PHARMACEUTICAL & DEVICE GLOBAL TRANSPARENCY INITIATIVES

Meeting Increasing Government Pressure for Reporting of Aggregate Spend & Expanding the Transparency of Relationships with Healthcare Professionals, all while Managing Internal Compliance Programs & Standards of Excellence

PROGRAM OVERVIEW:
As the governments around the world continue to increase their scrutiny of major corporations, the pharmaceutical industry is coming under heavy pressure from politicians and regulators who are calling for increased transparency from the industry. Although the Sunshine Act reporting requirements have been pushed back into 2012, all companies are preparing or have already begun disclosing their relationships with healthcare professionals; a bold and often controversial step for this highly competitive industry. On a global scale, European governments are now also calling for similar legislation, with countries such as France and the Netherlands most vocally calling for action. As a result, pharmaceutical companies throughout the world are looking to act upon their compliance programs in place and drive out transparency initiatives that will meet and exceed regulatory requirements.

Although this program will focus a great deal on international compliance considerations, the program will be highly applicable for US-based compliance executives; many of whom oversee global compliance teams. While all companies have compliance and transparency plans in place; many are struggling with the challenge of implementing these structures, gaining executive level support for compliance, as well as measuring the success of transparency and compliance programs.

DISTINGUISHED PRESENTERS INCLUDE:

Jeff Rosenbaum  
Chief Compliance Officer  
VERTEX PHARMACEUTICALS

Peter Burberry  
Senior Director, Global Practices  
ALLERGAN

Ty Edmondson  
Vice President & Associate General Counsel  
SUNOVION PHARMACEUTICALS

Jacob Springer  
Global Privacy Officer, Senior Counsel Ethics & Compliance  
BAXTER INTERNATIONAL INC

Nikki Reeves  
Partner, FDA & Life Sciences Practice  
KING & SPALDING LLP

Gus Pappandrinkos  
Director, Transparency Operations  
SANOFI-AVENTIS

Katrina Cahill  
Senior Manager, Corporate Compliance, Global Transparency Lead  
BIOGEN IDEC

Jennifer Sanfilippo  
Dir, Global Contracting & Business Ethics  
THE MEDICINES COMPANY

Nancy Grygiel  
Senior Director, International Compliance  
ALLERGAN

Don Soong  
Sr Director, Compliance Solutions Engineering  
CEGEDIM

Michelle Axelrod  
Vice President  
PORZIO PHARMACEUTICAL SERVICES

Kenneth Kleinhenz  
VP Regulatory Affairs and Quality Assurance  
CYTORI THERAPEUTICS

Garineh Dovletain  
Vice President, Head of Global Contracting & Business Ethics  
THE MEDICINES COMPANY

Joe Wholley  
Executive Director Internal Audit & Compliance  
SUNOVION PHARMACEUTICALS

Suzanne Rab  
Partner  
KING & SPALDING LLP

Gaurica Chacko  
Senior Director, Global HCP Compliance  
EDWARDS LIFESCIENCES
8:00 REGISTRATION & CONFERENCE WELCOME
8:45 CHAIRPERSON’S OPENING REMARKS
9:00 THE EVOLVING GLOBAL TRANSPARENCY LANDSCAPE: A VIRTUAL MINEFIELD FOR GLOBAL MANUFACTURERS
   As Compliance Functions have evolved and matured over the past decade, manufacturers are finding that focus on delivering on the expectations of the standard 7 elements of an effective compliance program are no longer sufficient. Transparency has become a global trend within the life science industry with approximately 13 countries having established disclosure regulations. Countries like France and Australia have recently developed legislation similar to the Physician Payment Sunshine Law to minimize conflicts and ensure that patient populations are well informed. These quickly emerging developments present a complicated set of challenges which companies must wrestle with.
   Jeff Rosenbaum, Chief Compliance Officer
   VERTEX PHARMACEUTICALS

9:45 LOOKING AHEAD: AGGREGATE SPEND AND TRANSPARENCY INITIATIVES IN THE US
   The US pharmaceutical industry has seen a great deal of regulatory growth over the past decade. One area in particular has focused on transparency and the open disclosure of activities relating to the public. While industry associations have long promoted their commitment to transparency, many have struggled with properly implementing and reporting new regulations due to delayed guidance from CMS.
   • Updates on the status of aggregate spend requirements
   • Detailing regulatory and practical challenges
   • Highlighting emerging trends and resources
   • What is not included?
   Gus Pappadirkos, Director, Transparency Operations
   SANOFI-AVENTIS

