THE SIXTH INTERNATIONAL

PHARMACEUTICAL COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

A Hybrid Conference & Internet Event

See page 2

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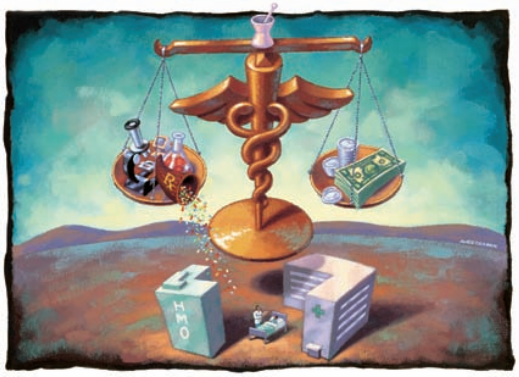
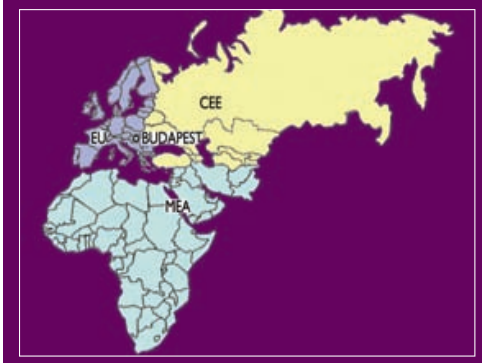


May 14 – 16, 2012

Budapest, Hungary • Hilton Budapest



Keynote Speaker:

Christopher Viehbacher, Chairman and Chief Executive Officer, Sanofi, Paris, France

Other Keynote Speakers:

Bulent Becan, Managing Partner, Atuva; Consultant, Turkish Research Based Pharmaceutical Companies Association (AIFD), Istanbul, Turkey

Richard Bergström, Director General, European Federation of the Pharmaceutical Industries and Associations (EFPIA); Former Director General, LIF Sweden, Brussels, Belgium

Jane de Lozey, Esq., Joint Head of Fraud, Serious Fraud Office, London, UK

Rosemary Donnabella, Esq., Head of Policy, Serious Fraud Office, London, UK

Joe Henein, President and Chief Executive Officer, NewBridge Pharmaceuticals, Dubai, United Arab Emirates

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

Andrew Jack, Pharmaceuticals Correspondent, *Financial Times*, London, UK

Aline Lautenberg, JD, Senior Legal Counsel, Eucomed, Brussels, Belgium

Bernard Maillet, MD, Treasurer, Belgian Association of Specialists (VBS-GBS); Member, EUCOMED's Compliance Panel; Former Secretary General, European Union of Medical Specialties (UEMS) and European Accreditation Council for Continuing Medical Education (EACCME), Antwerp, Belgium

Tamara Music, Manager, Influenza Vaccines & Code Compliance, IFPMA, Geneva, Switzerland

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

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

Sona Strachotova, MBA, Executive Director, Slovak Association of Research-Based Pharmaceutical Companies (SAFS), Bratislava, Slovak Republic

Matthijs M. van Blokland, Esq., General Counsel, Prosensa and Association Innovative Medicines Nefarma, Amsterdam, The Netherlands

Madina Torchinova, Esq., Regional Compliance Officer CEE, Sandoz; Former Director, Association of International Pharmaceutical Manufacturers (AIPM), Russia, Munich, Germany

Co Chairs:

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

Kelly B. Freeman, PhD, Ethics and Compliance Officer, Eli Lilly and Company; Executive Committee Member, Pharmaceutical Compliance Forum, Indianapolis, IN, USA

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

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

The Sixth International Pharma Congress is Dedicated to the Memory of

Gabor Danielfy, Vice-President and Global Compliance Officer, Sanofi, Paris, France

Sponsor: THE PHARMACEUTICAL COMPLIANCE FORUM

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Media Partners: Life Science Compliance; Rx Compliance Report

The first international Pharmaceutical Compliance Congress and Best Practices Forum was held in Brussels in June 2007 to bring together company compliance professionals, regulators, lawyers, and consultants working in this interesting and expanding field. The purpose was to hold a truly global conference, addressing the key issues of the day. The first international conference agenda was mainly developed by company compliance professionals around topics that they wanted to know more about, which is one of the great strengths of these conferences, and continues to be one of their key features.

In addition to Brussels, other international conferences have been held in Paris (2008), Rome (2009), Berlin (2010), and Istanbul (2011). Over the years the international conference agendas have developed to focus particular streams on the European Union (EU), Central and Eastern Europe (CEE), and Middle East and Africa (MEA), in addition to plenary sessions on global topics. The 2012 conference continues this trend.

