THE FIFTH INTERNATIONAL

# PHARMACEUTICAL COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

A Hybrid Conference & Internet Event

See pg. 2

www.InternationalPharmaCongress.com


## May 3 – 5, 2011

Istanbul, Turkey Renaissance Polat Istanbul Hotel

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Join us in Istanbul, a historic crossroads of cultures, that in May 2011 will become a crossroads for pharmaceutical compliance experts from the European Union, Central and Eastern Europe, and the Middle East and Africa.

## CONGRESS CO CHAIRS

Kelly B. Freeman, PhD, Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN, USA

Dominique Laymand, Esq., Executive Director Compliance & Ethics EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb, Paris, France

Roeland Van Aelst, Vice President EMEA & Canada, Office Health Care Compliance & Privacy, Johnson & Johnson, Brussels, Belgium

## KEYNOTE SPEAKER

David Brennan, Chief Executive Officer, AstraZeneca, President, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Past Chairman, Pharmaceutical Research and Manufacturers of America (PhRMA), London, UK

## OTHER KEYNOTE SPEAKERS

Philippa Foster Back, OBE, Director, Institute of Business Ethics, Chairman, UK Antarctic Heritage Trust, Past President, Association of Corporate Treasurers, London, UK

Prof. Dr. Cevdet Erdöl, Parliament Member and Chairman, Health, Family, Work & Social Works Commission, The Grand National Assembly of Turkey, Ankara, Turkey

Joe Henein, President and Chief Executive Officer, NewBridge Pharmaceuticals, Former Regional Managing Director, Middle East & North Africa, Wyeth Pharmaceuticals, Dubai, United Arab Emirates

Jose F. Zamarriego Izquierdo, Director Unidad de Supervision Deontologica, FARMAINDUSTRIA, Madrid, Spain

Philippe Montigny, Certification Committee President, ETHIC Intelligence International, President, ETHIC Intelligence France, Executive Director and Partner, International Development & Strategies - France, Paris, France

Marie-Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium

Mark Pieth, PhD, Professor of Criminal Law, Basel University, Chairman, Working Group on Bribery in International Business Transactions, Organization for Economic Co-operation and Development (OECD), Member, Swiss Federal Gaming Commission, Board Chairman, Basel Institute on Governance, Basel, Switzerland

Vladimir Shipkov, Chief Executive Officer, Association of International Pharmaceutical Manufacturers, Member, IFPMA Council, Former Head, Ministry of Health Pharmaceutical Inspectorate, Former Deputy Chief, Federal Service for Intellectual Property, Patents and Trademarks (Rospatent), Moscow, Russian Federation

Heather Simmonds, Director, Prescription Medicines Code of Practice Authority, UK

## FEATURING TRACKS ON

- European Union Compliance Update
- Central and Eastern Europe Compliance Update
- Middle East and Africa Compliance Update
- Global Compliance Case Studies, Including Social Media, Third Party Due Diligence, Data Protection and Competition Law
- Global Compliance Auditing and Monitoring
- FCPA and Global Anti-Corruption
- Global Transparency, Disclosure and Aggregate Spend Issues

Evolving developments in law and regulation applied to the pharmaceutical industry, public opinion on standards of ethical behavior and the global economic situation make this a challenging time to be a compliance professional or legal counsel responsible for ensuring adherence to applicable laws, regulations and codes of practice within our industry. Worldwide, industry leaders emphasize the importance of ethical behavior, reputation and compliance activities in forming a cornerstone for building trust by government and the public in the global pharmaceutical enterprise. The Pharmaceutical Compliance Forum International Pharma Congress brings together senior global compliance and ethics professionals and legal counsel from the European Union (EU), Central and Eastern Europe (CEE) and Middle East and Africa (MEA) to share experiences and best practices to clarify these challenges and discuss potential responses to them.

Across Europe, the Middle East and Africa, regulators are increasingly active at both national and regional levels. In the USA, aggressive FCPA enforcement and the new Federal Sunshine Act are beginning to have a significant impact across the pharmaceutical industry in EU, CEE and MEA. Emerging markets and notably Russia, CIS and Turkey are attracting more direct investment to address growing unmet medical needs. The growing importance of new regulations like the UK Bribery Act or the Anti-Corruption bills in Russia, in conjunction with increasing FCPA enforcement, indicate that authorities are now going to deeply influence business practices in these regions. Local trade associations in those markets are starting to close the gap with their peers from more advanced markets in addressing ethics and compliance issues.

