

2019 Pharmaceutical and Medical Device Compliance Congress Key Takeaways



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Over 500 life science compliance professionals recently gathered in Washington, DC, for the 20th annual Pharmaceutical and Medical Device Compliance Congress organized by the Pharmaceutical Compliance Forum (PCF). The forum provided attendees the opportunity to reflect on how far the compliance profession has come over the past two decades, to discuss issues of continued focus, and to address emerging industry challenges head-on. The PCF Conference was a successful event that continues to drive the compliance profession forward through insightful sessions by key enforcement agencies, seasoned compliance professionals, and new faces to provide fresh perspectives.

The following key themes emerged throughout the conference sessions:

Importance of Company Culture:

- Multiple presenters and panelists emphasized the importance of establishing a “culture of compliance,” or rather a “culture of integrity,” to emphasize personal ownership and accountability.
- Several speakers enumerated the importance of quantifying compliance, as well as connecting awards and incentives to ethical behavior. For example, compliance professionals can encourage employees to outline annual compliance goals, and then assess those same employees on how successfully they accomplished these goals. Additionally, compliance professionals can partner with senior leadership to sponsor and promote well-publicized recognition for employees who display exemplary compliance behavior. By encouraging employees to hold themselves professionally accountable for ethical behavior, and rewarding compliance champions, compliance professionals can keep ethics engrained in day-to-day work across an organization.
- Measuring company culture is critical to understanding where gaps exist within an organization. Compliance professionals can assess these gaps via employee surveys, targeted focus groups, or more anecdotally via business interactions, including field rides with sales representatives and medical science liaisons.

- In addition to a company's "tone at the top," the "mood at the middle" is an equally important component of a true culture of compliance and can serve as a barometer for an organization's appetite and acceptance for overall corporate compliance.
- The U.S. Department of Justice (DOJ) has also stressed the importance of culture, as seen in its April 2019 guidance, "Evaluation of Corporate Compliance Programs." It states, "Beyond compliance structures, policies, and procedures, it is important for a company to create and foster a culture of ethics and compliance with the law. The effectiveness of a compliance program requires a high-level commitment by company leadership to implement a culture of compliance from the top." Furthermore, the guidance emphasizes that senior leadership and middle management should enforce the idea of "shared commitment," asking leaders and managers to evaluate their tone of compliance, particularly in the face of competing interests.

Importance of a Risk-Based Compliance Program:

- In her keynote presentation, Health and Human Services-Office of Inspector General Senior Counsel Mary Riordan emphasized the importance of a risk-based compliance program, talking specifically about seeking out new and evolving risk areas that may cut across multiple functions (e.g., supply chain).

- During the Assistant U.S. Attorney panel, Rachael Honig, first assistant U.S. attorney, U.S. Attorney's Office, District of New Jersey, reinforced the importance of "nimble" risk assessment and devoting resources to areas of highest risk. For example, "[i]f opioid manufacturers were focused on off-label instead of diversion" they missed an opportunity to manage risk.

Effective Communication to the Business:

- During discussions surrounding a culture of compliance, several speakers alluded to the fact that the "language of compliance" is only effective to people who are "fluent" in it. To that end, they recommended that compliance professionals be mindful to speak to business colleagues using language they are familiar with and understand.
- Leveraging the root-cause analysis phase of the compliance cycle also proved to be a common theme. Specifically, panelists and speakers encouraged compliance professionals to translate root-cause analyses into process changes.

"Be Bold" and the Importance of Innovation:

- Several speakers discussed the importance of incorporating and leveraging analytical tools and strategies to leverage available data to enhance compliance insights.
- Some panelists mentioned that one way to innovate is to simplify. For example, compliance professionals can consider adopting efficiency measures to reduce procedural time and effort, for example in monitoring activities and related to the number of processes.



- Compliance professionals were also encouraged to incorporate elements of behavioral psychology to understand what motivates people to bad actions, and to identify more effective ways to promote and incentivize integrity and good judgment.

Enforcement Focus:

- Throughout the conference, there was a continued emphasis on the opioid industry, from manufacturers to distributors to prescribers. The Office of Inspector General stressed that there were “an unusually large number of settlements” this year, and that this area continues to be a critical priority.
- Enforcement bodies continue to scrutinize patient support programs at all stages of the supply chain. Indeed, enforcement agencies noted that as more distributors and other stakeholders get involved in the provision of products to the end consumer, the opportunity for fraudulent activity increases. Panelists discussed a specific focus on fraudulent behavior surrounding prior authorization forms by both manufacturers and specialty pharmacies.
- Multiple presenters and panelists underscored the continued focus on manufacturers providing funding to charitable copay assistance foundations. During presentations, speakers and panelists specifically called out the 10 settlements in the past year around ostensibly independent copay support programs, including two settlements involving large charitable foundations.
- High-priced drugs are a continued discussion point in health policy, and enforcement agencies stated that high-priced drugs bring with them compliance concerns as well. High drug prices create greater risk because expensive products are harder to sell, and each prescription likely contributes more to a sales representative’s incentive compensation and ultimate revenue for the company. In this way, there can be heightened Health Insurance Portability and Accountability Act risk in that sales representatives may be tempted to inappropriately access patient information to advance a prescription.
- Drug prices have been growing exponentially in the United States, but what has been less clear is the extent to which certain prescription drugs are contributing to that trend because prices are clouded by a complicated rebate system. Accountability and transparency are essential to developing a better understanding of rising pharmacy costs.
- Another notable area of focus centers around price-fixing, which may include elaborate schemes to fix prices and allocate customers.
- The DOJ also heavily emphasized its new guidance from April 2019, and particularly noted the important role of whistleblowers in identifying compliance program gaps.
- On Sept. 12, 2019, the DOJ announced that federal prosecutors will assess whether compliance officers make adequate use of data analytics in their reviews of companies that are under investigation (i.e., ensuring that leadership has access to internal data for decision-making). The DOJ recognizes that data analytics expedites case development, saves resources, and makes enforcement more effective.



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