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CLIENT ALERT

# Highlights from the Pharmaceutical Compliance Forum's 24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

The 24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress (PCF) convened in Washington, DC, the week of October 23, 2023. The 500+ in-person and virtual attendees included healthcare compliance experts 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. In addition, Epsilon Life Sciences had nine representatives at the conference, three of whom spoke during the mini-summits on topics including Market Access, Insights from Medical Device CIAs, Privacy and Online Tracking Litigation. This Client Alert will highlight key messages from enforcement agencies, accentuated risk areas discussed, considerations for the evolution of compliance programs, and an overview of new and forthcoming guidance documents from government agencies.

## Government Aims and Emphasis

Whether on the main stage or during breakouts, representatives from various enforcement agencies took advantage of the opportunity to speak to conference attendees in order to emphasize certain areas of focus.

## Patient Safety Focus

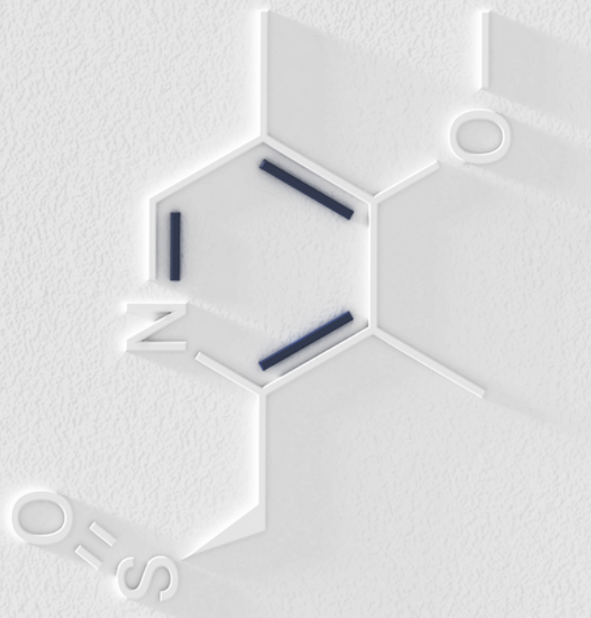
A reoccurring theme and important reminder throughout the conference was that the end goal of compliance related regulations, laws, policies, etc. is to help patients and ensure patient safety. Whether it is requirements for adverse event reporting, limiting instances of fraud and abuse, ensuring products adhere to the FDA's approval process, the prohibition of false claims, etc., the purpose is the same: the government is striving to ensure patient safety and hopefully better patient outcomes. Positioning of compliance risks and associated controls at your organization should highlight the ultimate rationale and purpose of laws, policies, and company controls as they relate to patient safety and patient outcomes.

Does your business understand the "why"?

## 4 OIG Principles

Representatives of the Office of Inspector General (OIG), emphasized their focus on 4 fundamental principles:

1. Encouraging self-disclosure;
2. Leveling the playing field so those who adhere to the rules are not put at a disadvantage;
3. Holding entities and individuals accountable to protect patients; and
4. Building strong compliance programs for the future.



## Individual Accountability

Enforcement agencies reinforced their focus on holding individuals accountable for bad or illegal behavior, including those who failed to prevent, or may have enabled or participated in the illegal behavior. Accountability may include clawbacks from those who participated in bad behavior, but also can extend beyond that to a broader picture of accountability for compliance and actions throughout the business. OIG representatives suggested that implementing regular compliance certifications can help broaden the ownership and accountability of compliance throughout an organization. Furthermore, developing and recognizing additional roles such as compliance champions can further the accountability for compliance throughout an organization.

Is compliance accountability and ownership purely within the compliance function or has the whole business taken this on? How are you increasing accountability across the business?

> "Transition Plan. Prior to the end of the fourth Reporting Period, Lincare shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's (Corporate Integrety Agreement's) term. A copy of Lincare's approved Transition Plan shall be included in Lincare's fourth Annual Report." – 2023 CIA with Lincare Inc.

## Self Disclosure

While the idea of self-disclosure is a challenging one for the industry, enforcement agencies are continuing to encourage self-disclosure and cooperation by the industry when there is suspected wrongdoing.