The Congress is keynoted by David Brennan, Chief Executive Officer, AstraZeneca and President, International Federation of Pharmaceutical, Manufacturers and Associations (IFPMA). Other keynote speakers include representatives of EFPIA, ETHIC Intelligence International, FARMAINDUSTRIA, the Institute of Business Ethics, the UK Prescription Medicines Code of Practice Authority and the OECD. Panel discussions will focus on disclosure and transparency; trust, reputation and the public perception of the global pharmaceutical enterprise; and the EFPIA Leadership Statement: one year's experience. There also will be track discussions on European Union compliance update; Central and Eastern Europe compliance update; Middle East and Africa compliance update; global compliance audits and monitoring; FCPA and global anticorruption; global transparency, disclosure and aggregate spend; and global compliance case studies. Pharmaceutical compliance leaders will share their views in a closing session on envisioning pharma compliance in 2015: a compliance crystal ball session

If you want to find out how to manage compliance in these challenging times, the PCF International Pharma Congress will give you the information that you need.

## Congress Co chairs

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

Dominique Laymand, Esq., *Executive Director Compliance & Ethics EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb, Paris, France*

Roeland Van Aelst, *Vice President EMEA & Canada, Office Health Care Compliance & Privacy, Johnson & Johnson, Brussels, Belgium*

## Who Should Attend

- Pharmaceutical Manufacturers
- Generic Pharmaceutical Manufacturers
- Site Management Organizations
- Clinical Research Organizations
- Management Companies
- Wholesale, Retail, Mail Order and Internet Pharmacies
- Health Care Regulators and Policy Makers
- Pharmaceutical and Health Care Executives and Board Members
- Regulatory and Compliance Professionals
- Medical Directors
- Physicians
- Pharmacists
- Food and Drug Law Attorneys
- Health Care Attorneys and In-house Counsel
- Compliance Officers
- Privacy Officers
- Ethics Officers and Corporate Social Responsibility Personnel
- Pharmaceutical Consultants
- Investment Bankers
- Venture Capitalists
- Health Services Researchers and Academics
- Auditors
- Promotion Signatories/Approvers
- Risk Management Personnel

## About the 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 sponsor a two-day international compliance congress in the Spring and a three-day US compliance congress each Fall.

**www.pharmacomplianceforum.org**

## Participation Options

### Traditional Onsite Attendance

Onsite

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

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

### 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 the six months following the event.

The archived conference includes speaker videos and coordinated PowerPoint presentations.

At your office . . .

. . . or home

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.

# International Pharma Congress Planning Committee

### Co chairs:

Kelly B. Freeman, PhD, Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN, USA

Dominique Laymand, Esq., Executive Director Compliance & Ethics EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb, Paris, France

Roeland Van Aelst, Vice President EMEA & Canada, Office Health Care Compliance & Privacy, Johnson & Johnson, Brussels, Belgium

### Committee:

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

Ann Beasley Bacon, Global Compliance Officer, Novartis Pharma AG, Basel, Switzerland

Wayne Baker, Senior Vice President, Advanced Health Media LLC, Bridgewater, NJ, USA

Karie Jo Barwind, Esq., Area Director Business Practices, Western Europe, Abbott Laboratories, Rungis Cedex, France

Bulent Becan, M.Sc.ChE, Managing Partner, Atuva Management Consultancy & Trade Ltd., Ethics Consultant to AIFD (Research-Based Pharmaceutical Companies Association), Consultant to IFPMA, Istanbul, Turkey

John T. Bentivoglio, Esq., Partner, Skadden Arps LLP, Washington, DC, USA

Gabor Danielfy, Senior Director, Health Care Compliance and Privacy EMEA, Johnson & Johnson, Issy-les-Moulineaux, France

Pierre E. Dupourque, Regional Compliance Director, Corporate Compliance, International Investigations and Programs, Pfizer Inc, Mannheim, Germany

Sue Egan, Director, Sue Egan Associates Limited, Former Vice President Compliance, AstraZeneca, London, UK

Sameh Farag, Regional Compliance Director, MEA, Merck, Member of the Phrma MEA Ethics Board, Dubai, United Arab Emirates

Gerard Geneen, Vice President, Compliance Officer, Pharma Europe, GlaxoSmithKline, Brentford, Middlesex, UK

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

Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA

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

Brian Riewerts, Partner, Global Pharmaceuticals and Life Sciences, PricewaterhouseCoopers LLP, Baltimore, MD, USA

Jeffrey Rosenbaum, Global Head, Ethics & Compliance, Novartis Oncology, Florham Park, NJ, USA

Guillaume Roussel, Vice President, Compliance Solutions EMEA, Cegedim Relationship Management, Paris, France

Joseph B. Tompkins, Jr., Partner, Sidley Austin LLP, Former Deputy Chief of the Fraud Section, Criminal Division of the United States Department of Justice, Washington, DC, USA

Paul B. Woods, BPharm, MA, MRPharmS, Independent Consultant, Former Global Compliance Policy Director, AstraZeneca, Macclesfield, Cheshire, UK

Elisabethann Wright, Esq., Partner, Hogan Lovells International LLP, Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium

# Tuesday, May 3, 2011

## DAY 1: OPENING PLENARY SESSION

**Noon** **Registration Commences**

**3:00 pm** **Welcome, Introductions and International Pharma Congress Vision and Overview**

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

Dominique Laymand, Esq., *Executive Director Compliance & Ethics EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb, Paris, France (Co chair)*

