nathaniel B. Edmonds, Esq., *Partner, Paul Hastings*; *Former Assistant Chief, Foreign Corrupt Practices Act Unit, Fraud Section, Criminal Division, US Department of Justice*, Washington, DC



Marilyn May, Esq., *Counsel, Arnold & Porter*; *Former Senior Litigation Counsel, US Attorney's Office, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA*



Lewis Morris, Esq., *Senior Counsel, Adelman, Sheff and Smith LLC*; *Former Chief Counsel to the Inspector General, Office of Inspector General, US Department of Health and Human Services, Annapolis, MD*



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



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 (Moderator)*

11:30 am The Future of Compliance



Arun Sharma, MBA, PhD, *Professor and Executive Director, JAE Leadership Institute, School of Business Administration, University of Miami, Miami, FL*

Noon ADJOURNMENT

POSTCONFERENCE SYMPOSIUM

**1:00 pm Postconference: Compliance
as a Strategic Function**

As the Compliance function has become more critical for pharmaceutical firms, it has become more specialized and compliance leaders have developed deep expertise in the intricacies of compliance. The core capabilities of compliance leaders can be divided into three distinctive but complimentary competencies. The first competency is in the area of compliance which incorporates skills such as risk management, policy development, regulatory knowledge, investigation and monitoring/auditing. Compliance leaders have strong competencies in this area. The second competency is in the area of leadership with skills associated with leading and motivating compliance teams. Compliance leaders are beginning to develop deep expertise in this area. The third area and focus of the workshop are the strategic skills required to give flight to the business and elevate the role of the compliance function within pharmaceutical firms. Compliance leaders have traditionally had very low expertise in this area.

The three-hour workshop will help the participants understand:

- Pharmaceutical market trends and the role of multinational, regional and domestic firms.
- How compliance leaders can provide a strategic advantage to firms through innovations in compliance strategies that enhance business (within the tenets of an ethical policy)?
- How can compliance leaders recognize the emerging changes in the environment and be the first-to-market with innovative compliance strategies?
- How multinational firms compete when their compliance policies do not match the policies of local competitors? How can compliance leaders better understand their customers and develop innovative non-duplicable compliance strategies such as brand leveraging to help their firms grow rapidly in developing markets?



Professor Arun Sharma, *Professor and Executive Director, JAE Leadership Institute, School of Business Administration, University of Miami, Miami, FL*

Dr. Arun Sharma is Executive Director of the JAE Leadership Institute and Professor in the Marketing Department at the School of Business Administration, University of Miami. Arun has extensive knowledge of the Pharmaceutical Industry and the Compliance function through his experience in consulting and conducting seminars. He has worked for over two decades in this industry and he has conducted compliance studies for multiple pharmaceutical firms. He has worked with industry leaders such as AstraZeneca, Novartis, Sandoz, Grunenthal, and Johnson and Johnson.

4:00 pm POSTCONFERENCE ADJOURNMENT

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SELECT YOUR MINI-SUMMITTS – Tuesday, October 29 (One from each group):

BLOCK A – 1:15 pm

- MS I: Adult Learning and Leading ...
- MS II: Anticorruption Update ...
- MS III: Handling Parallel ... Investigations
- MS IV: Aggregate Spend 2.0
- MS V: How to Grow a Chief Compliance Officer
- MS VI: Managing Third Party ... Risks
- MS VII: Government Pricing Update
- MS VIII: Changes to the Commercial Business Model ... Part I

BLOCK B – 3:00 pm

- MS IX: OIG Increases Auditing ...
- MS X: Fair Market Value Update
- MS XI: Emerging Pharma Compliance Issues ...
- MS XII: Off-label Promotion ...
- MS XIII: Life Sciences Privacy ...
- MS XIV: Ethics and Compliance: Laughter ...
- MS XV: The Interplay between Company Culture ...
- MS XVI: Changes to the Commercial Business Model ... Part II

BLOCK C – 4:30 pm

- MS XVII: Compliance in Commercial Operations ...
- MS XVIII: Update on Data Sharing ...
- MS XIX: How to Build a ... Compliance Organization
- MS XX: Medical Device Compliance ...
- MS XXI: Developing ... Target Lists ...
- MS XXII: Blowing the Whistle ...
- MS XXIII: Global Compliance Update
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* This price reflects a discount for registration and payment received through Friday, Sept. 20, 2013.

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