SEVENTEENTH ANNUAL **Pharmaceutical and Medical Device Compliance Congress**

TRANSFORMATIONAL LEARNING – EFFECTIVE KNOWLEDGE EXCHANGE

GHC LIFE SCIENCES
Global Health Care, LLC

October 20, 2016 12:30 – 1:30 pm

Mini Summit IX:

Medical Affairs

Presenters

- **Brian J. Conner,** Director, Huron Consulting Group; Former Senior Director, Assistant Compliance Officer, Global Compliance, Shire Pharmaceuticals, Atlanta, GA

- **William Hrubes, MHA**
  Vice President, Chief Compliance Officer, ACell, Inc., Columbia, MD

- **Kevin Ryan, JD, MS,** Senior Director, Compliance: New Products, Novo Nordisk, Princeton, NJ

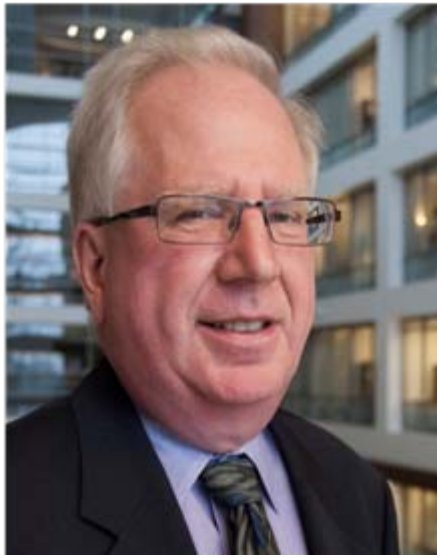
- **Nikki Reeves, JD, MPA,** Partner, King & Spalding, Washington, D.C. (Moderator)

Overview of Legal Framework and Current Landscape

Nikki Reeves

Medical Affairs

- "FDA holds the medical affairs department to the same standards as it does sales reps. It's important to keep from blurring the lines between promotion and responses to unsolicited requests."
- "Just because you have a person with a different hat in a different booth, if they are promoting a drug [providing off-label information is still] against the law."



Tom Abrams,
Director of FDA's
Office of Prescription
Drug Promotion (OPDP)

Overview of Legal Framework

As a general matter, the same laws and regulations apply to Medical Affairs personnel that apply to Sales and Marketing personnel. This includes, but is not limited to:

- The Federal Food, Drug, and Cosmetic Act
- The Anti-Kickback Statute

A primary purpose of Medical Affairs should be to help ensure that non-promotional interactions remain appropriately non-promotional and not tainted by Sales and Marketing considerations or influence

- Company organizational structure, processes, and incentives also should be designed and administered to avoid inappropriate influence or the appearance of inappropriate influence

Promotion v. Scientific Exchange

- Advertising
- Promotional labeling

Examples:

- Sales aids, brochures, notes, email messages, blog postings, social media, website materials, videos, etc.
- Proactive statements made during in-person, phone, or email discussions with HCPs
- Other activities that show "intended use"

- Dissemination and discussion of scientific research / medical findings, without making promotional claims about a product

Examples:

- Responding to unsolicited requests for off-label information in accordance with FDA draft guidance
- Distributing scientific and medical publications/reprints on off-label uses in accordance with FDA draft guidance
- Providing financial support for independent medical education programs
- Appropriate scientific discussions at legitimate scientific or medical conferences
- Scientific advisory board meetings, in appropriate circumstances and with limitations
- Appropriate communications intended for recruitment of clinical investigators and study subjects

First Amendment Cases

United States v. Caronia (2d Cir. 2012)

- Construes misbranding provisions not to criminalize truthful, non-misleading speech about off-label uses to avoid First Amendment violation

Pacira v. FDA (S.D.N.Y.) (dec. action, settled in 2015)

- Settlement with FDA permits company to market product for specific procedures not limited to those studied in the product's pivotal trials

Amarin v. FDA (S.D.N.Y.) (dec. action, settled 2016)

- Settlement with FDA provides that Amarin may engage in "truthful and non-misleading speech promoting the off-label use of [the product] . . ., and under *Caronia*, such speech may not form the basis of a prosecution for misbranding"

First Amendment Cases

United States v. Vascular Solutions, Inc. (W.D. Tex.) (acquittals in 2016)

- Jury instructions stated: "It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that VSI's promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense."
- Jury returned complete defense verdict on all counts for VSI and CEO Howard Root
- First time since *Caronia* that First Amendment protection for truthful off-label promotion has been recognized outside 2d Cir.