Roeland Van Aelst, *Vice President EMEA & Canada, Office Health Care Compliance and Privacy, Johnson & Johnson, Brussels, Belgium (Co chair)*

**3:30 pm** **Turkish Welcome Keynote**

Prof. Dr. Cevdet Erdöl, *Parliament Member and Chairman, Health, Family, Work & Social Works Commission, The Grand National Assembly of Turkey, Ankara, Turkey*

Bulent Becan, M.Sc.ChE, *Managing Partner, Atuva Management Consultancy & Trade Ltd., Ethics Consultant to AIFD (Research-Based Pharmaceutical Companies Association), Consultant to IFPMA, Istanbul, Turkey (Moderator)*

**4:00 pm** **Reflections on My MEA Pharma Compliance Past; Looking Forward: From Corporate to Private Equity — Compliance is a Way of Life**

Joe Henein, *President and Chief Executive Officer, NewBridge Pharmaceuticals, Former Regional Managing Director, Middle East & North Africa, Wyeth Pharmaceuticals, Dubai, United Arab Emirates*

**4:30 pm** **CEE Keynote**

Vladimir Shipkov, *Chief Executive Officer, Association of International Pharmaceutical Manufacturers, Member, IFPMA Council, Former Head, Ministry of Health Pharmaceutical Inspectorate, Former Deputy Chief, Federal Service for Intellectual, Property, Patents and Trademarks (Rospatent), Moscow, Russian Federation*

**5:00 pm** **OECD Bribery in International Business Transactions Update**

Mark Pieth, PhD, *Professor of Criminal Law, Basel University, Chairman, Working Group on Bribery in International Business Transactions, Organization for Economic Co-operation and Development (OECD), Member, Swiss Federal Gaming Commission, Board Chairman, Basel Institute on Governance, Basel, Switzerland*

**5:30 pm** **ADJOURNMENT AND NETWORKING RECEPTION**

## Hotel Information:

Special rates of €210.00 Standard Single Room/€220.00 Standard Double Room (including VAT and Buffet Breakfast) have been arranged. Buffet Breakfast is served in the Daphne Restaurant.

Please make reservations for the Renaissance Polat Istanbul Hotel by completing the hotel reservation form and emailing it directly to **nayiri.bagdat@polatholding.com**. Credit card details — credit card number and expiry date — must be provided at the time of booking. To book your hotel room online, please go to **http://cwp.marriott.com/istrn/hea/.**

Reservations will be accepted until April 12, 2011. After this date reservations will be accepted on a space-available basis at the prevailing rate.

**RENAISSANCE POLAT ISTANBUL HOTEL**
Sahil Yolu Coddesi No. 7 • Yesilyurt, 34149 Istanbul, Turkey

Fax: 0090 0212 414 19 72 for reservations • Email: nayiri.bagdat@polatholding.com
Tel: 0090 212 414 18 68

# Wednesday, May 4, 2011

## DAY II: MORNING PLENARY SESSION

**8:30 am Welcome and Overview**

Roeland Van Aelst, *Vice President EMEA & Canada, Office Health Care Compliance and Privacy, Johnson & Johnson, Brussels, Belgium (Co chair)*

**8:45 am Keynote Address**

David Brennan, *Chief Executive Officer, AstraZeneca, President, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Past Chairman, Pharmaceutical Research and Manufacturers of America (PhRMA), London, UK*

Stephen F. Mohr, Esq., *Global Compliance Officer, AstraZeneca, Wilmington, DE, USA (Moderator)*

**9:15 am Overview of EU Pharma Compliance Issues and Initiatives**

Gerard Geneen, *Vice President, Compliance Officer, Pharma Europe, GlaxoSmithKline, Brentford, Middlesex, UK*

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

Jose F. Zamarriego Izquierdo, *Director, Code of Practice Surveillance Unit, Farmaindustria, Madrid, Spain*

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)*

**10:00 am Break**

**10:30 am Overview of CEE Pharma Compliance Issues and Initiatives**

Olga Kozyr, Esq., *Partner, Hogan Lovells International LLP, Moscow, Russian Federation*

Artur Nagapetyan, *Country Compliance Officer, Novartis Pharma LLC, Moscow, Russian Federation*

Madina Torchinova, Esq., *Director Legal and Regulatory Affairs, Association of International Pharmaceutical Manufacturers (AIPM), Moscow, Russian Federation*

Martin Schloh, PhD, *Partner, Global Pharmaceuticals and Life Sciences, PricewaterhouseCoopers LLP, Munich, Germany (Moderator)*

**11:15 am Overview of MEA Pharma Compliance Issues and Initiatives**

Nabil Daoud, *Managing Director, Eli Lilly, Beirut, Lebanon*

Nidal Fakhoury, *Regional Director, MEA, Merck, Dubai, United Arab Emirates*

Liz MacGillivray, *Head of Compliance AMAC Region (Asia Pacific, Middle East and African Countries), Novartis, Jumeirah Village, United Arab Emirates*

Sameh Farag, *Regional Compliance Director, MEA, Merck, Member of the Phrma MEA Ethics Board, Dubai, United Arab Emirates (Moderator)*

**Noon NETWORKING LUNCHEON**

### Continuing Education Credits

For those attendees seeking continuing education credits, upon request the Congress will issue certificates of attendance which may be submitted to certification bodies.