The sixth international Pharmaceutical Compliance Congress and Best Practices Forum focuses on anti-bribery, transparency requirements and industry body code updates. In addition to the major topics, the whole conference agenda promises to deliver informative and useful discussions on the key topics that may be causing company compliance officers varied levels of concern. The speaker line-up for this conference is very impressive, as usual. Whether the discussions are led by those working in life science companies, industry bodies, regulators, or consultancy / solutions companies, the information imparted at these conferences is always of the highest quality. These conferences are also a great opportunity to network with fellow compliance professionals and build relationships that often last for many years of mutual support and assistance.

The 2012 conference agenda is also tinged with sadness as we pay our respects to Gabor Danielfy who died in late 2011.

—Sue Egan
Editor-in-chief,
Life Science Compliance

LIFE SCIENCE COMPLIANCE

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.

The archived conference includes speaker videos and coordinated PowerPoint presentations.

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

At your office . . .

. . . or home

Who Should Attend:

- Pharmaceutical Manufacturers
- Generic Pharmaceutical Manufacturers
- Medical Device 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

THE PHARMACEUTICAL COMPLIANCE FORUM

THE PHARMACEUTICAL COMPLIANCE FORUM (PCF), www.PharmaComplianceForum.org, 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.

GABOR DANIELFY

Vice-President & Global Compliance Officer, Sanofi

The world of healthcare compliance has been shocked and deeply saddened to learn of the loss of one its leading lights. Gabor Danielfy passed away in Paris on the morning of November 28th after his recent diagnosis against which he fought with characteristic strength and courage. Many of us felt privileged to count Gabor as a dear friend and he will be sadly missed. He exerted a huge and highly positive influence on healthcare compliance matters that reached worldwide and spanned many years. His passing is a major loss not only to his family and numerous friends, but also for the global pharmaceutical and medical device compliance and ethics movement.

Gabor had over 25 years experience in the healthcare field. Prior to joining Sanofi as Vice-President and Global Compliance Officer at the beginning of 2011 he worked a little less than three years for Johnson & Johnson in the Worldwide Office of Healthcare Compliance & Privacy as Senior Director for the Europe, Middle East & Africa region. Before that he was the Senior Director Global Compliance & Business Practices for Europe, Middle East & Africa at Schering Plough. Previously Gabor held various positions of increasing responsibility as Business Intelligence Analyst, Auditor, CFO, Sales Director and General Manager in other healthcare companies including, Merck & Co., and Bayer Pharma and in different regions including Europe, Latin America and the United States. Gabor was based in Paris and studied at the Law and Economic Sciences faculty of Paris, and subsequently at Sciences-Po Paris (Finance and Economics).

Gabor had a unique ability to enliven any gathering with his wit, friendliness and exuberance. He was a leading authority on compliance matters and was highly sought after as a knowledgeable, proficient and thought provoking speaker and chair at professional meetings. He was Co-Chair of the International Pharma Compliance Congress and it was at his instigation that the 'ETHICS' (EMEA Think-tank on Healthcare Integrity and Compliance Strategies) group was formed and flourished. He was also a dedicated and influential contributor to industry code of practice committees. Gabor was a member of the IFPMA Code Compliance Network for many years and also the EFPIA Code Steering Group. His enthusiasm and vision always enriched all discussions in which he took part.

We have lost a much loved friend and the industry has lost a true pioneer.

—Paul Woods, Dominique Laymand and Roeland van Aelst

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Featured Plenary Sessions:

- International Pharma Congress Vision and Overview
- The Role of Global Compliance in the Pharmaceutical Enterprise
- EU Annual Compliance and EFPIA Compliance Initiatives Update
- CEE Annual Compliance Update
- MEA Annual Compliance Update
- Regional Anti-Bribery Developments Roundtable: US FCPA, UK Bribery Act, Russian Anti-Bribery Act, OECD Anti-Bribery Convention
- E4ethics Congresses European Assessment Platform
- Regional Transparency and Disclosure Initiatives: UK, US, Netherlands, France, Slovak Republic
- Global Transparency Management: Industry Survey Key Findings
- Regional Compliance Code Update Roundtable: IFPMA, EFPIA, EUCOMED, MEA, Russia, Turkey, PhRMA
- Third-party Intermediaries: Due Diligence and Monitoring Considerations
- Business Ethics and Reputation in the Pharmaceutical and Medical Device Enterprises

And Track Sessions:

