



# KEY TAKEAWAYS

## 16th Annual Pharmaceutical Compliance Congress (2019)

The presentations and conversations at **CBI's 16th Annual Pharmaceutical Compliance Congress** offered familiar messages and content along with robust discussion around new trends in policy development, enforcement efforts, and best practices. Here are some of our key takeaways from this year's conference.

### The Medical Affairs and Field Sales Relationship is Changing

- Move to principle-based culture requires collaboration between Medical Affairs and Field Sales
- Communication is needed for MSL and sales rep to work together in a compliant manner
- Include Medical Affairs, along with Legal, Regulatory, Marketing, and Sales when creating policies
- Medical Affairs risk areas include proactive discussion of off-label uses; lack of fair balance in benefits and risks; and discussion of real-world evidence and health economics and outcomes research

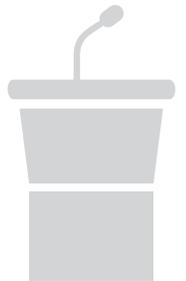


### The View from Former and Current Regulators

- Government is using data to help determine responsibility for opioid influx
- Some states are seeing issues with adverse events reporting
- Activity around PAPs and PSPs continues to grow
- New focus on public statements by company officers
- More guidance on PSPs is needed from HHS and DOJ
- Regulators are mining social media data

### Speaker Programs Risk is Real

- Documentation is key to a compliant speaker program: did the speaker do what he or she was contracted to do?
- Look for "frequent flyer" HCPs who repeatedly attend speaker programs
- HCPs speaking on behalf of the company must follow product promotion rules
- Must be a legitimate, documented need for speaker program



### Third-Party Risk is Prominent

- Tailor the training to vendors according to their conduct. "Scientists can't relate to field sales scenarios."
- Make time to travel to countries that present a higher risk and meet face-to-face
- Understand what people are using to communicate (text, IM, etc.) and have ground rules in place

### Social Media is Trending

- Promotion on social media is subject to the same requirements as traditional print promotion
- Ensure only authorized and trained employees are permitted to engage in social media on company's behalf
- Clearly identify boundaries on use of social media
- Conduct annual training on social media since platforms evolve and change



### PAPs and PSPs are Still an Issue

- Ensure everyone is aligned on definitions of the program
- Make sure field personnel are not speaking inappropriately about programs
- Monitor field interactions and monitor HUBs (listen in on calls, visit the HUB, monitor patients)
- Programs are a concern when they look like they could influence a clinical decision
- Problem occurs when programs make choosing a particular therapy easier
- Make sure the sales reps are using language to support the patient, not helping the HCP
- Support programs need to be "post prescription"