## DAY II: AFTERNOON PLENARY SESSION

**1:15 pm Introduction to Afternoon Plenary Session**

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

**1:30 pm EFPIA Leadership Statement: One Year's Experience**

Marie-Claire Pickaert, *Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium*

Jose F. Zamarriego Izquierdo, *Director, Code of Practice Surveillance Unit, Farmaindustria, Madrid, Spain*

Gabor Danielfy, *Senior Director, Health Care Compliance and Privacy EMEA, Johnson & Johnson, Issy-les-Moulineaux, France (Moderator)*

**2:15 pm Anti-Corruption Enforcement and Defense in the EU**

Federico Busatta, JD, *Partner, Gianni, Origoni, Grippo & Partners, Milan, Italy*

Eugenio Fusco, JD, *Senior Public Prosecutor, Public Prosecutor Office, Milan, Italy*

Kai Hart-Hoenig, Esq., *Rechtsanwälte, Former Prosecution Counsel, Prosecution's Office Frankfurt am Main, Wiesbaden, Germany*

Marco Sugarelli, Esq., *Legal Affairs Associate Director, Pfizer Italia, Rome, Italy*

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

**3:00 pm The Latest Regulatory & Compliance Trends and Developments in Asia, and an Overview of Issues to be Discussed at the PCF Inaugural Asian Pharma Congress**

John Auerbach, MA, *Partner, Fraud Investigation & Dispute Services, Ernst & Young China, Shanghai, China*

Yuet-Ming Tham, Esq., *Head of Asia Life Sciences Group, and Head of the Asia Regulatory, Compliance & Investigations Group, DLA Piper, Hong Kong. Former Regional Compliance Director, Pfizer, Inc., Former Deputy Public Prosecutor, Singapore*

**3:30 pm Break**

## DAY II: AFTERNOON TRACK SESSIONS

**TRACK I: EU COMPLIANCE ISSUES UPDATE**

**4:00 pm Welcome and Overview**

Gabor Danielfy, *Senior Director, Health Care Compliance and Privacy EMEA, Johnson & Johnson, Issy-les-Moulineaux, France (Co chair)*

Paul B. Woods, BPharm, MA, MRPharmS, *Independent Consultant, Former Global Compliance Policy Director, AstraZeneca, Macclesfield, Cheshire, UK (Co chair)*

**4:05 pm Update on Commission Proposal on Information to Patients and Related Developments**

Paul B. Woods, BPharm, MA, MRPharmS, *Independent Consultant, Former Global Compliance Policy Director, AstraZeneca, Macclesfield, Cheshire, UK*

**4:25 pm Roundtable on Pharmaceutical Company Participation in Conferences: Solving the Practical Challenges — Location, Venue, Etc.**

Sylvia Fondaneche, *Director, International Congresses & Events, sanofi-aventis, President, International Pharmaceutical, Congress Advisory Association (IPCAA), Paris, France*



*Session continued next page*

Marie-Claire Pickaert, *Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium*

Jose F. Zamarriego Izquierdo, *Director, Code of Practice Surveillance Unit, Farmaindustria, Madrid, Spain*

**4:55 pm** **Roundtable on the Future of Pharmaceutical Company Participation and Support for Continuing Medical Education**

Bernard Maillet, MD, *Secretary General, European Union of Medical Specialties (UEMS) and European Accreditation Council for Continuing Medical Education (EACCME), Brussels, Belgium*

Thomas Kellner, MD, *Global Academic and Professional Affairs, Merck & Co., Inc., Board of Directors, Global Alliance for Medical Education, Munich, Germany*

**5:30 pm** **Adjournment**

## TRACK II: CEE COMPLIANCE ISSUES UPDATE

**4:00 pm** **Welcome and Overview**

Olga Kozyr, Esq., *Partner, Hogan Lovells International LLP, Moscow, Russian Federation (Co chair)*

Madina Torchinova, Esq., *Director Legal and Regulatory Affairs, Association of International Pharmaceutical Manufacturers (AIPM), Moscow, Russian Federation (Co chair)*

**4:05 pm** **The Compliance Related Aspects, Peculiarities and Risks in the Russian Pharmaceutical Market**

Artur Nagapetyan, *Country Compliance Officer, Novartis Pharma LLC, Moscow, Russian Federation*

