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CLIENT ALERT

Highlights from the 20th Annual Pharmaceutical Compliance Congress

The 20th Annual Pharmaceutical Compliance Congress (PCC) convened the week of April 24th in McLean, VA. This was a hybrid event that included over 300 in-person and virtual attendees including enforcement agencies, seasoned healthcare compliance professionals representing the Life Sciences industry, and the supporting community of compliance products and expert services. The three-day event included several informative plenary sessions, workshops, and subject-matter specific mini-summits. This Client Alert is part of a series from Epsilon Life Sciences highlighting key themes, takeaways, and reminders.

Some of the most noteworthy sessions at every PCC are the plenary sessions, where there are keynote speakers, updates from enforcement agencies, fireside chats, and other prominent presentations. Below are some key takeaways from this year's sessions.

Enforcement Updates

During the various panels and discussions, current and former representatives from enforcement agencies highlighted recent cases and areas of focus Compliance Departments should be paying particular attention to.

One of the new areas of focus noted by some of the enforcement representatives is related to electronic health records (EHR) and companies using relationships with EHR providers to drive improper relationships with healthcare professionals (HCPs). These relationships need to be reviewed carefully and the information shared through pop-up advertisements and other means within EHR systems need to be scrutinized by Compliance Departments.

The topic of voluntary self-disclosure was also one that was discussed at length with both current and former enforcement representatives. Panelists emphasized that voluntary disclosure is not an admission of guilt; the main goal of government is to get an understanding of what is going on within the company. When contemplating the fines in a settlement, there are a few factors regarding voluntary disclosure that were noted across the agencies:

- Was there voluntary disclosure?
- Is the company conducting an investigation and uncovering facts?
- Are they acting upon what they find?

It was highlighted that if a company wants the benefit of voluntary disclosure, the disclosure must be made before it is determined that a government investigation is imminent.

In addition, a repeating topic for many recent years has been Speaker Programs. These programs are still squarely in focus by the government, as enforcement agencies still have a great deal of skepticism around the educational value these programs provide. Enforcement panelists mentioned a particular interest in needs assessments as they relate to Speaker Programs, as well as consulting arrangements, following the observations around these activities evidenced in the Biogen settlement.

A final key takeaway from the government enforcement panel is that the agencies are working more collaboratively than ever, with a greater number of resources and more accessible data to recognize key patterns.

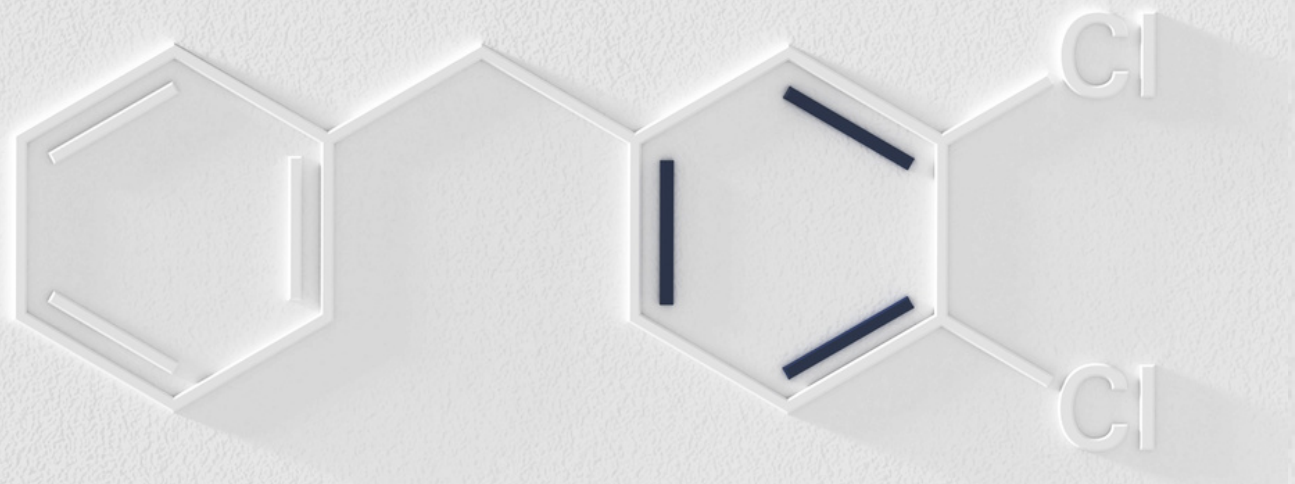
As regulators have enhanced their ability to access and analyze data, the expectation is that companies are one step ahead in understanding their own data and the story that it tells.

Evolving Risk Areas

As we have seen our industry evolve, the risk landscape evolves with it. Artificial Intelligence (AI) and the risks associated with this technology was a theme that weaved throughout PCC. AI was discussed at length during the Chief Compliance Officer plenary panel, and there were varied opinions on how companies are allowing their teams to use AI programs like ChatGPT. It was noted that these programs and the technology is still new and evolving and compliance departments play a role in educating their business partners on what AI is good for and what it is not. Specifically, it was noted that this technology is illegal in certain global markets and does not keep company information confidential. Essentially, once you feed information into these programs, you cannot get it back. There is also a risk of bias, as it is unclear if the outputs are being skewed based on bias in the inputs.

Many sessions covered additional evolving risk areas to consider, such as:

- Role of medical affairs – Are they being used in a promotional manner or to do things commercial cannot do?
- Other Field Roles – What exactly are the emerging roles in the field and related responsibilities (i.e. Thought Leader Liaison, Key Account Leaders, Access Liaison)? Are lines being blurred?
- Rethinking Compliance – How is compliance demonstrating its value to the organization? Is your compliance program moving at the speed of your business?
- Mergers & Acquisitions – Is compliance involved pre-acquisition? Does it appear that commercial objectives of the target can be executed in a compliant manner?
- Internal Incentives – How are you providing incentives for examples of good compliance across various roles in your organization?
- Clinical Trial Fraud – Do you have processes in place to detect potential irregularities in clinical trials?
- Covid Fraud – Were any of the government-funded relief programs used in an inappropriate manner?



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