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CLIENT ALERT

Top Ten Takeaways from the 2024 Pharmaceutical Compliance Congress

Epsilon Life Sciences had the opportunity to attend the Annual Pharmaceutical Compliance Congress (PCC) the week of April 15th, 2024. The compliance landscape continues to evolve for the industry, and the caliber of content is reflected by that. The role of the Chief Compliance Officer, the impact of technology such as Artificial Intelligence and social media, evolving and creative enforcement, and the role of "carrots," were a number of the topics covered by an excellent series of panels. Continue reading below for our "Top Ten" takeaways:

1. Enforcement agencies continue to "follow the money," and are uncovering new theories about what constitutes an inappropriate financial incentive.

While familiar kickback issues are of interest to the government (high consulting fees, nice meals, etc.), some recent items were discussed by several panels, such as:

- The recent Regeneron case, where the company's coverage of credit card processing fees is at issue.[1]
- The recent Ultragenyx settlement, where the company's coverage of free genetic testing for patients was at issue.[2]
- Evolving views on acceptable patient support donations; for example, a recent "favorable" opinion for a non-profit organization focused on rare diseases that's funded by manufacturers.[3]
- Examples where companies pay for data or other services from customers, but don't actually use the data or services (like medical adherence data).

2. PCC attendees view Compliance department boundaries as the most pressing topic for their organization – what does Compliance own, where should business stakeholders come in, etc.

- There were a lot of discussions across various sessions on the role of Compliance and the need to define where it begins and ends. For example, is Privacy part of Compliance? What about Government Pricing? What about oversight across other control functions?
- The difficulty of scope and responsibilities for Compliance becomes even more challenging in smaller organizations, where the Chief Compliance Officer (CCO) may wear several hats as it relates to support of the business.
- In a poll of the attendees, respondents stated that Compliance at their organization had oversight over certain departments such as Privacy, Commercial Ops., Clinical, and Medical, but NOT the entire organization.

3. Generative Artificial Intelligence (AI) is a hot topic with many unknowns – companies should begin structuring governance and policies around its use.

- Generative AI is moving fast and ever evolving – the use, application, and implications are constantly changing, and organizations are grappling with how best to regulate this. In a poll of attendees, almost 80% of respondents stated they felt either not prepared or only somewhat prepared to govern AI at their organizations
- Compliance Officers are well-positioned to take on the governance over Generative AI at their organizations, as they are well-versed in control frameworks and can bring the right partners to the table for technical expertise. As a first step, public generative AI platforms (e.g., ChatGPT) are already commonly used by individuals at your organization. Do you have a policy on the use of Generative AI?

- While no one knows yet what the "one" issue will be from an enforcement perspective, the White House Executive Order[4] is a good place for companies to start referencing when building control frameworks.

4. The Enforcement Panel expressed clear preference for an independent Compliance department (not reporting to Legal or Finance), but acknowledged that each organization is unique.

- Following up on last year's OIG General Compliance Program Guidance[5], the conference's "Enforcement Panel" of government prosecutors discussed the importance of the Compliance department having the stature and resourcing commensurate with any other executive team member/ department.
- While it's "not a deal-breaker" if Compliance is affiliated with a business unit, there needs to be accountability for the Compliance department that isn't business-driven, and resources need to be allocated to support the function.

5. "Off-Label" enforcement is dwindling, but the government is focused on false statements and misrepresentations about products, especially when patient harm is at issue.

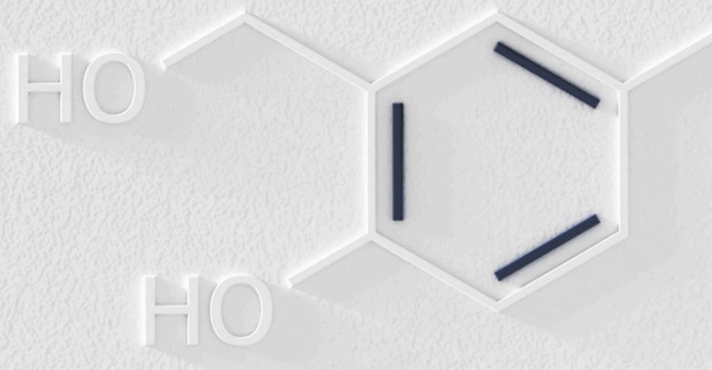
- Recent enforcement activity from FDA's Office of Prescription Drug Promotion (OPDP)[6] and the UK's Prescription Medicines Code of Practice Authority (PMCPA)[7] make clear that live and virtual communications are in scope for scrutiny, as well as communications directed both at HCP and patient/ consumer audiences.
- Additionally, the government remains on the lookout for companies aiming to use allegedly non-promotional activities – like medical information responses, journal reprints, advisory boards, etc. – as opportunities to make promotional claims about unapproved drugs or additional indications.
- Companies should "make sure materials are thoroughly vetted and supported by medical literature."