10:30 COFFEE & NETWORKING BREAK

10:50 UNDERSTANDING THE INTERNATIONAL TRANSPARENCY LANDSCAPE
   Similar to the US, many countries are adopting new measures intended to support transparency and disclosure between pharmaceutical manufacturers and HCPS. France, in particular, has seen its share of medical scandals and enormous fines; most notable was a diabetes drug that resulted in the death of hundreds of individuals before being taken off the market. This is just one instance that has contributed to a push for regulatory guidelines relating to the public disclosure of potential conflicts of interest between physicians and the pharmaceutical industry. Should these bills come to fruition, FCPA and related regulatory repercussions for companies operating outside of the US will be significant.
   • Proposed guidelines and consequences of non-compliance
   • Outlining timelines and deadlines
   • Defining thresholds for potential reporting
   • Key takeaways from US aggregate spend systems and reporting
   Ty Edmondson, Vice President & Associate General Counsel
   SUNOVION PHARMACEUTICALS

11:35 CASE STUDY – IMPLEMENTING A GLOBAL HCP TRANSPARENCY PROCESS
   The importance of a Global Customer Master
   Streamlining the HCP Request Process
   The role of a Data Steward
   Gaufica Chacko, Senior Director, Global HCP Compliance
   Edwards Lifesciences

12:20 LUNCHEON FOR ALL ATTENDEES, SPEAKERS, AND SPONSORS

12:50 DISCLOSURE AND COMPLIANCE LAWS IN THE UK: COMPETITION, BRIBERY, AND THE ABPI CODE
   An industry study released at the end of 2010 found that 93% of respondents agreed that “regulatory compliance in Europe will become a major challenge”. The British pharmaceutical industry in particular has seen a number of transparency related initiatives in the past 2 years, most recently the Association of British Pharmaceutical Industry (ABPIs) amendments to its code of practice regarding consultant payments and sponsorship. ABPI championed these changes sighting that they will enhance trust between HCPs and the industry; however, many feel that these changes might not have the desired effect.
   • Discussing key revisions and important timelines
   • 4 key offences of UK Bribery Act
   • Clarification on promotional regulations
   Suzanne Rab, Partner
   KING & SPALDING LLP

Nikki Reeves, Partner, FDA & Life Sciences Practice
KING & SPALDING LLP

2:35 MANDATORY & STRATEGIC DISCLOSURES FOR CLINICAL & REGULATORY FILINGS
   Successfully meeting regulatory requirements for product approvals with the FDA and other international regulatory bodies can be a significant challenge for global pharmaceutical manufacturers. Required disclosures in regulatory filings for product approvals differ depending on location and can be quite burdensome for companies looking to obtain product approval in multiple markets. Understanding the approval processes and various disclosure considerations can assist companies in minimizing the potential for litigation and FDA compliance issues.
   • Understanding disclosures specific to:
     • Regulatory agencies and IRBs for clinical trials
     • Regulatory agencies for existing approved product
     • Disclosures to patients, doctors / users
     • Scientific data
     • Financial conflicts of interest
   Kenneth Kleinhenn, VP Regulatory Affairs and Quality Assurance
   CYTORI THERAPEUTICS

3:20 COFFEE & NETWORKING BREAK

3:40 DEFINING BEST METHODS FOR CAPTURING PHYSICIAN SPENDING OUTSIDE OF THE US
   The US has historically served as a pioneer within the life science industry for establishing necessary benchmarks and regulations which were later enacted by other prominent countries. As a result, US based global compliance teams are often given the strenuous responsibility of capturing and reporting data involving payments to physicians both in the US and abroad. Accurate reporting of physician spending in the US can be a taxing endeavor for teams unto itself and only increases in complexity when viewed on a global scale.
   • Strategies for collecting physician spend outside the US
   • Highlighting common regulatory and cultural considerations
   • Analyzing trends within global physician spending and reporting
   Peter Burberry, Senior Director, Global Practices
   ALLERGAN

4:25 ASSESSING AND DETERMINING FAIR MARKET VALUE ON AN INTERNATIONAL SCALE
   Establishing fair market value for consultant fees can be a complex process, and when tasked with determining the appropriate fee for a consultant in another country, the obstacles only continue to increase. A recent industry study found that determining appropriate fees for physician activity in many European countries is just now coming into play. Establishing the appropriate fair market value and spend reporting is imperative responsibility for global manufacturers and continues to deepen as more countries develop their own regulations.
   • Global methodologies used in FMV calculations
   • Outlining proper documentation procedures
   • Recognizing the implications of cultural customs
   Nancy Grygiel, Senior Director, International Compliance
   ALLERGAN