- Global Compliance Auditing and Monitoring Best Practices
- New EU Provisions Governing Compliance with Pharmaceutical Regulatory Laws
- Global Transparency, Disclosure and Aggregate Spend
- The Italian Regulatory and Compliance Scene in Depth: A Case Study
- Middle East Africa Compliance Issues Roundtable
- Lessons from Global Compliance Issues and Initiatives in the Medical Device Sector
- The Chinese Regulatory and Compliance Scene in Depth: A Case Study
- Central and Eastern Europe Compliance Issues Roundtable

Monday, May 14, 2012

11:00 am **Registration Opens**

DAY 1: OPENING PLENARY SESSION

1:00 pm **Welcome and Introductions**

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

1:15 pm **International Pharma Congress Vision and Overview**

Ann Beasley Bacon, *Global Compliance Officer, Novartis Pharma AG, Basel, Switzerland (Co chair)*

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

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

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

1:30 pm **Gabor Danielfy Memorial Keynote Address: The Role of Global Compliance in the Pharmaceutical Industry**

Christopher Viehbacher, *Chief Executive Officer, Sanofi; Chairman, Genzyme, Paris, France*

2:00 pm **EU Annual Compliance and EFPIA Compliance Initiatives Update**

Richard Bergström, *Director General, European Federation of the Pharmaceutical Industries and Associations (EFPIA); Former Director General, LIF Sweden, Brussels, Belgium*

Discussion Facilitators:

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

Dave O'Shaughnessy, *Vice President, Global Compliance, AstraZeneca, Former Vice President and Compliance Officer, Emerging Markets and Asia Pacific, GlaxoSmithKline, London, UK*

3:00 pm **CEE Annual Compliance Update**

Madina Torchinova, Esq., *Regional Compliance Officer CEE, Sandoz; Former Director Legal and Regulatory Affairs, Association of International Pharmaceutical Manufacturers (AIPM), Russia, Munich, Germany*

3:30 pm **Break**

4:00 pm **MEA Annual Compliance Update**

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

4:30 pm **Regional Anti-Bribery Developments Roundtable**

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*

4:40 pm **US FCPA Update** (audio presentation)

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

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, USA (Moderator)*

5:20 pm **UK Bribery Act** (audio presentation)

Rosemary Donnabella, Esq., *Head of Policy, Serious Fraud Office, London, UK*

Jane de Lozey, Esq., *Joint Head of Fraud, Serious Fraud Office, London, UK*

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

6:00 pm **ADJOURNMENT AND NETWORKING RECEPTION**

Tuesday, May 15, 2012

7:30 am **Registration Commences**

MORNING PLENARY SESSION

8:00 am **Welcome and Overview**

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

8:15 am **Regional Anti-Bribery Developments Roundtable** (Continued)

UK Bribery Act

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*

Russian Anti-Bribery Act

Paul J. Melling, Esq., *Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia*

OECD Anti-Bribery Convention

Peter Dieners, Esq., *Partner, Clifford Chance, Düsseldorf, Germany*

US FCPA

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

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)*

9:15 am **Keynote Panel: E4ethics Congresses European Assessment Platform**

Aline Lautenberg, JD, *Senior Legal Counsel, Eucomed, Brussels, Belgium*

Bernard Maillet, MD, *Member, Flemish Chamber of the Board for Specialists for Pathology; Treasurer, Belgian Association of Specialists (VBS-GBS); Member, EUCOMED's Compliance Panel; Former Secretary General, European Union of Medical Specialties (UEMS) and European Accreditation Council for Continuing Medical Education (EACCME), Antwerp, Belgium*

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

Elisabethann Wright, Esq., *Partner, Hogan Lovells; Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium (Moderator)*

10:00 am Break

10:30 am Regional Transparency and Disclosure Initiatives

United Kingdom

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

Netherlands

Matthijs M. van Blokland, Esq., *General Counsel, Prosensa; General Counsel and Senior Policy Advisor Legal Affairs, Association Innovative Medicines, Nefarma; Board Member, Stichting CGRz, Amsterdam, The Netherlands*

France

Julie Bonhomme, Esq. (Invited), *Legal Counsel, LEEM, Paris, France*

Slovak Republic

Sona Strachotova, MBA, *Executive Director, Slovak Association of Research-Based Pharmaceutical Companies (SAFS), Bratislava, Slovak Republic*

United States

Yogesh Bahl, MBA,*Partner, National Practice Leader - Life Sciences, Deloitte Financial Advisory Services LLP, New York, NY, USA (Moderator)*