**4:30 pm** **Roundtable on CEE Compliance Issues Update**

Track Faculty

Kersten Schmahl, Esq., *Senior Manager Global Corporate Compliance, Biogen Idec Int'l., Visiting Lecturer Health Care & FCPA-Compliance, Business Law Institute, Leuphana University, Zug, Switzerland*

Mariusz Witalis, *Partner, Fraud Investigation and Dispute Services, Ernst & Young LLP, Warsaw, Poland*

**5:30 pm** **Adjournment**

## TRACK III: MEA COMPLIANCE ISSUES UPDATE

**4:00 pm** **Welcome and Overview**

Nabil Daoud, *Managing Director, Eli Lilly, Beirut, Lebanon (Co chair)*

Nidal Fakhoury, *Regional Director, MEA, Merck, Dubai, United Arab Emirates (Co chair)*

**4:05 pm** **Culture and Translation: The Challenges Inherent in MEA Countries Adopting and Embedding the Ethical Standards set by Western Corporations**

Liz MacGillivray, *Head of Compliance AMAC Region (Asia Pacific, Middle East and African Countries), Novartis, Jumeirah Village, United Arab Emirates*

**4:30 pm** **MEA Pharma Compliance Legal Issues Update**

Yasser A. Omar, LL.B., *Partner, Shalakany Law Firm, Dubai, United Arab Emirates*

**4:55 pm** **South Africa Code Implementation Case Study**

Kirti Narsai, MSc(Pharm), MBA, *Head: Scientific and Regulatory Affairs, Pharmaceutical Industry Association of South Africa, Vorna Valley, South Africa*

**5:20 pm** **Track Faculty Q&A**

**5:30 pm** **Adjournment**



## TRACK IV: GLOBAL COMPLIANCE CASE STUDIES, INCLUDING SOCIAL MEDIA, THIRD PARTY DUE DILIGENCE, DATA PROTECTION AND COMPETITION LAW

**4:00 pm** **Welcome and Introductions**

Sue Egan, *Director, Sue Egan Associates Limited, Former Vice President Compliance, AstraZeneca, London, UK (Co chair)*

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

Maxine Nogard, *Senior Director, Global Corporate Compliance, Biogen Idec Inc., Weston, MA, USA (Co chair)*

Elisabethann Wright, Esq., *Partner, Hogan Lovells International LLP, Former Senior Legal Officer and Hearing Officer, EFTA, Surveillance Authority, Brussels, Belgium (Co chair)*

**5:30 pm** **Adjournment**

Istanbul Maiden Tower photo: iStock Photo © 2008 sumbul

# Thursday, May 5, 2011

**7:30 am** **Registration Commences**

## DAY III: MORNING TRACK SESSIONS

### TRACK V: GLOBAL COMPLIANCE AUDITING AND MONITORING

**8:30 am** **Welcome and Introductions**

Ted Acosta, Esq., *Principal, Ernst & Young LLP, Global Leader, Life Sciences Fraud Investigation and Dispute Services, New York, NY, USA and Paris, France (Co chair)*

Pierre E. Dupourque, *Regional Compliance Director, Corporate Compliance, International Investigations and Programs, Pfizer Inc, Mannheim, Germany (Co chair)*

**8:45 am** **Perspectives on Auditing and Monitoring for Compliance**

THE LEGAL BACKGROUND: UNITED STATES AND GERMANY

Bret A. Campbell, Esq., *Partner, Business Fraud and Complex Litigation Practice, Cadwalader, Wickersham & Taft LLP, Washington, DC, USA*

Dr. Peter Dieners, *Rechtsanwalt, Clifford Chance, Frankfurt am Main, Germany*

THE INDUSTRY'S EFFORTS

Jose F. Zamarriego Izquierdo, *Director, Code of Practice Surveillance Unit, Farmaindustria, Madrid, Spain*

EXAMPLES FROM TWO COMPANIES: BIOGEN IDEC AND PFIZER INC

Barbara R. Giddings, RN, MHA, CHC, *Global Commercial Compliance, Biogen Idec, Weston, MA, USA*

Pierre E. Dupourque, *Regional Compliance Director, Corporate Compliance, International Investigations and Programs, Pfizer Inc, Mannheim, Germany*

Ted Acosta, Esq., *Ernst & Young LLP, New York, NY, USA and Paris, France (Moderator)*

**10:15 am** **Break**

**10:45 am** **Being in a Hundred Places at Once: A Scalable Approach to Assessing and Monitoring Risk in a Global Organization**

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

**11:15 am** **Auditing and Monitoring Global Third Party and Distributor Due Diligence and Compliance Risk Management**

Patricia A. Etzold, CPA, *Partner, PricewaterhouseCoopers LLP, New York, NY, USA*

Ryan Murphy, *Director, PricewaterhouseCoopers LLP, Chicago, IL, USA*

**11:45 am** **Networking Luncheon**

### TRACK VI: FCPA AND GLOBAL ANTI-CORRUPTION

**8:30 am** **Welcome and Introductions**

John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP, Washington, DC, USA (Co chair)*