Jeff Rosenbaum, Chief Compliance Officer
VERTEX PHARMACEUTICALS

5:10 DAY ONE CONFERENCE CONCLUSION
Global compliance executives are all too familiar with the US requirements related to transparency and disclosure reporting. A key challenge for many companies is what these laws do not say—particularly how to effectively implement and operationalize aggregate spend while aligning global activities and requirements. Although many organizations have already implemented systems and/or processes to capture and report data, few are using the data generated beyond meeting their basic legal obligations. Developing and implementing systems and processes to satisfy the requirements of the varying state laws and preparing for compliance with the federal sunshine act is a time consuming and costly venture. And like many compliance initiatives, it can be difficult to get organizational commitment and buy-in when cost appears to outweigh value. In this interactive session, we will highlight best practices for aggregate spend implementation to meet current and future reporting requirements while allowing for more effective and strategic use of the transparency data. We will also identify and discuss the many opportunities for optimizing the use of the data to increase operational efficiencies, improve compliance practices and enable more strategic business decision-making.

Michelle Axelrod, Vice President
PORZIO PHARMACEUTICAL SERVICES, LLC

10:30 NAVIGATING DATA PRIVACY LAWS WHILE MAINTAINING TRANSPARENCY

New technologies and methods of communication have continued to develop within the pharmaceutical industry; coincidentally, this also began a new era of privacy violations and identity theft for manufacturers. FCPA and further related requirements pose significant risks to patient, employee and customer privacy protection laws, while enhanced reporting requirements also create similar privacy risks such as internet usage reporting and medical data monitoring. Increased media attention on these incidents has added the pressure on organizations to prevent the disclosure of sensitive information.

• Discussing key global privacy provisions
• Designing and implementing risk management policies and procedures
• Guidance on internal investigations and systems monitoring
• Understanding data breach notification regulations

Jacob Springer, Global Privacy Officer, Senior Counsel Ethics & Compliance
BAXTER INTERNATIONAL INC

11:15 COFFEE & NETWORKING BREAK

11:45 CLARIFICATION AND INSIGHT INTO DISCLOSURE AND CONFLICT OF INTEREST POLICIES

Multiple forms of legislation have been passed by global institutions relating to the disclosure of physicians, HCP and pharmaceutical industry relationships—most often financial relationships which carry a long history of scrutiny. These collaborations provide mutual benefits, but can also potentially lead to a number of conflicts of interests which may influence clinical decisions. While the intent of transparency is to ensure that patient populations are well informed and minimize conflicts, both physicians and manufacturers find it difficult to balance conflict of interest policies while conducting compliant research.

• Defining issues specific to conflict of interest
• Managing conflict of interest policies
• Following up post-declaration of a conflict

Garineh Dovletain, VP, Head of Global Contracting & Business Ethics
THE MEDICINES COMPANY
Jennifer Sanfilippo, Director, Global Contracting & Business Ethics
THE MEDICINES COMPANY

12:30 LUNCHEON FOR ALL CONFERENCE ATTENDEES, SPEAKERS, AND SPONSORS

UPCOMING Q1 EVENTS INCLUDE:

• Regulatory Clearance & Commercialization of Generic Drugs & Biosimilars
  July 12-13
  Alexandria, VA

• Device Safety: Regulations, Reporting & Tracking
  August 27-28
  Baltimore, MD

• Post-Approval Research: Design, Execution & Outcomes
  Oct. 22-23
  Alexandria, VA

CONTACT Q1 PRODUCTIONS:

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today’s leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees.

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KEY SPEAKER HIGHLIGHT:

Jeff Rosenbaum
Chief Compliance Officer
VERTEX PHARMACEUTICALS

Jeff Rosenbaum has recently joined Vertex Pharmaceuticals as their Chief Compliance Officer. Prior to joining Vertex, Jeff was the Global Head of Ethics & Compliance with Novartis, where he is was responsible for developing, implementing, and monitoring Novartis Oncology’s compliance program, globally.

Prior to his appointment at Novartis, Jeff was a Director in PricewaterhouseCoopers’ Global Pharmaceutical Advisory Practice advising pharmaceutical, biotechnology, and medical device companies around various matters of corporate governance, non-financial risk, and regulatory compliance. His global consulting work at PwC ranged from corporate compliance program development to designing and implementing effective compliance controls to rolling out and executing compliance auditing. Additionally while with PwC, Jeff served as the Independent Review Organization (IRO) for Pfizer’s CIA related to the Neurontin settlement.

