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CLIENT ALERT

Highlights from The Pharmaceutical Compliance Forum's 23rd Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

The 23rd Annual Pharmaceutical and Medical Device Ethics and Compliance Congress (PCF) convened the week of October 24, 2022. The over 500 in-person and virtual attendees included healthcare compliance luminaries representing industry, enforcement agencies, and the supporting community of compliance products and expert services. The packed agenda included several thought-provoking Workshops, Plenary Sessions, and Mini-Summits with a variety of speakers and panelists. 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 PCF 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.

ESG

Early Monday morning, a packed room listened and discussed the role of the Chief Compliance Officer in Environmental, Social, and Governance (ESG) initiatives of their Companies. The hottest ESG topics were highlighted including supply chain, human rights, Diversity/Equality/Inclusion (DEI), greenhouse gas emissions and corporate governance. Within Life Sciences, access to affordable medicine and healthcare, developing lifesaving vaccines, and broader transparency into clinical trials were identified as potential ESG priorities.

Through informal polling, the audience shared how the ESG function reports into Legal or Compliance and may have a direct line into the executive committee and Board of Directors. Overcoming the cost of ESG argument will continue to be a challenge. Recommendations included designing a program around a company's most obvious impacts, and to consider an ESG-focused risk assessment.

Polling also suggested that having a better public perception for doing the right thing, meeting regulatory requirements, and demonstrating ethical business conduct could ultimately lead to higher valuations.

For more insights on ESG and the role of the Chief Compliance Officer, look out for our upcoming Client Alert covering **An Overview of ESG and the role of Ethics and Compliance.**

What are effective compliance programs?

Representatives of enforcement agencies reminded the audience that they understand no program is perfect. They explained their efforts to increase their understanding of what it is like to be a compliance officer and to help them better appreciate what is realistic. While there was understanding that each compliance program should be tailored to address the risks and circumstances of their specific organization, speakers encouraged organizations to use the lens of the three basic questions raised by the DOJ's Evaluation of Corporate Compliance Programs guidance:

1. "Is the corporation's compliance program well designed?"
2. "Is the program being applied earnestly and in good faith?" In other words, is the program adequately resourced and empowered to function effectively?
3. "Does the corporation's compliance program work" in practice?

A well-designed program is based around risk, which should be continuously assessed as risk changes over time. Along those lines, a compliance program must be designed to continuously evolve with the business. A well-designed program builds a culture of compliance that not only mitigates risk and learns of misconduct but also influences positive behavior.

For more insights on inspiring ethical and compliant behavior see our upcoming Client Alert on **Behavioral Compliance**.

An adequately resourced program is one that aligns its resources to the risks the company has identified – including the number of resources and how those resources are used. As Compliance Departments' remits are expanding to include other assurance functions, such as Privacy and ESG responsibilities, this reminder is particularly important. There are a myriad of responsibilities falling under the Privacy and ESG umbrellas that are important for our industry to tackle, but in most circumstances your organization cannot cover them all immediately. This is in part due to the consistently evolving landscape of state laws emerging in the Privacy arena, as well as the continued attempts to create a common reporting standard as it relates to ESG. Therefore, companies should identify priority areas and focus on attainable and measurable actions within those pre-determined areas. Look out for our upcoming Client Alert: **An Overview of ESG and the role of Ethics and Compliance.**

A program working in practice demonstrates continuous improvement through periodic testing and review. Developing a "culture of compliance" supports an effective compliance program by guiding individuals' actions, empowering people to speak up, listening to those questions or concerns, and providing meaningful responses and/or corrective actions. A culture of compliance is influenced through the organization, from "tone in/from the middle," to "tone at/from the top," permeating from the tone established by the Board of Directors.

For more insights on Board of Director engagement in the Compliance program, look out for our upcoming Client Alert: **Getting the Board Onboard.**

Enforcement Updates

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

Based on enforcement actions described by speakers, there appeared to be close scrutiny of discount arrangements. In June 2022, AdvaMed made updates to their code to address value-based care arrangements and the recent updates to the Anti-Kickback Statute (AKS) value-based safe harbor rules. The AdvaMed Code notes that even if a certain arrangement is not eligible for protection under the value-based safe harbor, the arrangement does not then automatically violate the anti-kickback statute. An arrangement that does not fit in a safe harbor should be reviewed for compliance with the AKS based on the totality of facts and circumstances, including the parties' intent[1].