11:30 am Responding to Global Transparency and Disclosure Compliance Laws

Update on Global Transparency Management: Industry Survey Key Findings

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

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

Global Transparency and Disclosure Compliance Strategies

Ronny Arijs, *Vice President Global Sustainability and Chief Compliance Officer, Grunenthal; Member, EFPIA Compliance Workgroup; Former Senior Compliance Manager, GE Healthcare, Brussels, Belgium*

Michael Bartke, PhD, *Director Compliance Management, Daiichi Sankyo Europe GmbH, EFPIA Vice chair Compliance Committee, Munich, Germany*

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

Jonathon Kellerman, *Partner, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers LLP, Florham Park, NJ, USA (Moderator)*

12:30 pm NETWORKING LUNCHEON

International Pharma Congress Planning Committee

Ann Beasley Bacon, Global Compliance Officer, Novartis Pharma AG, Basel, Switzerland (Co chair)

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

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

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

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

Ronny Arijs, Vice President Global Sustainability & Chief Compliance Officer, Grunenthal; Former Senior Compliance Manager GE Healthcare, Brussels, Belgium

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

Wayne Baker, Senior Vice President & Chief Sales Officer, Advanced Health Media LLC, New Providence, NJ, USA

Bulent Becan, Managing Partner, Atuva Management Consultancy and Trade Ltd.; Consultant in Ethics Issues, Turkish Research Based Pharmaceutical Companies Association (AIFD), Istanbul, Turkey

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

Hugh C. Bigwood, Ethics and Compliance Officer, International Operations, Abbott Laboratories, Horsham, West Sussex, United Kingdom

Antonio Cavallaro, Compliance & Internal Auditing Senior Manager, Takeda Italia Farmaceutici, Rome, Italy

Peter Dieners, Esq., Partner, Clifford Chance, Düsseldorf, Germany

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

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

Annette Schutt Fiig, Director, Risk Office, Novo Nordisk, Copenhagen, Denmark

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

Sameh Farag, Associate Vice President Compliance, Intercontinental Zone Corporate Compliance, Sanofi, Paris, France

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

Jonathon Kellerman, Partner, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers LLP, Florham Park, NJ, USA

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

Marc L. Miller, Partner, KPMG LLP, New York, NY, USA

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

Dave O'Shaughnessy, Vice President, Global Compliance, AstraZeneca; Former Vice President and Compliance Officer, Emerging Markets and Asia Pacific, GlaxoSmithKline, London, United Kingdom

Guillaume Roussel, Vice President, Compliance Solutions EMEA, Cegedim, 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; Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium

AFTERNOON TRACK SESSIONS I

TRACK I A: GLOBAL COMPLIANCE AUDITING AND MONITORING BEST PRACTICES

1:45 pm Welcome and Overview

Dave O'Shaughnessy, *Vice President, Global Compliance, AstraZeneca; Former Vice President and Compliance Officer, Emerging Markets and Asia Pacific, GlaxoSmithKline, London, UK (Co chair)*

L. Stephan Vincze, J.D., LL.M., MBA, *National Managing Director, Life Sciences/Forensic and Dispute Services, Deloitte Financial Advisory Services, LLP, Boston, MA, USA (Co chair)*

2:00 pm Overview of Best Practices in Global Auditing

Luca M. Liberatore, *Director Large European Affiliates and CEE, Amgen International HealthCare Compliance, Milan, Italy*

L. Stephan Vincze, J.D., LL.M., MBA, *National Managing Director, Life Sciences/Forensic and Dispute Services, Deloitte Financial Advisory Services, LLP, Boston, MA, USA*

2:30 pm Compliance Management Systems: Complying with German and European Standards

Stefan Heissner, *Managing Partner, Fraud Investigation and Dispute Services, Ernst & Young GmbH, Düsseldorf, Germany*

3:00 pm Best Practices in Monitoring Global Compliance Programs

Dave O'Shaughnessy, *Vice President, Global Compliance, AstraZeneca; Former Vice President and Compliance Officer, Emerging Markets and Asia Pacific, GlaxoSmithKline, London, UK*

Michael J. Morgan, *Ethics and Compliance Officer, Australia, Canada and Europe, Eli Lilly and Company, Windlesham, Surrey, United Kingdom*

3:30 pm Break

TRACK I B: NEW EU PROVISIONS GOVERNING COMPLIANCE WITH PHARMACEUTICAL REGULATORY LAWS — WHAT IS KEEPING YOU AWAKE AT NIGHT?

