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False Claims Act enforcement risk for private equity investors

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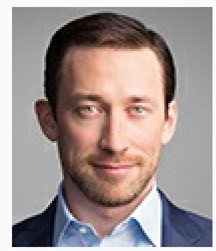

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The U.S. Department of Justice (DOJ) is using the False Claims Act (FCA)[1] to pursue private equity investors for alleged violations committed by portfolio companies.[2] While several case resolutions have become public, multiple ongoing cases remain confidential. This article describes recent FCA case settlements involving private equity and what proactive steps investors can take to protect themselves.

Private equity investors take substantial risk to provide capital when traditional lending institutions are unwilling to extend the credit necessary for businesses to innovate and expand. Any fair review of the role private equity plays in the healthcare economy must include consideration of the growth and enhancements in the delivery of care made possible by investors. During the COVID-19 pandemic alone, for example, private equity played an outsized role in the expansion of telehealth[3] and vaccine development.[4] While investors may be rewarded, casting private equity investors in a negative light is misguided. While some criticize private equity for profit-taking,[5] investors play a vital role in the development of new technology and expansion of the economy.

With a new era of heightened regulatory scrutiny and enforcement risk, investors should be aware that whistleblower attorneys who file qui tam suits on behalf of the United States are the main driver behind DOJ's investigations. These plaintiff attorneys have found a receptive audience in both legislative and executive branches of government,[6] and those branches are pressuring DOJ to bring more cases against private equity investors—a perceived deep pocket in FCA cases.

The False Claims Act

The FCA allows DOJ or whistleblowers, known as relators, to file suit to recover treble damages, per claim penalties, as well as legal fees and costs from companies that defraud the government. For 2022, FCA penalties can range up to $25,076 per claim.[7] Any time a qui tam suit is filed, DOJ must investigate the allegations.[8] Thereafter, DOJ has the option of intervening in and litigating the qui tam suit on behalf of the United States. As most companies that operate in the healthcare and life sciences sectors know well, there are hundreds of qui tam suits filed by whistleblowers every year.[9] DOJ declines to intervene in nearly two-thirds of these cases, and most of these are dismissed.

A private equity investor may have FCA liability where it "devises or implements" an unlawful scheme with the intent to defraud the government.[10] But the FCA goes further to penalize any individual or entity that *knowingly* presents, or causes to be presented, a false or fraudulent claim for payment or approval by the government.[11] The FCA also creates liability for any entity or individual that *knowingly* makes or uses, or causes to be made or used, a false record or statement in connection with a claim.

"Knowingly" means (a) actual knowledge, (b) deliberate ignorance, or (c) reckless disregard.[12] Reported caselaw is sparse, however, on what the "causes" standard means in the context of investors. We can expect whistleblowers and DOJ to take the broadest view imaginable—a view that can lead to liability where an investor is not aware of the wrongful conduct but still stands accused of failing to correct the gap in compliance or submission of false claims.[13]

Comprehensive due diligence

DOJ has taken the position in recent cases that issues raised during a private equity investor's due diligence of a potential investment, that are not immediately corrected, are enough to hold an investor liable under the FCA.[14] DOJ also has taken the position that an investor can be liable for violations that occur prior to acquisition.[15] Given that FCA qui tams are under seal, DOJ has no obligation to inform a potential buyer about the existence of a suit. In fact, there is at least one recent case where whistleblower counsel stood idly by knowing an investment was likely to occur, and then amended their complaint to add the private equity firm as a named defendant post-closing.[16] The amended pleading simply alleged that the private equity firm should have discovered the improper activity during due diligence.

To limit exposure, investors must make sure that their investment target has the resources to address and is well-trained in compliance and FCA risks. The investor should conduct comprehensive due diligence focused on high-risk regulatory areas. If an issue does come to light during due diligence, investors could consider requiring the company to implement remedial measures (e.g., policy revisions, enhanced training, corrective actions, revisions to existing commercial or other contracts, or even using the Office of Inspector General self-disclosure protocol if appropriate), not to mention incorporating specifically tailored indemnification provisions in the relevant investment agreements.