United States v. Facteau and Fabian (D. Mass. 2016)

- 2 former executives prosecuted for alleged off-label promotion of device
- Acquitted of felony charges. Convicted of misdemeanors.
- Difference between *VSI* and *Facteau/Fabian* outcome may have been jury instructions
- Jury instructions stated: "[t]ruthful, non-misleading speech may be used as evidence of intent to determine whether there is a violation of the law, although truthful/non-misleading speech is not a criminal act in and of itself."

Enforcement Examples

There is risk of enforcement if Medical Affairs engages in improper Sales or Marketing activities and/or are inappropriately influenced by Sales and Marketing

Settlements involving Medical Affairs activities have included allegations of, among other things…

- Promoting MSLs based on ability to sell
- Funding CME on off-label uses and creating and controlling content
- Training MSLs to prompt off-label questions
- Paying HCPs to speak on off-label uses
- Developing KOLs to support and promote off-label uses
- Using advisory boards to promote off-label uses
- Using IIS grants to promote off-label uses
- Ghostwriting articles on off-label uses
- MSLs accompanying sales representatives on in-office visits and providing presentations on off-label uses
- Creating teams of Reimbursement, Sales, and Medical personnel to track off-label promotion and use and to target HCPs for visits by MSLs
- Preparing and publishing a misleading journal article that misreported clinical trial results
- Publicizing and circulating positive study results and failing to discuss negative study results

CIA Requirements

Recent CIAs require manufacturers to implement at least some of the following measures:

- Creation of policies/procedures to control the provision of off-label information by Medical Affairs personnel
- Creation of policies/procedures to require sales reps to refer requests for off-label information to Medical Affairs
- Development and maintenance of inquiries databases to track and monitor HCP requests for off-label information and company responses
- Policies/procedures related to the manner and circumstances under which Medical Affairs personnel participate in meetings or events with HCPs (either alone or with Sales representatives or account executives) and the role of the Medical Affairs personnel at such meetings or events
- Representations that Sales and Marketing departments have no involvement in medical education grants or charitable contribution requests, and that all such grants requests will be processed in accordance with standardized criteria developed by Medical Affairs
- Requirements to develop annual publication plans and establish a publication monitoring program

Commercial and Medical Affairs

Industry Challenges

- Separation of Medical Affairs and Marketing
- Expanding areas for Medical Affairs with customers
  - Payers
  - IDNs
  - Professional Societies/Advocacy Organizations
  - Health Economic Outcomes Research
  - Observational Research
  - Investigator Initiated Studies

Commercial and Medical Affairs

What is the appropriate firewall between Medical Affairs and Commercial?

The changing healthcare environment has encouraged the formation of independent Medical Affairs departments

There is not a rigid set of requirements that dictate how a Medical Affairs department should look or operate

As a result, the industry has developed a wide variety of models, all seeking to address intensified public and regulatory scrutiny

Typical models:

1. Prohibit all communication between medical affairs and commercial
2. Allow open communication between medical affairs and commercial
3. Establish guardrails and protocols to allow compliant communication between medical affairs and commercial

Commercial and Medical Affairs Alignment

- Disease analysis and indication sequencing
- Initial commercial opportunity assessment and revenue target
- Product concept/TPP testing
- Initial access environment assessment

- Long range forecast
- Market positioning strategy and messaging
- Access planning (payer needs, by country)
- HEOR requirements
- Field resourcing (sales, clinical, scientific support)

- Competitive monitoring and response
- Marketing strategy evolution
- New indications, formulations, publications
- Pre/peri LOE planning
- Franchise/portfolio planning

Medical Affairs Functions (Examples)		
• Clinical Context/Expertise	• Medical Education	• Scientific Communications
• Investigator Management/IIS	• MSL Management	• Surveillance
• KOL Engagement and Relations	• Publications	• Trial Design and Demonstration

Commercial and Medical Affairs

Key Life Sciences Trends

- More aggressive and sophisticated access management
- Outcomes metrics being used more broadly (indications, payers)
- Provider integration and IT investment as enabler of HECON--and new payer audience
- Emergence of new decision-makers (e.g. hospital admin, hospitalists, patients/ advocacy, etc.)
- Increasingly patient centric (and longitudinal) approach to care delivery
- Increasing biopharma and medtech reliance on emerging markets

Medical Affairs Imperatives

- Address shift in definition of value and associated information requirements
- Engage new stakeholders and tailor content of communication accordingly
- Embrace “patient journey” approach
- Understand and harness new, digital media channels where appropriate
- Build expertise and structure organization in a way that addresses needs (region specific)

…execute in an increasingly rigorous and transparent regulatory environment

Q & A

Thank you for Participating in Today's Session