- New European Pharmacovigilance Rules
- New Falsified Medicines Directive, including The Proposed Changes in GMP Rules
- Information to Patients Proposal & Recent Advertising Cases
- Upcoming Clinical Trial Directive and other
- Pharma Regulatory Recent Developments

1:45 pm Welcome and Overview

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

Evelyn Lemaire, *Director, PricewaterhouseCoopers LLP, Zurich, Switzerland*

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

Maurits J.F. Lugard, MA, JD, LLM, *Partner, Sidley Austin LLP; Former Member of the European Commission's Legal Service, Brussels, Belgium (Co chair)*

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

3:30 pm Break

TRACK I C: GLOBAL TRANSPARENCY, DISCLOSURE AND AGGREGATE SPEND

1:45 pm Welcome and Overview

Ronny Arijs, *Vice President Global Sustainability and Chief Compliance Officer, Grunenthal; Member, EFPIA Compliance Workgroup; Former Senior Compliance Manager, GE Healthcare, Brussels, Belgium (Co chair)*

Jonathon Kellerman, *Partner, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers LLP, Florham Park, NJ, USA (Co chair)*

2:00 pm Global Transparency

David Wysocky, *Director, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers LLP, Boston, MA, USA*

2:30 pm Lessons Learned from Aggregate Spend Reporting in the United States — Impacts for Europe and Global Transparency

Erik Eglite, Esq., *Vice President, Chief Compliance Officer and Corporate Counsel, Lundbeck Inc., Deerfield, IL, USA*

John Patrick Oroho, Esq., *Executive Vice President, Porzio Pharmaceutical Services; Principal, Porzio Bromberg & Newman PC, Morristown, NJ, USA*

3:00 pm Best Practices in Global Fair Market Value Determinations

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

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

3:30 pm Break

TRACK I D: THE ITALIAN REGULATORY AND COMPLIANCE SCENE IN DEPTH: A CASE STUDY

1:45 pm Case Study: The Italian Compliance Environment — Main Requirements and Best Practices regarding Company Criminal Liability

Presented by the Italian Pharma Compliance Network "Osservatorio 231 Farmaceutiche"

Maurizio Arena, Esq., *Criminal Lawyer, President and Founding Member, Osservatorio 231 Farmaceutiche, Rome, Italy*

Maurizio Bortoletti, *Colonel, Carabinieri Corps, Extraordinary Commissioner, Public Healthcare Company, Salerno, Italy*

Maria Teresa Brassiolo, *President and Founding Member, Transparency International Italia, Milan, Italy*

Edoardo Lazzarini, *European Compliance Officer, Biomet Italia, Milan, Italy*

Giuseppe Palmieri, *Chief Compliance Officer, Head of Risk and Compliance Management and Internal Audit, Boehringer Ingelheim Italia, Milan, Italy*

Antonio Cavallaro, *Compliance and Internal Auditing Senior Manager, Takeda Italia Farmaceutici, Rome, Italy (Co chair)*

3:30 pm Break

TRACK I E: MEA COMPLIANCE ISSUES ROUNDTABLE

1:45 pm MEA Compliance Issues Roundtable

Hulya Baran, *Director, Ethics and Compliance TMEA - CIS, Eli Lilly and Company, Istanbul, Turkey*

Meltem Ozker Gunduz, *Regional Legal Counsel and Compliance Officer, Business Area Near East, Novo Nordisk, Istanbul, Turkey*

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

Liz MacGillivray, *Compliance Director, Corporate Integrity and Compliance, Novartis International AG Basel, Switzerland*

Laura Nassar, *Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon*

Sameh Farag, *Associate Vice President Global Compliance, Intercontinental Zone Corporate Compliance, Sanofi, Paris, France (Co chair)*

3:30 pm Break

AFTERNOON TRACK SESSIONS II

TRACK II A: LESSONS FROM GLOBAL COMPLIANCE ISSUES AND INITIATIVES IN THE MEDICAL DEVICE SECTOR

4:00 pm Welcome and Overview

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, USA*

Peter V. Rother, Esq., *Associate General Counsel and Senior Compliance Director, Cardiovascular Division, St. Jude Medical, Plymouth, MN, USA*

Tamara Tubin, *Director Ethics and Compliance International, CareFusion International; Former Associate Director Compliance EMEA, ZIMMER GmbH, Zürich, Switzerland*

Peter Dieners, Esq., *Partner, Clifford Chance, Düsseldorf, Germany (Co chair)*

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

5:45 pm Adjournment

TRACK II B: GLOBAL ANTI-BRIBERY UPDATE

- Practical Compliance Strategies in Response to Regional Anti-Bribery Developments
- Hidden Risk Areas in FCPA, UK Bribery Act, OECD Anti-Bribery Convention, Russian Anti-Bribery Act, etc. Compliance
- Developing and Implementing Global Anti-Bribery Policies and Procedures