Jeffrey Rosenbaum, *Global Head, Ethics and Compliance, Novartis Oncology, Florham Park, NJ, USA (Co chair)*

Joseph B. Tompkins, Jr., *Partner and Global Coordinator, Complex Commercial Litigation Practice, Sidley Austin LLP, Former Deputy Chief of the Fraud Section, Criminal Division of the United States Department of Justice, Washington, DC, USA (Co chair)*

**8:45 am** **Recent Developments in FCPA Enforcement**

Joseph B. Tompkins, Jr., *Partner and Global Coordinator, Complex Commercial Litigation Practice, Sidley Austin LLP, Former Deputy Chief of the Fraud Section, Criminal Division of the United States Department of Justice, Washington, DC, USA*

**9:10 am** **The UK Bribery Act**

Jeremy Cole, Esq., *Partner, Hogan Lovells International LLP, London, UK*

Michael Roberts, Esq., *Senior Associate, Hogan Lovells International LLP, London, UK*

**9:35 am** **How to Manage a Global Corruption/Bribery Investigation**

Gary DiBianco, Esq., *Partner, Skadden Arps LLP, Former Trial Attorney, Criminal Division, Former Special Assistant US Attorney, Eastern District of Virginia, US Department of Justice, London, UK*

**10:00 am** **Navigating Data Privacy Issues and Performing Computer Forensics in Corruption Investigations**

SanDee Priser, MA, JD, *Partner, Fraud Investigation and Dispute Services, Ernst & Young LLP, Frankfurt am Main, Germany*

**10:25 am** **Break**

**10:45 am** **Roundtable on Practical Approaches to Anti-Bribery/Anti-Corruption (ABAC) Programmes**

Track Faculty

John Parsons, *Associate Director, Head of EUMEA Legal and Compliance, BioMarin Europe Limited, London, UK*

John Wilson, *Global Lead - AntiBribery and AntiCorruption Programme, AstraZeneca, London, UK*

John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP, Washington, DC, USA (Moderator)*

**11:45 am** **Networking Luncheon**

**TRACK VII: GLOBAL TRANSPARENCY, DISCLOSURE AND AGGREGATE SPEND ISSUES**

**8:30 am** **Welcome and Introductions**

Gabor Danielfy, *Senior Director, Health Care Compliance and Privacy EMEA, Johnson & Johnson, Issy-les-Moulineaux, France (Co chair)*

Guillaume Roussel, *Vice President, Compliance Solutions EMEA, Cegedim Relationship Management, Paris, France (Co chair)*

**8:45 am** **An Overview of US State Disclosure Laws and Sunshine Act and Implications for Related Federal Investigations and Prosecutions**

Michael K. Loucks, Esq., *Partner, Skadden Arps LLP, Former Acting United States Attorney, US Attorney's Office for the District of Massachusetts, Boston, MA, USA*

**9:15 am** **European Transparency and Disclosure: Perspectives in Light of ABPI Amended Code of Conduct**

Heather Simmonds, *Director, Prescription Medicines Code of Practice Authority, UK, London, UK*

**9:45 am** **International FMV: Creating a Consistent Payment Methodology**

Bridget Bourgeois, *Partner, Ernst & Young LLC, Atlanta, GA, USA*

Jeffrey Rosenbaum, *Global Head, Ethics and Compliance, Novartis Oncology, Florham Park, NJ, USA*

## Contact Information

**INTERNATIONAL CALL CENTER: LONDON, UK**
The International Pharma Congress has engaged the UK firm of Bamboo Events Ltd. as agent to handle telephone and email enquiries.
Hours: 9:00 – 1700 (UK time)
Phone: +44 (0)208 407 6167
Email: IPCcallcenter@hcconferences.com

**UNITED STATES CALL CENTER: WASHINGTON STATE, USA**
Hours: 7:00 a.m. - 5:00 p.m. (Pacific)
Toll-free: 800-503-8171 (Continental U.S., Alaska and Hawaii only)
Phone: +1 206-452-5528 Fax: +1 206-319-5303
E-mail: registration@hcconferences.com

**EXHIBIT/SPONSORSHIP INFORMATION: PENNSYLVANIA, USA**
Hours: 9:00 a.m. - 5:00 p.m. (Eastern)
Toll Free: 800-546-3750
(Continental U.S., Alaska and Hawaii only)
Phone: +1 206-452-5528, Ext. 2 Fax: +1 215-952-0664
E-mail: exhibits@hcconferences.com

**10:15 am** **Break**

**10:45 am** **Roundtable on Operational Tips and Key Success Factors to Develop a Global Transparency Initiative**

Track Faculty

Ronny Arijs, *Vice President Global Sustainability and Chief Compliance Officer, Grünenthal Pharma, Aachen, Germany*