Additionally, enforcement agency representatives emphasized that what may be considered a transfer of value by the government is broad in scope.

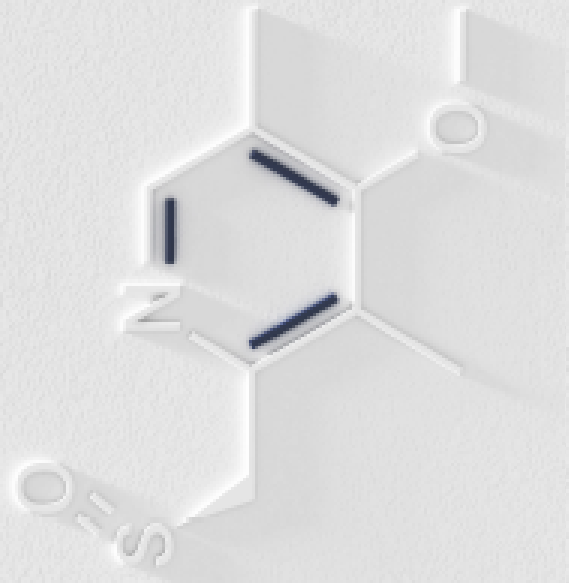
In addition, enforcement agency representatives emphasized that what is considered a transfer of value by the government is broad in scope. Some examples shared included royalties, data, interest free loans, payments for services, lavish meals, travel, holiday parties, and winery tours.

Government representatives also emphasized their growing use of data in numerous ways, including to:

1. Develop new cases;
2. Corroborate cases; and
3. Find others conducting similar activity as seen in an existing case.

Government representatives stressed that while they understand an outlier in the data does not always equate to wrongdoing, it does help them find where to look deeper. Furthermore, enforcement agencies expect compliance programs to utilize the data they have within their organization.

This starts with identifying and collecting the data your organization collects from a myriad of sources, and then configuring the data to effectively utilize it to mitigate compliance risk[2].



1 Epsilon Life Sciences maintains a checklist for organizations to consider when entering into these arrangements. Advice from outside counsel might also be sought.

2 Epsilon Life Sciences regularly helps organizations build and maintain data inventories which document and map the various assets, processes, and third parties which process organizational data using a technology-enabled approach.

Individual Accountability

In addition to the above, representatives from enforcement agencies repeatedly provided messaging that was consistent with the Lisa O. Monaco Memo and her recent update to this memo, emphasizing the DOJ's focus on individual accountability for actions and inactions. Individuals are being held accountable for their own personal wrongdoing, and for turning a blind eye or covering up someone else's wrongdoing.

As part of the focus on individuals, representatives reminded the audience that in order to receive cooperation credit in any resolution, companies must reveal all individuals involved, not just those who were substantially involved in wrongdoing.

The DOJ also provided clarification regarding their intent with the requirement for both the Chief Executive Officer and Chief Compliance Officer (CCO) to certify to the effectiveness of the Compliance Program and the Company's adherence to Federal Healthcare Laws in recent resolutions. This was a loud message to the Company and Board that the CCO is viewed as a Responsible Corporate Officer. This requirement for attestation should further reinforce the role of the CCO and empower the CCO within their organizations.

Evolving Risk Areas

Finally, as we have seen our industry evolve, the risk landscape evolves with it. Many sessions covered evolving risk areas to consider, including:

- **Medicaid drug rebate program** – How is your organization ensuring compliance with this program?
- **Role of medical affairs** – Are they being used in a promotional manner or to do things commercial cannot do?
- **Cybersecurity** – Is your organization complying with the new laws? Are you accurately representing your controls and practices? Do you have processes in place that have been tested when needing to disclose a breach in a timely manner?
- **Patient assistant programs** – How are you ensuring independence?
- **Engagement of patients** (e.g., patient ambassadors) – What are your controls in place to ensure these engagements are appropriate?
- **Internal incentives** – How are you incentivizing good compliance for various roles in your organization?
- **Covid Fraud** – Was any of the government funded relief programs used in an inappropriate manner?

While evolving risks impact our entire industry, the rapid evolution of technology has presented a myriad of privacy and cybersecurity risk for the Medical Device industry. Not only are there greater levels of patient and provider interaction, but some of the devices being developed are dependent and include technology that generates, stores, and informs clinical decision support through a host of patient data.

For more insights on risks related to medical devices companies see our upcoming Client Alert on **New and Emerging Risks for Medical Device Manufacturers**.

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