ResEcon Life Sciences & Healthcare

Key Takeaways from 25th Annual Pharma Congress

General Counsel, outside counsel, compliance executives, representatives of regulatory bodies and forensic practitioners met and discussed an array of issues at the 25th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress. The following highlights a few key topics.

Artificial Intelligence (AI) in the Life Sciences Industry

- Robust AI governance is essential, requiring multidisciplinary collaboration among legal, IT, compliance, subject matter experts, and AI experts. Organizations must vigilantly monitor the use of AI tools, establish scalable pathways for AI implementation, and conduct thorough risk assessments.
  - Continuous monitoring and testing are vital to detect and address various biases in AI systems, ensuring fair and ethical application.
- The rapidly evolving AI regulatory landscape, including state and local laws (e.g., Colorado AI Act) and international frameworks (e.g., EU AI Act), is intensifying compliance challenges. Auditing AI systems demands new approaches, emphasizing transparency, explainability, and human oversight.
  - The allocation of liability between AI vendors and deployers is bound to be a contentious topic, likely to be shaped by emerging legislation and case law.
  - Compliance teams must stay abreast of developments like the National Institute of Standards & Technology (NIST) AI framework and prepare for a complex, nuanced regulatory environment in AI governance.
- AI-powered real-time analytics is transforming compliance in life sciences and understanding the distinction between predictive AI tools (e.g., outcome forecasting) and generative AI tools (e.g., content creation) is crucial for proper implementation and assessment.
  - Companies must also adapt their evaluation methods to the specific type of AI tool, ensuring effective use in areas such as patient outcome prediction, drug discovery, and synthetic data generation for training purposes.
- With the growing focus on managing data and AI, executives are looking for more efficient and reliable ways to digest available information and metrics to facilitate effective decision making; the art of storytelling and leveraging behavioral compliance principles to facilitate learning continues to evolve at the executive levels.

Regulatory Update

- Regulators' approach to speaker programs has changed from its initiation to today. It began in 2007 with a focus on off-label promotion and has evolved to a current focus on a number of factors, such as the purpose of the speaker program (i.e., educational vs selling), how long the drug is on the market, list of speakers, number of events, repeat attendees to same event, and retention of healthcare professionals that are qualified.
- The Office of the Inspector General (OIG) provided an update on the issuance of Industry Compliance Program Guidance (ICPG): it intends to issue ICPG for Medicare Advantage, hospitals, and clinical laboratories in early 2025 and for hospice and pharmaceutical manufacturers in late 2025 or early 2026.
- The Department of Justice (DOJ) does not look at large and small companies differently and has the same level of expectations when it comes to scrutiny of compliance program infrastructure.

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

ResEcon Life Sciences & Healthcare Team

Yogesh Bahl
Partner
917.374.4386
ybahl@resecon.com

Andrew Coles
Partner
917.567.8176
acoles@resecon.com

David Amendola
Director
914.954.4269
damendola@resecon.com

ResEcon Artificial Intelligence (AI) Specialists

Victoria A. Lipnic
Partner
202.769.2426
vlipnic@resecon.com

Gurkan Ay
Director
202.800.2723
gurkan@resecon.com

Ye Zhang
Director
202.655.4587
yzhang@resecon.com