Sue Egan, *Director, Sue Egan Associates Limited, Former Vice President Compliance, AstraZeneca, London, UK*

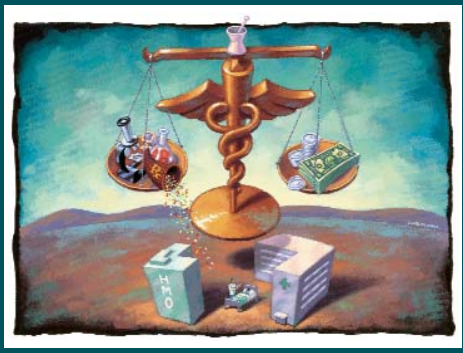
Gabor Danielfy, *Senior Director, Health Care Compliance and Privacy EMEA, Johnson & Johnson, Issy-les-Moulineaux, France (Moderator)*

Guillaume Roussel, *Vice President, Compliance Solutions EMEA, Cegedim Relationship Management, Paris, France (Moderator)*

**11:45 am** **Networking Luncheon**

SAVE THE DATE!

# THE TWELFTH PHARMACEUTICAL COMPLIANCE CONGRESS AND BEST PRACTICES FORUM



A Hybrid Conference & Internet Event
See Website


November 2 - 4, 2011

Washington, DC
Mandarin Oriental

www.PharmaCongress.com

## DAY III: CLOSING PLENARY SESSION

**1:00 pm Introductions and Overview**
Dominique Laymand, Esq., *Executive Director Compliance & Ethics EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb, Paris, France (Co chair)*

**1:15 pm Envisioning Pharma Compliance in 2015: a Compliance Crystal Ball Session**
Michael H. Friedland, Esq., *Deputy Compliance Officer, Internal Investigations, and Assistant General Counsel, Pfizer Inc., New York, NY, USA*

Stephen F. Mohr, Esq., *Global Compliance Officer, AstraZeneca, Wilmington, DE, USA*

Sheila E. Stranks, MBA, *Senior Director and Deputy Compliance Officer, Shire Pharmaceuticals Group PLC, Hampshire, UK*

Brian Riewerts, *Partner, Global Pharmaceuticals and Life Sciences, PricewaterhouseCoopers LLP, Baltimore, MD, USA (Moderator)*

**2:15 pm Global Transparency Management: 2010 Industry Survey Key Findings**
William E. Buzzeo, MS, *Vice President and General Manager Compliance, Solutions Division, Cegedim Relationship Management, Richmond, VA, USA*

Guillaume Roussel, *Vice President, Compliance Solutions EMEA, Cegedim Relationship Management, Paris, France*

**2:45 pm Closing Keynote Panel: Ethics and Compliance — Trust, Reputation and the Public Perception of the Global Pharmaceutical Enterprise**
Philippa Foster Back, OBE, *Director, Institute of Business Ethics, Chairman, UK Antarctic Heritage Trust, Past President, Association of Corporate Treasurers, London, UK*

Philippe Montigny, *Certification Committee President, ETHIC Intelligence International, President, ETHIC Intelligence France, Executive Director and Partner, International Development & Strategies - France, Paris, France*

Paul B. Woods, BPharm, MA, MRPharmS, *Independent Consultant, Former Global Compliance Policy Director, AstraZeneca, Macclesfield, Cheshire, UK (Moderator)*

**3:30 pm ADJOURNMENT**

## THE FOLLOWING REGISTRATION TERMS AND CONDITIONS APPLY FOR THE INTERNATIONAL PHARMA CONGRESS:

### PAYMENTS
All payments must be made in Euros. Payments are only accepted through credit card or bank transfer. A person will not be deemed to be formally registered until payment in full has been received. To receive the early bird discount, payment must be received by the early bird date. All payments must be made within 10 days of registration in order to reserve your seat at the conference. Delegates with outstanding payment balances will be asked for payment on site, proof of payment or a guarantee by credit card and seating will be subject to availability.

### PRO FORMA INVOICES
Complete one of the online forms and generate a Pro Forma Invoice, or fill out the downloadable form to email, fax, or mail in your request for a Pro Forma Invoice. For questions about the registration process, contact the Registration Office at 800-503-8171 and +1 206-452-5528, or send an email to registration@hcconferences.com.

### CANCELLATIONS/SUBSTITUTIONS
No refunds will be given for "no-shows" or for cancellations. You may send a substitute or transfer your onsite registration to an online registration. Please call the Conference Office at 800-503-8171 and +1 206-452-5528, or send an email to registration@hcconferences.com.

### 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. There will be no refunds for "no-shows" or cancellations.

### TERMS AND CONDITIONS
Program subject to change. Registration form submitted via fax, mail, email or online constitutes a binding agreement between the parties.

### REGARDING ONLINE ATTENDANCE
Individuals or groups may register for Internet access. 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.

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.

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

Only one user (per user name and password) may view or access archived conference. It is not permissible to share 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.

