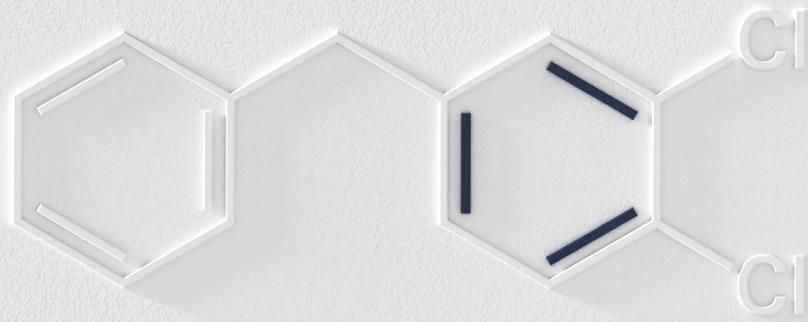


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CLIENT ALERT



CLIENT ALERT: Prosecutor Panel at Compliance Congress for Specialty Products Shares Perspectives on New Monaco Memo and Other Areas of Focus

Monaco doubles down on individual accountability, a company's history of misconduct, self-disclosure and incentivizing good compliance. Prosecutors share their perspectives at the Informa Compliance Congress for Specialty Products.

Epsilon Life Sciences recently sponsored and attended the Informa Compliance Congress for Specialty Products and appreciated the opportunity to participate (in person!) in important discussions within this increasingly evolving and complex space.

Among the many interesting sessions at the conference included a prosecutors' panel with attorneys from the U.S. Attorney's Health Care Fraud Unit and Department of Justice ("DOJ") Consumer Protection Branch. This panel shared helpful perspectives on the September 15, 2022 memo from Deputy Attorney General Lisa Monaco regarding Corporate Enforcement (see [here](#) for a link to the full 15-page "Monaco Memo").

Below we provide a summary of our key takeaways from the Monaco Memo and the

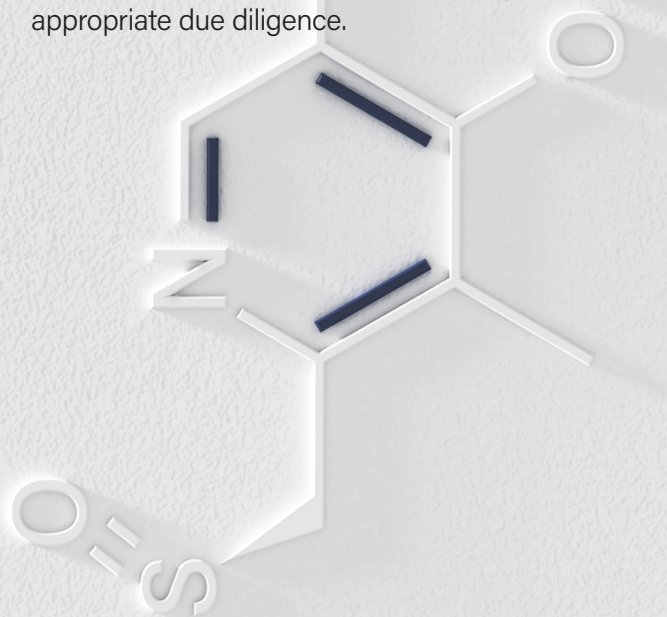
panel's commentary, as well as additional areas of enforcement focus the panel discussed:

- > **Entities Act Through Individuals:** The Monaco Memo reflects clear renewed interest on individual accountability (per the panel, "entities act through individuals"). Indeed, the Monaco Memo states that the Department of Justice's "first priority in corporate criminal matters is to hold accountable the individuals who commit and profit from corporate crime."
- > **Company History Matters:** The Monaco Memo reiterates previous instructions that when determining how to resolve investigation of corporate criminal activity, prosecutors consider the corporation's history of past misconduct, including a wide variety of inputs – "criminal, civil, and regulatory resolutions, both domestically and internationally". The Monaco Memo clarifies that prosecutors should always be mindful of each company's facts and circumstances (for example: "Prior resolutions that involved entities that do not have common management or share compliance resources with the entity under investigation" should "generally receive less weight").



"Let me start with our top priority for corporate criminal enforcement: going after individuals who commit and profit from corporate crime."
Deputy Attorney General Lisa O. Monaco

- > **There are Benefits to Self-Disclosure:** The Monaco Memo incentivizes companies to come forward and disclose identified misconduct with what the panel described as “concrete assurance” of a material benefit for doing so. Per the Monaco Memo, the DOJ “will not seek a guilty plea where a corporation has voluntarily self-disclosed, fully cooperated, and timely and appropriately remediated the criminal conduct” and “will not require the imposition of an independent compliance monitor for a cooperating corporation ...”
- > **Detect and Prevent:** The panel provided a concise summary of two main issues prosecutors see: (1) companies don’t or can’t identify concerning conduct or risks; or (2) companies CAN identify risks but lack authority or culture to effect change (per the panel, knowledge of an issue and failure to address it = a bad spot to be in).
- > **Set Controls Around Personal Devices and Third-Party Messaging Platforms:** The panel acknowledged that they are increasingly seeing use of personal phones, apps, and other methods for business-related communications. Texts, chats, e-messages, and other work-related communications stored on phones, tablets, and other devices “need to be preserved and accessible” for cooperation credit, and companies should have clear policies on their use.
- > **Look At Your Own Data:** Reflecting consistent messaging from enforcers over the years, the panel stated that they frequently see companies fail to use their own technology or data to find problems that seem glaring or obvious to enforcement agencies. Per the panel, this may exemplify an issue where “Compliance doesn’t always grow with the company”.
- > **Utilize a Carrot and Stick Approach for Promoting Compliance:** The Monaco Memo emphasizes the importance of tying compliance considerations to compensation – utilizing both rewards and penalties that impact individual pay. The panel repeatedly mentioned “claw back” provisions on incentive compensation as an effective tool.
- > **Added Clarity on Monitorships and “Monitoring the Monitor”:** The Monaco Memo includes a long list of factors for prosecutors to consider when determining the necessity of a monitor and provides details around the monitor selection process aimed at ensuring consistency and transparency. The Monaco Memo also indicates a desire for frequent communications between prosecutors and monitors, and a more thorough ongoing review of the monitor’s work by the department.
- > **The Government is Pursuing “Invalid” Prescriptions:** The DOJ has brought misbranding cases under the Food, Drug, and Cosmetic Act against pharmacies and other healthcare stakeholders for fraudulently obtaining prescriptions through false statements to consumers and payments to authorizing doctors. According to the panel, the department may utilize this misbranding “pathway” against companies with a reason to know that prescriptions are invalid – such as where prescriptions aren’t being written by legitimate doctors, or where products and programs are pushed to patients who don’t need them.
- > **CRO/Sponsor Diligence is Key to Combatting Clinical Trial Fraud:** The panel reiterated previous communications that clinical trials are at “the heart” of how the review and approval process operates. It is essential for such data to be accurate and based on sound science. More actors in the clinical trial process creates opportunities for misconduct, the panel stated, and while investigators are often responsible for defrauding drug sponsors, those sponsors and associated CROs have an obligation for appropriate due diligence.





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