4:00 pm Welcome, Overview and Discussion

John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, 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, USA*

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

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

5:45 pm Adjournment

TRACK II C: ISRAEL COMPLIANCE UPDATE AND THE CHINESE REGULATORY AND COMPLIANCE SCENE IN DEPTH: A CASE STUDY

4:00 pm Israel Compliance Issues Update

Daniel Kessler, *Principal, ITR Group; Former Chief Counsel, International Trade Controls, Pfizer; Former Chief Counsel, International Trade Controls, Wyeth, Tel Aviv, Israel*

4:25 pm China Pharma Compliance Case Study

- Regulatory and Compliance "Hot Topics"
- Enforcement
- Market Access and Pricing Issues
- Pharmacoeconomics
- Expected Future Developments/Areas of Special Attention
- Operational Challenges of Rapid Growth

Erinn Hutchinson, *Director, PricewaterhouseCoopers LLP, Philadelphia, PA, USA*

Yuet-Ming Tham, Esq., *Partner and Head, Regulatory, Compliance and Investigations Group, AsiaDLA Piper; Former Regional Compliance Director, Legal Division, Corporate Compliance, Pfizer Inc., Hong Kong*

John Auerbach, MA, *Partner, Fraud Investigation and Dispute Services, Ernst & Young China, Shanghai, China (Co chair)*

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

5:45 pm Adjournment

TRACK II D: CEE COMPLIANCE ISSUES ROUNDTABLE

4:00 pm Welcome and Overview of CEE Compliance Issues Roundtable

- Update on CEE Developments
- Regulatory
- Enforcement
- Compliance "Hot Topics"
- Managing Compliance in CEE - Opportunities and Challenges
- Compliance Best Practices for CEE
- Expected Future Developments/Areas of Special Attention

Ildikó Flautner, *Compliance Officer, Lilly, Budapest, Hungary*

Tomasz Kruk, LLM, MBA, *Director of Ethics and Compliance, Actavis, Zug, Switzerland*

Paul J. Melling, Esq., *Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia*

Anna Romany, *Managing Director, Janssen, Budapest, Hungary*

Madina Torchinova, Esq., *Regional Compliance Officer CEE, Sandoz; Former Director Legal and Regulatory Affairs, Association of International Pharmaceutical Manufacturers (AIPM), Russia, Munich, Germany*

Mariusz Witalis, *Partner, Fraud Investigation and Dispute Services, Ernest & Young LLP, Warsaw, Poland (Co chair)*

5:45 pm ADJOURNMENT

Wednesday, May 16, 2012

7:30 am **Registration Commences**

MORNING PLENARY SESSION

8:30 am **Welcome and Introductions**

Ann Beasley Bacon, *Global Compliance Officer, Novartis Pharma AG, Basel, Switzerland (Co chair)*

8:45 am **Regional Compliance Code Update Roundtable**

IFPMA Code Update

Tamara Music, *Manager, Influenza Vaccines and Code Compliance, IFPMA, Geneva, Switzerland*

EFPIA Code Update

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

EUCOMED Code Update

Aline Lautenberg, JD, *Senior Legal Counsel, Eucomed, Brussels, Belgium*

Bernard Maillet, MD, *Member, Flemish Chamber of the Board for Specialists for Pathology; Treasurer, Belgian Association of Specialists (VBS-GBS); Member, EUCOMED's Compliance Panel; Former Secretary General, European Union of Medical Specialties (UEMS) and European Accreditation Council for Continuing Medical Education (EACCME), Antwerp, Belgium*

MEA Code Update

Sameh Farag, *Associate Vice President Compliance, Intercontinental Zone Corporate Compliance, Sanofi, Paris, France*

Russia Code Update

Paul J. Melling, Esq., *Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia*

Turkey Code Update

Bulent Becan, *Managing Partner, Atuva Management Consultancy and Trade Ltd.; Consultant in Ethics Issues, Turkish Research Based Pharmaceutical Companies Association (AIFD), Istanbul, Turkey*

PhRMA Code Update

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 (Moderator)*

10:15 am **Break**

10:30 am **Third-Party Intermediaries: Due Diligence and Monitoring Considerations**

Karl Boonen, Esq., *Senior Director Business Practices and Compliance EMEA and Canada, Johnson & Johnson, Antwerp, Belgium*

Nieves Liste, MBA, *Global Business Compliance Director, Covidien, Barcelona, Spain*

