



# TOP TAKEAWAYS

CBI's 15th Annual Pharmaceutical Compliance Congress

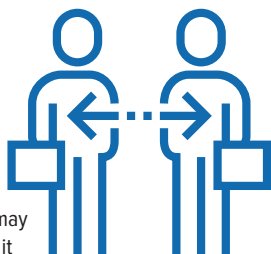
The **15th Annual Pharmaceutical Compliance Congress** featured industry leaders and government representatives espousing the usual best practices for building and maintaining an effective compliance program, but this year's agenda offered a few surprises and changes in the regulatory wind. Here is a list of our key takeaways from the conference.

## The Modern Compliance Program

- The government cares about how you document that you are preventing issues
- Ensure 3rd party vendors are applying your compliance standards to their work
- Use data to be smarter about how you monitor
- Can you quantify that your program is actually working?
- Review recent Corporate Integrity Agreements for government focus and where you can improve

## Partnering with the Business

- Compliance shouldn't be a goal, it should be a baseline objective that underlies the entire business
- Compliance must earn a "seat at the table," and be invited back
- Use simplified business language in compliance policies, instead of legalese
- Compliance should have their own branding within the business
- Spread the resource load by partnering with the business to accomplish compliance objectives
- Be candid about where your compliance program may have fallen short, and the steps you're taking to fix it



## Federal Promotion Enforcement

- Off-label emphasis has shifted away from larger companies to smaller, emerging companies
- Enforcement focus changed when companies argued that off-label marketing should be protected under the First Amendment
- Companies that market opioids are under intense scrutiny
- Less emphasis on standalone off-label promotion cases, but continued enforcement of False Claims Act and Anti-Kickback Statute cases
- Social media marketing must remain on-label, fair-balanced, and consistent
- Data is front and center in investigations



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## Patient Assistance Programs (PAPs) and Charities

- PAPs are a focus for enforcement agencies and pose a serious kickback risk
- Any coordination between a charity and a company showing that the company is trying to pay for its product being prescribed is a concern
- Collect and monitor compliance data regarding the company's relationship with PAPs
- Commercial must be removed from all involvement with donations to PAPs
- Companies must monitor their relationship and interactions with PAPs closely
- Companies need clear guidelines and talking points for sales representatives who interact with charities

## Updates to State Laws

- Continued emphasis on drug pricing transparency
- A new focus on aggregate spend laws, as well as licensing and reporting laws
- Maryland's drug pricing law recently declared unconstitutional
- Oregon law requires documentation to support your documents
- New Jersey governor considering major changes to law in 2018
- At least two new drug pricing laws are expected to be implemented in 2018
- Train the entire company on aggregate spend, not just the sales force

## Training to Reduce Risk and Strengthen the Compliance Culture

- Create and implement clear SOPs and guidelines for training
- Update training as existing social media platforms evolve, and new ones emerge
- Incorporate "ethical nudges" to promote compliant behavior and ethical decision making
- Use micro-training to support and reinforce ethical decision-making practices
- Create a positive and fun brand for compliance
- Don't just check the boxes on compliance training; build a robust, effective program
- Train the entire company on compliance, not just the sales force
- Build your training curriculum in line with your company's current growth stage