Enforcement agencies at this conference and at several speaking opportunities this year have emphasized the benefits for companies, including the potential for up to 50% off of the low end of sentencing guidelines fines. Furthermore, they clarified that there could be benefits even if a company were to come forward late, as later would be better than never.

## Influencing Behaviors

The notion of "carrots" (or positive reinforcement) and "sticks" (or reinforcement through discipline/ punishment) to motivate compliant behavior continues to be an important topic in developing modern effective compliance programs. There were sessions at the conference on utilizing psychology and behavioral economics in compliance programs – for example, harnessing the idea that a real or potential loss is perceived as more severe than an equivalent gain.

How are you influencing behaviors?

## Government Hints

Representatives of enforcement agencies reminded the conference attendees to pay attention to documents coming from their agencies, such as Advisory Opinions, Fraud Alerts, CIAs, and other settlements, as well as Guidance Documents. Both the Food and Drug Administration (FDA) and the OIG have been recently active in the development and updating of various guidance documents that will be very important for the industry to monitor and implement. The last section of this Alert outlines a few of these recent or forthcoming guidance documents that were highlighted at the conference.

How are you staying up to date with these documents and how do you plan to implement updates to your compliance program?

## Post CIA Planning

Recent CIAs have included transition planning, asking what companies will do after the CIA ends. This is a re-emphasis on sustainability of a compliance program and a reminder that one purpose of a CIA is to help build an effective compliance program that is sustainable and continues beyond the term of the agreement.

How are you ensuring your program continues to evolve, and be effective long-term?

## Clawbacks

The Department of Justice (DOJ) continued its awareness campaign on compensation incentives and clawbacks[1]. Representatives of the DOJ described the intent of the program is to discourage recidivism, shift the burden to those more directly responsible for the alleged behavior, and to better align executive compensation with the corporate compliance function.

Do you have procedures in place for managing clawbacks?

## M&A Safe Harbor

The "new safe harbor policy for voluntary self-disclosures made in connection with mergers and acquisitions" was reinforced as a mechanism designed to empower companies with effective compliance programs to continue with M&A activity when acquiring another entity with compliance concerns[2].

What due diligence are you conducting prior to a merger? Are you conducting compliance assessments after a merger?

## Messaging Monitoring

Another popular discussion topic was what companies are doing to control and monitor messaging apps, including ephemeral messaging platforms*. While recognizing the challenges in enforcing policies related to monitoring messages, enforcement agencies underscored the importance of knowing what data is out there and making a good-faith effort to implement controls.

What controls do you have related to messaging?

## CMS Audits of Open Payments

As the first round of Centers for Medicare & Medicaid Services (CMS) Open Payments audits are currently underway, the topic was top of mind for many attendees. Enforcement agencies expressed a continued interest in using Open Payments data to look for potential kickback concerns. While CMS audits are the latest way an organization's data may be audited, companies should already have in place data management, system controls, and third-party oversight to ensure their data is accurately reported.

How prepared are you for a potential CMS Audit?


1. The Criminal Division's Pilot Program Regarding Compensation Incentives and Clawback from March 2023
2. M&A Safe Harbor

* Communication platforms that automatically erase a conversation between parties immediately or after a short amount of time

## Key Risk Areas

Conference sessions and lunchtime discussions focused on risks – old and new – that were top of mind for Compliance departments. Next is a short synopsis of the discourse about some of these key risk areas at the conference this year.

## Medical Affairs

Medical Affairs, which was once considered mainly a reactive organization, is becoming a strategic partner in many organizations, conducting more proactive and customer-facing activities. As the methods by which Medical Affairs are sharing their insights with external stakeholders have evolved, the core role of Medical Affairs providing scientific and medical expertise remains the same. Therefore, the organization must find a way to bring a consistent message to customers while ensuring there is a clear divide between the promotional and medical functions. These changes have brought upon adjusted risk profiles for many companies.

To manage these risks, companies should consider ensuring there is:

> A clear understanding of what is considered scientific exchange;
> Appropriate review committee oversight over external communications;
> Clear guidance on interactions between medical and commercial personnel (both internally and externally with HCPs and the healthcare community); and
> Related compliance controls in place.

