



# The Evolving Role of Medical Affairs: Going Digital

November 6, 2017

Mark Lange

Asst General Counsel

*Lilly*

# Context

Driving forces:

- HCP preferences
- Ability for enhanced communication
- (Relative) cost efficiency

Two illustrations:

- Medical Information
- Publications

# Medical Information: Med Info Websites

- Legal/regulatory context for Med Information: Responding to Unsolicited Requests for off-label information (RUR)
- Challenges: Making the website and content known and used and user-friendly while navigating RUR principles...
  - Unsolicited questions
  - Narrow and specific questions and answers
  - Limited to HCPs
- phactMI initiative

# Medical Information: Call Center Channels

- Introduction of text, chat, webconferencing options
- Challenges:
  - Privacy/telecomm laws (e.g., TCPA)
  - Questions and answers appropriate for the channel?
  - Retention for discovery/litigation
  - Monitoring?

# Medical Information: Dynamic Data and Demonstration Tools

- New ways to display or analyze data
  - Ex: videos showing 3D modeling of MOA
  - Ex: programs showing data graphically
- Challenges:
  - Appropriate review processes?
  - Appropriate response to narrow and specific question?
  - More sophisticated tools could drift beyond med info responses (e.g., clinical decision-making?)

# Publications: On-line Journal business models

Legal/regulatory context for publications: Scientific  
Exchange

Challenge:

- New business models and practices lessen prior clear distinctions from paid promotional content
  - Pub fees; enhanced fees for expedited publishing
  - Greater number of publications
  - Reduced rigor of peer review?

# Publications: Augmented Journal Content

Supplemental authors' video summaries or discussion

- Challenge: peer reviewed?

Supplemental supporting transparency materials (*e.g.*, protocols, study reports, data)

- Challenges:
  - commercial confidential information?
  - IP concerns related to public disclosure of raw data?

# Publications: Social Media Activity

- Discussions in social media about specific publications
  - By whom? (publisher; external author; company author; company; etc.)
  - Source of content?
  - Content of post?
  - Compensated/underwritten?
- Challenges:
  - What are limits of scientific exchange?
  - Whose speech?

*Lilly*