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

Continued next page

# The Fifth International Pharma Congress

## REGISTRATION FORM

**HOW TO REGISTER:** Fully complete the following (one form per registrant, photocopies acceptable). Credit card information or request for Pro Forma Invoice must accompany each registration.

**ONLINE: Secure online registration at www.InternationalPharmaCongress.com.**

**FAX: +1 206-319-5303** (include credit card information with registration)

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

**FOR REGISTRATION QUESTIONS:**
**PHONE:** 800-503-8171 (Continental US, Alaska and Hawaii only) or +1 206-452-5528 (United States) or +44 (0)208 407 6167 (Outside US)

**E-MAIL:** registration@hcconferences.com (Registration not available by phone)

**REGARDING VISA INFORMATION FOR FOREIGNERS ENTERING TURKEY,** please refer to **http://www.mfa.gov.tr/visa-information-for-foreigners.en.mfa**. This has the list of countries with visa details. The drop down menu under "Visa Information" provides forms and pricing per country.

**COMPLETE THE FOLLOWING. PLEASE PRINT CLEARLY:**

NAME

SIGNATURE OF REGISTRANT - REQUIRED

JOB TITLE

ORGANIZATION

ADDRESS

CITY/STATE/ZIP/COUNTRY

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.

## INDIVIDUAL REGISTRATION — CONFERENCE REGISTRATION:

**Standard Rate:**

| | |
|---|---|
| ❑ Through Friday, February 18, 2011* | €1595 |
| ❑ Through Friday, March 25, 2011** | €1695 |
| ❑ After Friday, March 25, 2011 | €1795 |

**PCF Rate:**

| | |
|---|---|
| ❑ PCF Member Rate*** | €1295 |

* This price reflects a discount for registration & payment received by February 18, 2011.

** This price reflects a discount for registration & payment received by March 25, 2011.

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

## SELECT YOUR TRACK SESSIONS:

| | |
|---|---|
| **Wed. May 4 – 4:00 pm** | ❑ I: EU COMPLIANCE ISSUES UPDATE |
| | ❑ II: CEE COMPLIANCE ISSUES UPDATE |
| | ❑ III: MEA COMPLIANCE ISSUES UPDATE |
| | ❑ IV: GLOBAL COMPLIANCE CASE STUDIES... |
| **Thurs. May 5 – 8:30 am** | ❑ V: GLOBAL COMPLIANCE AUDITING AND MONITORING |
| | ❑ VI: FCPA AND GLOBAL ANTI-CORRUPTION |
| | ❑ VII: GLOBAL TRANSPARENCY, DISCLOSURE AND AGGREGATE SPEND ISSUES |

## CONFERENCE ELECTRONIC MEDIA

Following the Congress, the video and presentations are made available in the following format. To take advantage of the discounted price below, you must reserve media WITH your Congress registration:

**Conference Audio/Video and Powerpoint on:**

| | |
|---|---|
| ❑ Flash Drive (€99 + €30 shipping) | €129 |
| ❑ Web (6 month access) | € 99 |

Terms and Conditions, continued

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 start of next month so long as registration period has not lapsed and subject to same capacity cap.

### 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.

# ONLINE CONFERENCE ATTENDANCE

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

## INDIVIDUAL REGISTRATION — CONFERENCE REGISTRATION

**Standard Rate:**

| | |
|---|---|
| ❑ Through Friday, February 18, 2011* | € 895 |
| ❑ Through Friday, March 25, 2011** | € 995 |
| ❑ After Friday, March 25, 2011 | €1095 |

**PCF Rate:**

| | |
|---|---|
| ❑ PCF Member Rate*** | € 695 |

## GROUP REGISTRATION

Group registration offers the substantial volume discounts set forth below.

All group registrants are enrolled in the full International 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 employees' conference participation.

**Conference Access:**

| | | | |
|---|---|---|---|
| ❑ 5 or more | €595 each | ❑ 20 or more | €395 each |
| ❑ 10 or more | €495 each | ❑ 40 or more | €295 each |

## CONFERENCE ELECTRONIC MEDIA

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| | |
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| ❑ Flash Drive (€99 + €30 shipping) | €129 |

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# PAYMENT

## TOTAL FOR ALL OPTIONS, ONSITE OR ONLINE:

**DISCOUNT CODE**

Please enclose payment with your registration and return it to the Registrar at The International Pharma Congress, 22529 39th Ave SE, Bothell, WA 98021, USA or fax your credit card payment to +1 206-319-5303.
You may also register online at www.InternationalPharmaCongress.com.

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

If a credit card number is being given to hold registration until funds have been transferred, 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 HCCA Conferences.

TOTAL €

ACCOUNT #

EXPIRATION DATE SECURITY CODE

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SIGNATURE OF CARDHOLDER

THE FIFTH INTERNATIONAL
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## May 3 – 5, 2011

Istanbul, Turkey

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