Jeff began his career in the pharmaceutical industry working for Wyeth Pharmaceuticals where he worked in a number of line functions, including: product marketing, business development, and field sales.

Jeff holds a B.A. from the University of Pennsylvania and a M.B.A. from the University of Virginia’s Darden School of Business.

WHO SHOULD ATTEND:

Executives that will find this conference program of the greatest applicability for themselves and their teams are those responsible for the overall compliance of their organization on a global level. Those executives overseeing corporate compliance initiatives in the US will also find this event of great interest, and with a strategic approach to the topic will find themselves learning and understanding how compliance is impacting the pharmaceutical industry globally. Job titles of those that will attend this program include:

- GLOBAL COMPLIANCE OFFICERS
- INTERNATIONAL COMPLIANCE OFFICERS
- GLOBAL & INTERNATIONAL CORPORATE COUNSEL
- CHIEF COMPLIANCE OFFICERS
- DIRECTORS, INTERNATIONAL COMPLIANCE

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documenta-

PREVIOUS ATTENDEES INCLUDE:

Sr. Counsel, Anti-Corruption, ABBOTT LABORATORIES
Ethics & Compliance Officer, ABBOTT LABORATORIES
Sr. Director, Regulatory Compliance, ATELIEN
Compliance Officer, ADVANCED BIOHEALING
Compliance Officer, ADVANCE BIOSCIENCES
Director, Corporate Compliance, ALCON LABORATORIES
Associate General Counsel, ALCON LABORATORIES
VP Global Regulatory Affairs, ALLERGAN
Sr. Manager, Healthcare Compliance Audit, ALLERGAN
Dir, Corporate Compliance, AMERICAN MEDICAL SYSTEMS
Director, Healthcare Compliance, AMGEN
Director of Compliance, AMGEN
Director, Corporate Compliance, ASTELLAS
Chief Regulatory Counsel, ASTELLAS
Director, Compliance & Ethics, ASTRAZENECA
Corporate VP & Chief Compliance Officer, BAUSCH & LOMB
Director, Global Regulatory Affairs, BAUSCH & LOMB
Sr. Compliance Counsel, BAXTER HEALTHCARE
Ethics & Compliance Officer, BAXTER INTERNATIONAL
Corporate Counsel, BAYER
Compliance Monitor, BAYER
Associate General Counsel, BECKMAN COULTER
Director, US Compliance, BIOMEDIC
Global Chief Compliance Officer, BIOMET
VP Compliance, BIOTRONIK
Sr. Compliance Counsel, BOSTONSCIENTIFIC
Director, Ethics & Compliance, CAREFUSION
SVP, General Counsel, CARDIAN BCT
Regulatory Counsel, CELGENE
Chief Compliance Counsel, COVIDIEN VASCULAR
Deputy General Counsel, DAICHI SANKYO
Sr. Director, Ethics & Compliance, ELI LILLY & CO
Director, US Regulatory Affairs, EMD SERONO
Manager, Corporate Compliance, ENDO PHARMACEUTICALS
Vice President, Legal Affairs, ETHICON ENDO SURGERY
Chief Compliance Officer, FERRING PHARMACEUTICALS
Global Leader, Regulatory Intelligence, GE HEALTHCARE
Corporate Counsel, GENZYM
Compliance Director, GLAXOSMITHKLINE
Corporate Compliance Counsel, HILL-ROM
Sr. Director, CIO Management, JOHNSON & JOHNSON
VP Healthcare Compliance, JOHNSON & JOHNSON
VP Healthcare Compliance, KINETIC CONCEPTS
Chief Compliance Officer, LUNDBECK
Chief Compliance Officer, MCKESSON PHARMACEUTICALS
Director, Regulatory Affairs, MEDIJUNE
Director, Compliance, MERCK
Ex. Director, HQ Operations & Policy, MERCK
Director, Regulatory Compliance, NOVARTIS
Global Head of Ethics & Compliance, NOVARTIS
Chief Compliance Officer, ORTHOFIX
Sr. Compliance Counsel, OTSUKA AMERICA
Assistant General Counsel, PFIZER
Sr. Corporate Counsel, Compliance, PFIZER
Director, US Corporate Compliance, SANOFI AVENTIS
Director, Compliance, SEATTLE GENETICS
Compliance Officer, SIEMENS HEALTHCARE
Compliance Officer, SMITH & NEPHEW
Compliance Officer, TEVA
Chief Compliance Officer, WATER PHARMACEUTICALS
Associate General Counsel, WELCH ALLYN

...AND MANY MORE!