



# Private Equity (PE) Investor Risks: PE funds invested in U.S. life sciences companies face enforcement actions for portfolio company misconduct

## PE ENFORCEMENT TRENDS:



In the U.S., both the government and whistleblowers increasingly are pursuing PE investors in False Claims Act (FCA) cases based on alleged violations of healthcare fraud and abuse laws.



Both majority and minority investors are exposed to this FCA risk.



PE funds face increased risk in 2022 as the U.S. Department of Justice (DOJ) renews its focus on curbing perceived fraud and abuse in the life sciences industry and as government scrutiny of PE investment in the sector increases.



In 2022, PE funds should expect the DOJ and whistleblowers to continue to assert claims against them relating to the conduct of their life sciences portfolio companies. This risk will continue to be of concern to PE firms that are active in the operations of their portfolio companies and may be of concern to all firms that identify potential issues of noncompliance during diligence and, if they assume managerial responsibility, do not take steps to ensure appropriate actions are taken to bring operations into compliance.

Across the board, PE funds may find themselves at further risk as DOJ enforcement scrutiny of actors in the life sciences industry, including equity investors, in the U.S. ramps back up to pre-pandemic levels in 2022. Enforcement priorities are predicted to include:

- federal Anti-Kickback Statute issues implicated by provider referral source arrangements, compensation by drug and device manufacturers of contract sales forces, and rebate arrangements with pharmacy benefits managers;
- issues related to promotion of products for new intended uses in alleged violation of the Food, Drug, and Cosmetic Act and violations of current Good Manufacturing Practice regulations; and
- issues related to CARES Act funding and the Provider Relief Fund.

PE funds invested in the healthcare and life sciences industries should stay up to date on the latest enforcement trends to calibrate their investment opportunities and to manage risk in their portfolios.

## PE ENFORCEMENT TIPS:

- Funds need to be attuned to the specific areas of high-priority enforcement risk facing their life sciences portfolio companies.
- PE firms should ensure that their portfolio companies are resourced for sound compliance programs and there is a documented process for board oversight.
- PE firms should follow up on issues of noncompliance identified during diligence and document that follow-up.

### **Contacts**

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