



# ResEcon Life Sciences & Healthcare

## Key Takeaways from 24<sup>th</sup> 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 24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress. The following highlights a few key topics.

### Behavioral Economics and How It Can Enhance Compliance

- The use of behavioral economics has the potential to improve any organization's compliance function, throughout all groups and departments within a company. A deeper understanding of behavioral economics theories and tools is needed to improve a compliance program.
- Behavioral economics provides theories and tools that can be mixed and matched so that methods that are appropriate for a particular company can be utilized in designing, developing, and disseminating an updated and enhanced training program, with the goal of reducing the administrative and psychological hurdles that face almost all compliance functions.

### R&D Compliance Program Design

- Obtain leadership support of documented principals, policies, and procedures that clearly differentiate between the medical affairs and commercial roles within an organization.
- Conduct appropriate levels of due diligence of Contract Research Organizations (CRO), which may include site identification; fair market value for transfers of value to investigators; use of same investigator for multiple or competing studies; and similar patient recruitment population.
- Execute audit rights of CROs and leverage your company's internal audit department.

### Regulatory Update

- Individual accountability is critical and compliance programs should be tailored to address your organization's specific risks and the need to continue to evolve a compliance program to address emerging risks.
- Self-disclosure, even late, is better than never disclosing. For example, the recent Albermarle settlement involved a late self-disclosure: cooperation credit was still granted along with a reduction in the fine amount equal to the amount of compensation clawed back.
- There is no longer just a "tone at the top" focus; instead, it is repurposed to "tone throughout the organization."
- While the guidance on ephemeral apps remains vague, there will be consequences if records are not available or cannot be retrieved during the course of an investigation. As a result, regulator guidance is to use your best judgement and ensure your practices align with your risks.

### The Future of The Chief Compliance Officer

- The responsibilities of being a Chief Compliance Officer (CCO) continue to evolve as the role is returning to its original intent of being an organization's Chief Risk Officer.
- CCOs and their teams should analyze current processes to determine if there are ways to create efficiencies, improve the quality and remove the roadblocks that lead to delays, inefficiencies, and frustrations within the organization.
- With the advent and integration of new technologies and techniques, CCO's should be bolder and more aggressive in identifying and remediating issues before they become significant risks to the company.

## Health Equity

- Health equity is seen as a need to better understand how disease and illness effects different ethnicities and racial groups. Achieving this requires focused and ongoing efforts to overcome economic, social, and other obstacles to health and healthcare and to eliminate preventable health disparities.
- Companies should be cognizant of the increasing need to have clinical trials and commercial strategies that address all populations to potentially improve efficacy and consumer awareness.
- Private equity and sovereign wealth funds are actively pursuing investments in companies that have health equity as part of their strategy.

## Data Analytics to Monitor Payments to HCPs, HCOs, Distributors, and Other Third Parties

- To meet evolving expectations of enforcement agencies and to ensure compliance programs are effective, advanced data analytics need to be continually refined in light of the increasing volume of transactions and changes in business operations.
- Advanced analytics continue to be leveraged for third-party payments to identify issues involving kickbacks, channel margins, donations, and marketing reimbursements.
- Identifying and leveraging common data across the organization and among systems is key to avoiding challenges, such as data readiness and completeness.

## Artificial Intelligence – The Good, The Risks and The Takeaway

- **The Good** – while the Life Sciences and Healthcare industry are behind other industries in their investment and development of artificial intelligence tools, there has been a significant increase of invested capital in this emerging technology.
- **The Risks** – As with almost all emerging technologies, there are new risks that must be considered and remediated. These risks include bias in the coding, insufficient review of results, and unclear processes for confirming the accuracy of the results.
- **The Takeaway** – The use of artificial intelligence is already becoming a necessity rather than a differentiating factor, but companies need to be prudent in their development and utilization of AI to avoid unintended consequences.

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



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