Sandeep Sharma, Esq. (Invited), *Assistant Counsel, Merck & Co., Inc., New York, NY, USA*

Marc L. Miller, Partner, KPMG LLP, *New York, NY, USA (Moderator)*

11:15 am **Business Responsibility as it Applies to Pharmaceutical and Medical Device Enterprises**

Andrew Jack, *Pharmaceuticals Correspondent,* Financial Times, *London, UK*

11:35 am **Business Ethics and Reputation in the Pharmaceutical and Medical Device Enterprises**

Richard Bergström, *Director General, European Federation of the Pharmaceutical Industries and Associations (EFPIA); Former Director General, LIF Sweden, Brussels, Belgium*

Andrew Jack, *Pharmaceuticals Correspondent,* Financial Times, *London, UK*

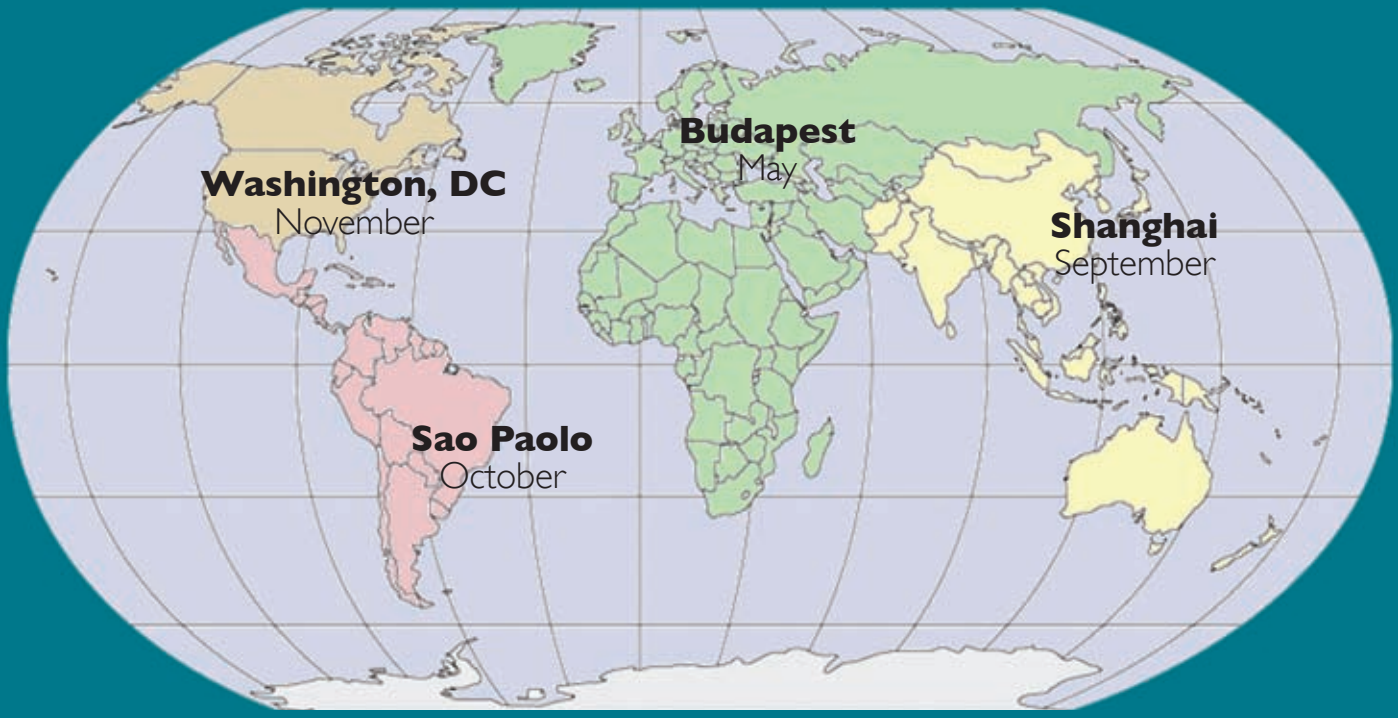
Dominique Laymand, Esq., *Vice President Compliance and Ethics, EMEA (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb, Paris, France*

Andy Powrie-Smith, *Director for Trust and Reputation, Association of the British Pharmaceutical Industry (ABPI), London, UK*

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

12:30 pm **ADJOURNMENT**

Save These Dates in 2012!



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A Hybrid Conference & Internet Event

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www.LatinAmericanPharmaCongress.com

Thirteenth Pharmaceutical Regulatory and Compliance Congress

Sponsored by Pharmaceutical Compliance Forum
Media Partners: *Life Science Compliance* and *RX Compliance Report*

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www.PharmaCongress.com

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• Online at www.InternationalPharmaCongress.com.

