19th Annual Pharmaceutical and Medical Device Compliance Congress

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Mini Summit 24: Evolving Risks and Opportunities related to Medical Affairs, e.g. Professional Medical Education, Digital Information, etc.

Panel Introductions

- **BJ D'Avella**, Senior Manager, Life Sciences Regulatory and Operational Risk, Deloitte, Parsippany, NJ *(Co-moderator)*
- **Mark A. DeWyngaert, PhD, MBA** Managing Director, Life Sciences Regulatory and Operational Risk, Deloitte, New York, NY *(Co-moderator)*
- **Stefanie A. Doebler, JD** Of Counsel, Covington & Burling LLP, Washington, DC
- **Philip Lo Scalzo, JD** Senior Vice President, Chief Compliance Officer, BioMarin; Former Assistant General Counsel, sanofi-aventis, Novato, CA
- **Stephanie Macholtz, JD, MBA** Director, Compliance and Ethics, Global Medical Affairs and Business Development, Alexion Pharmaceuticals, Inc.; Former Compliance Officer, Biogen; Former Associate Director, Compliance, R&D, Eisai, Boston, MA
- **Donna White** Vice President, Contracts and Compliance, Chiesi USA, Inc.; Former Senior Director, Contracts and Compliance, Cornerstone Therapeutics, Cary, NC

The focus of the panel discussion:

- Pharmaceutical and medical device industries are becoming more patient- centric.
- Companies are upgrading and expanding their Medical Affairs teams.
- Medical Affairs is best positioned to:
  - Generate and present critical scientific knowledge
  - Holistically pull together scientific and clinically relevant results regarding patient outcomes, relevant health economics, and patient safety at all stages of the product life cycle.
- Rapid growth of proactive and deeper relationships with prescribers and the broader patient/patient advocacy community may also lead to new areas of risk.

The focus of the panel discussion:

- Risks include:
  - Privacy
  - Data security
  - Transparency
  - Value-based care
  - Bias in publications
  - Charitable giving
  - Reimbursement support
- Tension with customer-facing and proactive informational efforts that may look commercial in nature.
- As medical affairs teams align more with the commercial sectors, this could potentially undermine the benefit of medical affairs' independent perspective and judgment.

How are your peers working to help their organizations improve the quality of healthcare while also mitigating risk?

- Use of Health Economics and Real World Data
- Interactions with Patient Advocacy groups
- Patients demands for more information and involvement at ever earlier stages of drug/device development
- Digital technology and advanced forms of communications including text messages, Facebook, Twitter, other web enabled interactions, and learning on demand
- What to do when your patient population numbers in the hundreds not tens of thousands?

How are your peers working to help their organizations improve the quality of healthcare while also mitigating risk?

- Vulnerable populations (pediatrics, aging, and indigent segments)
- More proactive interactions in the field where should you draw the line
- Use of MSLs as speakers
- Crossing the line into medical care in discussion with HCPs and Patients
- What is off-label in light of recent litigation and FDA guidance?

Specific questions:

- How to develop guidelines on use of patient information when you are in the ultra-rare disease space? who can share the information
- What payments/transfers of value are permissible in supporting patients undergoing therapy?
  - What if they are children?
- Former HCPs as Medical Liaisons- how to train on not providing medical advice?
- How to discuss treatment guidelines and standards of care ?
- Involvement with Commercial Colleagues in joint account teams what are the guidelines?

Specific questions:

- Misuse of REMs programs to acquire additional data or provide additional non-mandated services ?
- Virtual MSL programs – no longer a one to one but possibly one to many?
- Where do we draw the firewall between medical and commercial especially in the era of specialty and rare disease drugs?
- What level of coordination is appropriate between medical and commercial, particularly at higher levels in the company?
- How has the role of the MSL changed recently? What controls are companies putting in place to reflect the new role?

Specific questions:

- What kinds of interactions can medical have with patient groups Foundations?
- What rules are being used for presentations of HEOR and RWE data ?
  - Who can access this data internally at the Company
- Is the Medical Information Review process robust enough?
- How do we deal with new modes of communication text messages, Facebook, Twitter etc.. what controls do you have in place?


Questions?
Thank you!