ResEcon Life Sciences & Healthcare

Key Takeaways from 2024 Annual Pharma Congress

General Counsel, outside counsel, compliance executives, representatives of regulatory bodies and forensic practitioners met to discuss an array of issues at the 2024 Pharmaceutical Compliance Congress. The following highlights a few key topics.

Top Considerations for Compliance Professionals

- Managing the continued expansion of the compliance department's scope and ensuring the department is appropriately resourced with headcount and budget
- Continuing discussions of The Office of the Inspector General's (OIG) General Compliance Program Guidance from November 2023 regarding the separation of legal and compliance departments
- Leveraging people leaders to incorporate compliance objectives -- such as an open-door culture, encouraging the reporting of potential violations of law or company policy, and tone at the top -- into annual employee performance metrics
- Centers for Medicare & Medicaid Services (CMS) leveraging Medicare Advantage and Prescription Drug Program audits to learn more about the Life Sciences business. Compliance taking the lead and coordinating legal department's involvement during CMS program audits.

Regulatory Update

- Regulators continue to have expectations that a company's compliance program have:
  - Compliance departments separate from legal departments to "mitigate the risk of being distracted with issuing legal opinions and losing focus on compliance areas"
  - A Chief Compliance Officer at the C-Suite level to have more effective input
  - Appropriately resourced Compliance departments
  - Compliance departments with access to data and links to actions and financial outcomes
  - Rewards for the compliance department that are not business driven
  - Incentive bonuses for compliant employees and executives that measure how the employee contributed to the compliance culture, such as no corrective actions, taking proactive steps to foster a culture of compliance with laws, regulations, and company policies, and completing compliance training
- Regulators continue to focus on:
  - Different versions of off-label marketing, such as misrepresentation or false statements of product benefits that may result in patient harm
  - In-kind kickbacks involving compound pharmacies, such as waiving patient copays for prescriptions to induce patients to purchase certain products
  - Independence of the foundations managing Patient Assistance Programs (PAPs) from the manufacturer
  - Looking behind the "paper" and focusing on the support for third-party agreements, such as data contracts where manufacturers are not using the data

Patient Assistance Programs (PAP) and Patient Support Programs (PSP)

- Effective PAP and PSP monitoring and auditing programs considerations:
  - Gaining an understanding of the different services and risks related to PSPs across the organization
  - Ensuring the appropriate level of detail in contract language and business rules to set expectations on auditing records, such as frequency and access to supporting data (i.e., call center recorded customer calls and transcripts, and call calibration)

Artificial Intelligence (AI) in Life Sciences Companies

- Start assessing risk by first developing an inventory of the varying types of AI and where within the organization AI is being used.
- Develop an AI risk committee with representation from key stakeholders, such as medical, compliance, IT, legal, and regulatory.
- The European Union AI Act is coming into effect in May 2024 and will have a broad reach similar to GDPR.

For further information and discussion on these points or other matters facing the Life Sciences and Healthcare, please contact us.

Yogesh Bahl
Partner
917.374.4386
ybahl@resecon.com

Tricia Etzold
Partner
732.261.1992
tetzold@resecon.com

Andrew Coles
Partner
917.567.8176
acoles@resecon.com

Jonathan Hecht
Director
646.573.7155
jhecht@resecon.com

David Amendola
Director
914.954.4269
damendola@resecon.com