Have Medical Affairs' activities at your company changed over time? If so, are there clear guidelines and understanding of the different roles and responsibilities? How are these employees compensated?

Please see our recent client alert about Medical Affairs: A Reminder on Compliance Considerations in Medical Affairs.

## Market Access

Market Access is another area that routinely evolves to address payor needs and the increasingly complex reimbursement space. Some topics that were discussed were:

> Clarification of field roles and responsibilities in interactions with payors and other population-based decision-makers;
> Mechanisms for alternative funding (e.g., copay maximizers);
> Interactions with specialty pharmacies;
> Pre-approval interactions with payors; and
> Considerations in the Rare Disease space.

## Patient Interactions

While the enforcement agencies emphasized how their laws, regulations and guidances are centered around protecting patients, they also expressed concern for inappropriate influence on patients stemming from increased interactions and economic support from the industry. When your organization is interacting with patients, it could be worth considering:

> Who is interacting with patients or patient organizations?
> What are they doing?
> What is the business rationale?

What controls do you have in place to ensure appropriate interactions with patients and patient organizations?

## Social Media

Social media can provide great outreach opportunities for an organization, but that comes with a variety of risks. To address these evolving risks, you should be asking:

> What is your company posting on social media?
> What do you need to monitor (content you develop, or all the content related to your company on social media)?
> Are companies using influencers?

- How do you determine fair market value (FMV) for influencers?
- What are employees permitted to do on social media?
- How do you ensure all information on social media is appropriate (e.g., is the communication truthful; is it balanced)?
- Is social media use compliant with privacy laws and recent regulator guidance from the Federal Trade Commission (FTC) and U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR)?

## Artificial Intelligence (AI)

AI is a hot topic (not only to Compliance departments, but in all aspects of business, healthcare, and day-to-day communication). AI could be used to automate manual processes, create or review and revise materials, and many other potential uses we are just beginning to understand.

As discussed throughout the conference, Compliance departments should consider the ways in which their organization may be using or intending to use AI and what controls may be needed to mitigate the risks that come with it.

> "Artificial Intelligence (AI) holds extraordinary potential for both promise and peril. Responsible AI use has the potential to help solve urgent challenges while making out world more prosperous, productive, innovative, and secure. At the same time, irresponsible use could exacerbate societal harms such as fraud, discrimination, bias, and disinformation; displace and disempower workers; stifle competition; and pose risks to national security. Harnessing AI for good and realizing its myriad benefits requires mitigating its substantial risks." – Executive order issued by President Biden

Do you know where your Company is using or planning to use AI? Do you have controls or a framework in place to safeguard legal and business-related risks, such as the inadvertent disclosure of intellectual property? What steps are you taking to remove bias?

## Kickbacks

New risks and activities may be emerging, but that does not mean the "old" ones went away. What may change is how companies, providers, and others in the supply chain are utilizing financial incentives to drive business. Enforcement agencies stated they continue to be concerned about the "corrupting influence of money" stemming from kickbacks and other forms of illegal renumeration.

What controls do you have to reduce the risk of actual or perceived inappropriate influence?

## Manufacturer PAPs

In particular, enforcement agencies expressed interest related to manufacturer patient assistance programs (PAPs), specifically:

- What are you doing?
- Who are you helping?
- What kind of vendor oversight do you have?

## Independent PAPs

Enforcement agencies also communicated concern regarding whether guidances aimed at appropriate independent PAP interactions are being followed. Specifically, questions were raised related to the independence between donors and foundations and the government's focus on ensuring foundations are not used as inappropriate conduits to drive prescriptions.

If you are donating to independent PAPs, how are you ensuring independence?

## Data Protection and Online Privacy

As companies become more innovative in their interactions with HCPs and patients (e.g., technology on websites and mobile apps) new risks have emerged as high enforcement priorities. For example, cookies, pixels, and data harvesting and reselling are raising privacy and protected health information concerns.

How well does your team understand the technology? Do you understand the risks associated with the technology?

## Private Equity

Enforcement agencies expressed concern about the growing prominence of private equity in the industry as they were not sure what impact such ownership could have on healthcare. Specifically, concerns about ownership incentives and return on investment strategies were mentioned. This is not only in the healthcare provider environment where consolidation and cost-cutting has been seen already, but also in the life sciences industry, particularly with service providers that provide critical support to the industry, such as contract research organizations and contract manufacturing organizations.