6. The Department of Justice (DOJ) emphasizes the importance of "carrots" in a company's incentive programs as evidence of good culture, but doesn't offer many specific examples.

- Representatives from the DOJ (currently employed and recently employed at the agency) emphasized the importance of adding Compliance to the performance management process in a structured way.
- Compliance incentive programs are often a challenge to define to promote behavior that some argue is already expected. However, conference attendees shared examples of rewarding employees who take proactive steps to avoid compliance issues and creating goals at a business unit level related to Compliance.

7. The majority of companies at the conference regularly monitor employee use of social media, and regulators do to.

- PCC attendees agreed that governance and oversight of social media continues to be a challenge with an ever-increasing array of platforms; however, monitoring social media activity is no longer a "nice to have."
- Social media posts, employee comments/ reactions, or other activities that could be construed as making inappropriate product claims are high priorities for oversight agencies and have been regularly enforced (for example, by the PMCPA).[8]



8. Enforcement agencies increasingly see access to company data as a "fundamental" requirement for Compliance departments to carry out their jobs.

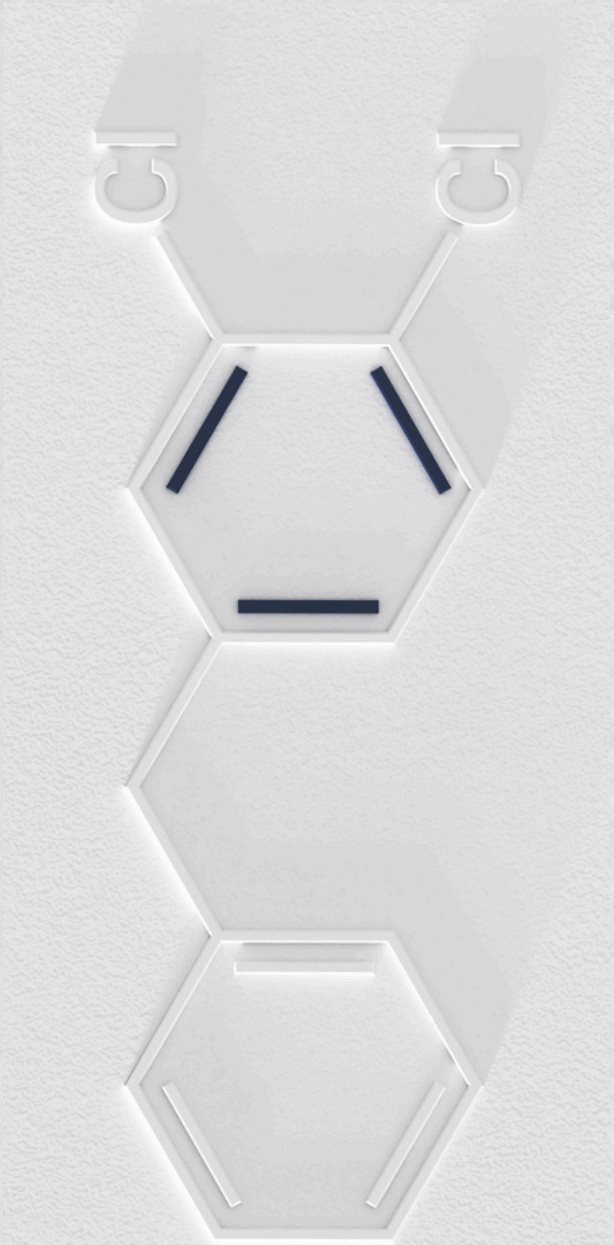
> DOJ representatives noted that they look for gaps in a Compliance department's access to data throughout the organization in assessing the effectiveness of the compliance program.

9. Attendees discussed increasing expectations for Compliance departments to "do more with less."

> Forming good business partner relationships, outsourcing certain workstreams, leveraging technology and tools where available to automate processes, and setting clear boundaries on the Compliance role were examples of ways to maximize limited resources.

10. The government continues to stress that timely voluntary disclosure will earn "bonus points" and introduces pilot program on voluntary self-disclosure for individuals.

> The week of the conference (on April 15), the DOJ announced a new "pilot" program on voluntary self-disclosure by individuals, which offers the prospect of a Non-Prosecution Agreement (NPA) to individuals that bring the DOJ "actionable, original information about criminal conduct that might otherwise go undetected or be impossible to prove."[9]



1. https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-regeneron-pharmaceuticals-alleging-fraudulent-drug
2. https://www.justice.gov/usao-ma/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce
3. https://oig.hhs.gov/documents/advisory-opinions/9864/AO-24-02.pdf
4. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/
5. https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf
6. https://www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/untitled-letters
7. https://www.pmcpa.org.uk/cases/completed-cases/#?cludoquery=*&cludosort=Case_CompletedDate_date%3Ddesc&cludopage=1&cludoinputtype=standard
8. https://www.pmcpa.org.uk/media/x2pbqzy1/pmcpa-social-media-guidance-2023.pdf
9. https://www.justice.gov/criminal/media/1347991/dl?inline

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