TOP TAKEAWAYS

18th Annual Pharmaceutical and Medical Device Compliance Congress

The **18th Annual Pharmaceutical and Medical Device Compliance Congress** in Washington DC featured an array of government representatives and industry thought leaders who provided ideas and best practices for building and maintaining a modern and effective compliance program. Here's our key takeaways from two busy days of presentations:

The View from the Government

OIG and DOJ

- Patient Assistance Programs need to be conducted independently (do not share information)
- Failure to comply with Risk Evaluation and Mitigation Strategies (REMS) leads to off-label marketing
- When you don't have sufficient resources to address risks, you have a problem
- Don't measure effectiveness by number of people trained
- Measure what employees know before and after training
- Concerns raised repeatedly become problems over the course of years
- Compliance programs should be dynamic, evolving and responsive
- Make sure what's on paper is being internalized, operationalized, and pushed by key leaders
- Training must be early and constant and include documentation

FCPA Enforcement

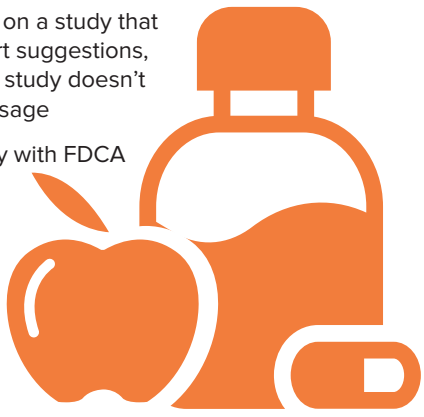
- International partners are cooperating more with the DOJ on FCPA enforcement
- DOJ doesn't investigate based on size of the company
- Tips and whistleblowers come in all shapes and sizes, including small companies
- DOJ considers if problem is emblematic of a larger corporate problem
- Everyone must understand how compliance fits into their roles
- Make compliance part of employee reviews and bonuses

The US Attorneys

- Trend toward more compliance and higher-level employees as relators
- Agencies are analyzing data sets to look for outliers
- Were HCPs top prescribers before they became top paid speakers?
- Be careful about incentive compensation plans
- Communicate the limits to vendors, in writing

The FDA

- Product communications that lack evidentiary support are likely to be false and cause harm
- If communication relies on a study that is inadequate to support suggestions, disclosing limitations of study doesn't correct misleading message
- Messaging must comply with FDCA
- Healthcare Economic Information must relate to an approved indication



The View from the Industry ▶

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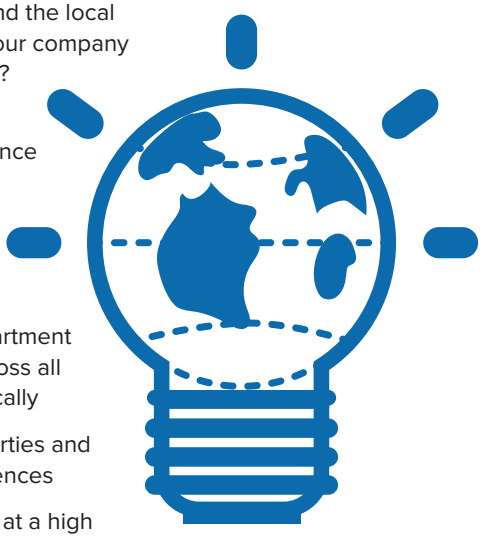
The View from the Industry

Strengthening the Compliance Program

- Compliance is not a checklist, one size does not fit all
- Look for specific risks related to the product
- Change the monitoring program to match changes in risk
- Are your decisions aligned with your values?
- Be motivated by what's in the patients' best interests
- Know how you're going to address issues before they exist
- Educate the businesses about the type of third parties that are of concern
- Plan for the local nuances related to transparency around the world
- Make sure everyone across the company feels connected
- What are the right resources for the right markets?
- Keep responsibility on the country level, with in-country management teams
- Look for patterns, focus on the data
- Board diversity improves decision making around risk
- Create an ethical checklist for decision making
- Give employees ability to say I made a mistake, help me fix it
- Ask questions to help business understand what they're trying to accomplish, propose solution to mitigate the risk

Think Globally

- Do you understand the local cultures where your company is doing business?
- Make difference between compliance and legal clear
- Law department advises on risks of programs
- Compliance department assesses risk across all programs, holistically
- Interview third parties and check their references
- Push policies out at a high level and explain the "why"
- Explain how the controls help the country and help them
- Get buy in from local leadership



pharmacertify
by NXLevel Solutions

Dan O'Connor
609.483.6875
doconnor@nxlevelsolutions.com
www.pharmacertify.com