Does your due diligence detect Private Equity ownership interests?

## Evolution of Compliance Programs

The future of the industry and how people think compliance programs will and should evolve were also popular topics. Below are some brief notes around the discussions related to the evolution of compliance programs.

## Design

Compliance programs will evolve; they must keep up with developing risks. However, the basic tenants that an effective compliance program should detect, prevent, and correct wrongdoing will always remain. While not discussed in this context specifically, business partnership was frequently mentioned in relation to how a program should function.

Furthermore, the DOJ's 3 fundamental questions continue to be the standard to evaluate compliance program effectiveness:

1. Is a program well designed?
2. Is the program adequately resourced and empowered to succeed?
3. Does the program work in practice?

## Prominence of the Compliance Function

Enforcement agencies have taken actions to reinforce the importance of compliance programs within organizations, including through CCO certifications. Enforcement agencies underlined the importance of compliance programs having eminence within companies. This included:

> The Responsible Corporate Officer role of CCOs, essentially imposing strict liability upon individuals for misdemeanor violations of the Federal Food, Drug, and Cosmetic Act
> The importance of minimizing Compliance officer distractions with non-compliance matters;
> An increase in authority given to Compliance Officers (e.g., senior management roles); and
> Advocating for compliance to have a meaningful seat at the table (compliance as a part of initiatives and business strategy).

Enforcement agencies even mentioned that if a Compliance Officer ever felt brushed aside by leadership, they should consider their other options, such as being a whistleblower.

Other presenters stressed how just a seat at the table is not enough. They delineated the difference between just being in the room and being a partner and resource.

What is the eminence of your compliance program?

## Data Analytics

Besides being a topic in many sessions, enforcement agencies took the opportunity to emphasize the importance of analyzing your own data. They reiterated that they believe it is fair for them to see if companies are using data readily available, but they will not dictate how this should be done as what is appropriate will vary from company to company. Below are a few of the many important questions you should be considering in relation to data analytics:

> What data do you have and what data is relevant for analyzing potential compliance risks?
> What teams are responsible for managing the data and what is your relationship with those teams?
> What data can and should you collect?
> What are potential flags and what are you doing once you determine information has raised a flag?
> How have you managed privacy and security obligations?

What are your analytic capabilities?

## Behavioral Compliance

Theories and tools from behavioral economics can be used to influence behavior in your organizations. As mentioned earlier, enforcement agencies are expecting compliance programs to influence behaviors.

This topic was the focus of main stage session, as well as a mini summit that highlighted among other behavioral compliance topic various theories (e.g., framing, anchoring, time preferences, loss aversion, etc.) and tools (e.g., incentives and rewards, nudging, default options, feedback, social norms, etc.).

Have you started to utilize behavioral economics? How are you incorporating theories of behavioral compliance? What behavioral compliance tools are you using?

## Scope of Your Remit

Multiple sessions covered how presenters felt that compliance programs need to expand beyond traditional healthcare compliance to include oversight of risk across the business. Some of the presenters clarified that they did not see increased oversight as "owning everything" but taking a more holistic risk-based approach.

What is the scope of your remit and does it make sense for your particular organization?

## Skills/ Capabilities

As compliance programs grow to meet the needs of the ever-evolving life sciences industry, Compliance departments need to expand their skills, capabilities, and knowledge sets. While trainings and other certifications is one way to achieve this, speakers also mentioned how there may be a need to diversify Compliance departments with new hires who have expertise in areas such as:

> Data analytics
> Technology
> Privacy
> Adult learning
> Auditing
> Communications

How can you expand your teams or your own skills, capabilities, and knowledge sets?

## Business Partnership

Multiple sessions covered how compliance programs need to continue to evolve from the "police officer" to valued business partners. This evolution can allow for the eminence of the compliance program within the organization and transform the culture to one where operating compliantly is second nature to the business.

Trainings provide a great opportunity for business partnerships. The inclusion of hypothetical situations based on real-life examples shared by the business was mentioned as a positive example of partnership through training. Incorporating such scenarios into training provides an opportunity to not only be a business partner in working through how to operate, but can also be an effective training method in and of itself.