• Fax/Mail/Email using this printed registration form. Mail the completed form with payment to the Conference registrar at 22529 39th Ave SE, Bothell, WA 98021, USA, or fax the completed form to +1 206-319-5303, or scan and email the completed form to registration@hcconferences.com. Checks or money orders should be made payable to Health Care Conference Administrators LLC.

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International Pharma Congress

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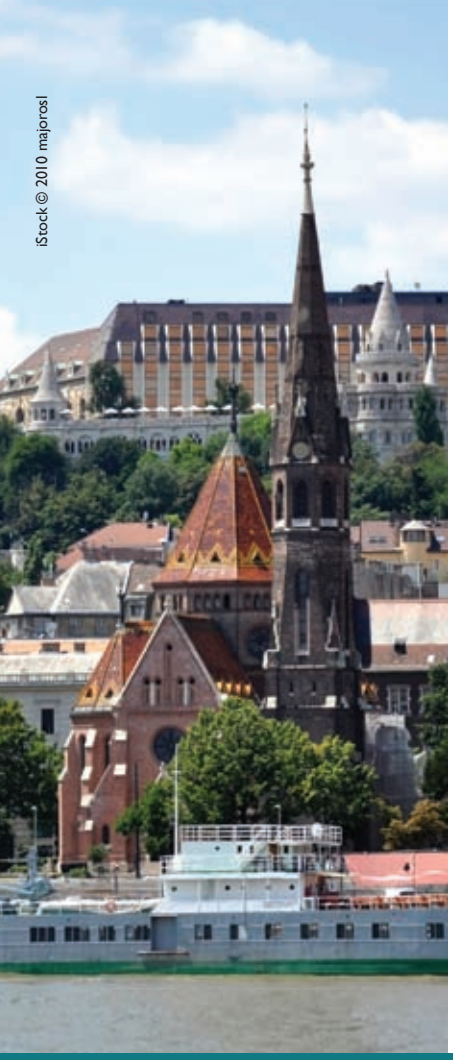

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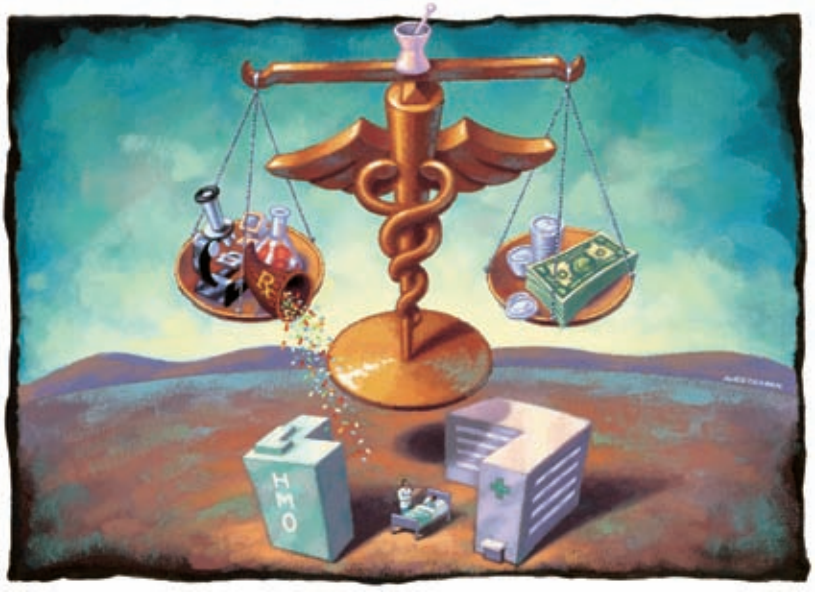

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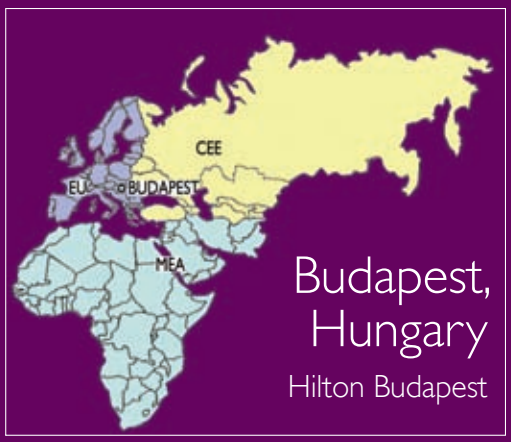

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