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Compliance Congress for Specialty Products 2023 Takeaways

Choate recently sponsored the Compliance Congress for Specialty Products in Boston where attendees heard from industry experts on the latest compliance trends in the pharmaceutical industry.

Emily Hodge, partner in Choate's Government Enforcement and Compliance Group, moderated the panel, "Prosecutor Perspectives: Focal Points, Top Enforcement Trends and Priorities for Specialty Pharma and Biotech Companies in 2023," while Sara Frank moderated the fireside chat, "The Rise of Cell and Gene Therapy and How to Remain Compliant Amid Industry Shifts." Below are key takeaways from both panels.

Prosecutor Perspectives: Focal Points, Top Enforcement Trends and Priorities for Specialty Pharma and Biotech Companies in 2023 – Key Takeaways

- The government continues to focus on fraud and abuse issues in healthcare, including issues arising from speaker programs, clinical trial fraud, third-party relationships, FDA inspections, and lab activities.
- DOJ's recent policy updates on self-disclosure and compliance programs (among others) are important for companies to be aware of and consider.
- Companies can benefit from voluntary self-disclosure in some cases. The prosecutors explained that early disclosure by the company, even if fact-gathering is ongoing, is preferred – the government understands that the facts may evolve from there.
- When companies present their compliance programs to the government:
  - The government wants to hear all the relevant facts and companies should not minimize or overstate the role that the compliance program plays at the company.
  - It can be helpful for the government to hear directly from the compliance personnel themselves. The prosecutors recalled instances where compliance personnel were asking the right questions, but perhaps could have probed underlying documents more to uncover alleged misconduct.
- Companies should ensure that they have policies to address the use of ephemeral messaging and are considering the risks associated with it.

"The Rise of Cell and Gene Therapy and How to Remain Compliant Amid Industry Shifts" – Key Takeaways

- Although gene therapy manufacturers share the general risks and requirements of a compliance program that other manufacturers face, they also have additional nuances to consider.
- Gene therapies are treatments that modify a person's genes to treat or cure disease – they are the ultimate personalized medicine.
- Gene therapies are customized to a particular patient, which presents some unique potential risks that manufacturers of traditional pharmaceutical products may not face, including:Relationships with qualified treatment centers – e.g., information sharing, interactions among various functions, onboarding process and timing for a qualified treatment center.

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- Enhanced need to ensure privacy and patient consent.
- Unique aspects of patient services programs – recent favorable OIG advisory opinions rely on some of the particular facts and circumstances of treatment with a gene therapy.

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