Has your compliance program evolved from being the "bad cop?" Do you strive to be an effective business partner?

## Speed of Business

Sessions covered the need for compliance programs to work at the speed of business. How can your program be more efficient without losing effectiveness?

The hope is a program working at the speed of business will be more effective as it will likely be more integrated into how the organization works.

Working at the speed of business is not just about making fast decisions; it is about becoming part of the team and working to the cadence of the business calendar. To become part of the team, Compliance Officers are well-served to understand the core business, provide expertise in a language the business understands, and always be open to feedback.

Is your compliance program working at the speed of business?

## Reduce Bureaucracy

While some level of bureaucracy (e.g., implementing controls, written standards, trainings) is necessary, compliance programs have the opportunity to embed controls seamlessly into the ways people work. Do your written standards help people with their work or are they only looked at when it is required? Do trainings have to be as long as they are? Do all trainings need to be done within a limited time? Do all trainings need to actually be done? Or, can training be more engaging and broken up throughout the year? Can trainees test out of training?

Embedding controls into processes can be complex and difficult, especially when there are clunky old systems. However, being involved in overhauling systems or developing systems can provide positive wins for compliance programs with members of the business.

How can your compliance program help reduce bureaucracy?

## Culture

The plenary sessions included fireside chats with a CEO and CCO who both emphasized the importance of culture in their organizations. But how can you fit ethics and compliance into your organization's culture?

> Feedback – Individuals within the business generally want to do a good job and want feedback.
> Partnership – Individuals within the business are not compliance experts who spend their days thinking about compliance – they need and appreciate a business partner who can help share their compliance knowledge. It was mentioned that compliance professionals should meet business leaders where they are in their compliance understanding.
> Accountability – Does the business view compliance as everyone's responsibility, or something the Compliance department will take care of?

- Rewards – Rewarding individuals who exhibit good compliance behaviors, such as individuals who speak up to relay a concern, can influence behaviors and exhibit a healthy ethical culture.
- Messaging and Tone – Tone from the top, middle, and bottom of the organization is important.

Is ethics and compliance part of your organization's culture?

### DEI

DEI came up in multiple sessions in different scenarios, including in the context of clinical trial diversity, corporate diversity, and leadership diversity. Diversity discussions tied into the discussion of compliance teams for the future – bringing together diverse experiences and expertise to the growing capabilities required to be an effective compliance program. The broader topic of health inequity was also discussed and how organizations and Compliance Officers might be able to support activities of the organization to address health inequity.

What can you do to reduce biases and increase inclusion?

## Forthcoming Guidances

### Unapproved Uses Guidance

On October 24, 2023, the FDA released a draft guidance "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/ Cleared Medical Products Questions and Answers"[3]. This draft guidance supersedes the revised draft guidance issued in 2014 entitled "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices."

The Draft Guidance introduces:

- A New Term Scientific Information on Unapproved Use(s) (SIUU) - Communications by firms to HCPs about Scientific Information on Unapproved Use(s) of approved/ cleared medical products (e.g., published scientific or medical journal articles and published clinical reference resources)
- A New Safe Harbor for firm-generated presentations of scientific information from an accompanying published reprint

Our upcoming client alert, SIUU What?, provides further insights on this draft guidance.

### Modernization of Compliance Program Guidance Documents

During the OIG session, the OIG confirmed that they are moving forward with announced plans to "modernize" their compliance program guidelines[4].

Life sciences compliance professionals have relied heavily on the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers for years. While there continues to be great information in this document, OIG acknowledged that much has changed over the last 20 years, and they further noted that the current compliance guidance was issued prior to implementation of the Medicare Part D prescription drug benefit.

OIG stated they will "soon" release a General Compliance Program Guidance (CPG) that applies to all individuals and entities involved in the healthcare industry. They will follow this guidance with industry-specific guidance documents based on areas of priority – starting with managed care and nursing homes-based guidance.

Furthermore, the OIG confirmed that there will also be an update to the pharmaceutical manufacturers guidance sometime next year.

3. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses
4. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses

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