Corporate form and independent management

In evaluating motions to dismiss, courts have focused on whether the private equity investors were acting as the management of their portfolio companies.[17] For this reason, it is important for private equity investors to assure that the portfolio company management operates independently and reports to the board of directors. When investors operate outside of the corporate form and become involved in management decisions, they place themselves in potential jeopardy. Private equity investors may be liable under the FCA for *causing* the submission of false claims where they take on managerial roles.

Courts have opined that where a firm uses its ability "to control or influence another to submit false claims, that entity is not shielded from liability based on its mere status as a separate entity."[18] In evaluating a motion to dismiss in a recent private equity–related FCA matter, for example, a court looked to common public statements that a private equity investor provided "management, oversight, and strategic guidance for the operations of" its portfolio company as grounds to allow a case to move forward.

Private equity investors should be deliberate in assessing their desired level of involvement in the day-to-day operations of their portfolio companies. Experienced executives and compliance personnel in the portfolio company are the best option when driving a young company to innovate and grow. When faced with allegations that an investor was causing the submission of false claims, courts look to the connection between the investor and portfolio company. Where employees or owners of a private equity firm assume management positions in a portfolio company without resigning from their investment firm, courts have concluded that the "overlap of officers and board members for the various entities" effectively merged the entities for purposes of FCA liability.

Use of language

Communications from private equity investors, whether email, text, or oral, can easily be misconstrued. When promoting investments in news releases, investors and portfolio companies should carefully select the language they use to describe their relationship. Courts evaluate both external and internal communications between investors and portfolio companies that do not "distinguish among the various entities." In one recent decision, a court noted that the managing partner of an investment firm sent emails that failed to "distinguish among the entities, and he appears to speak on behalf of them all." In the emails reviewed by the court, the partner used "the collective pronoun 'we' to discuss volumes of drugs to be acquired and rebates to be paid" to the portfolio company. The court held that the "email is one voice speaking collectively for" the private equity investor and its portfolio company. In addition, the court referenced a portfolio company news release announcing its acquisition where the chief operating officer was quoted as saying that the private equity investor was "the perfect *partner* to accelerate growth from a regional company to a national platform" (emphasis added).

Conclusion

For private equity firms invested in healthcare and life sciences, avoiding DOJ investigations, whistleblower claims, reputational damage, and adverse disclosure requirements is paramount. Investors must approach acquisitions in healthcare with caution, well-thought-out due diligence, respect for corporate formalities, and a commitment to immediately remediate compliance issues and gaps. Finally, investors should retain experienced counsel when FCA issues arise and to advise on appropriate remedial compliance measures when material issues arise.

Takeaways

- U.S. Department of Justice is using the False Claims Act to pursue private equity investors for alleged violations committed by portfolio companies.
- Private equity companies should undertake *comprehensive due diligence* of target investments focused on high-risk regulatory areas.
- Private equity companies should be mindful of maintaining the *corporate form* of portfolio companies and work to ensure that portfolio company management *operates independently*.
- Private equity companies should be mindful of *how they describe the level and extent of involvement* with portfolio companies in all internal and external communications.
- Experienced counsel can help investors best understand potential FCA issues when they arise and can provide advice on remedial compliance measures, as appropriate.

1 31 U.S.C. §§ 3729–3733.
2 *See, e.g.*, U.S. ex rel. Ebu-Isaac, et al. v. Insys Therapeutics, Inc., et al., Case No. 2:16-CV-07937-JLS-AJW, 2021 WL 3619958 (C.D.Cal. June 9, 2021).
3 McKinsey & Company, "Telehealth: A quarter-trillion-dollar post-COVID-19 reality?," July 9, 2021, https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-

trillion-dollar-post-covid-19-reality.
4 Laura Cooper, “Covid-19 Vaccine: How Private-Equity Portfolio Companies Played a Role,” *The Wall Street Journal*, accessed June 1, 2022, https://graphics.wsj.com/glider/behind-the-scenes-of-the-covid-19-vaccine-rollout-c5ffacbe-1007-4cb7-a739-2803699f6ed4.
5 The White House, “Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation’s Nursing Homes,” February 28, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes.
6 Bill Pascrell, “Pascrell Op-ed: Private Equity’s Growing Control of Health Care Endangers the Underserved,” news release, April 12, 2021, https://pascrell.house.gov/news/documentsingle.aspx?DocumentID=4682.
7 15 C.F.R. § 6.3(a)(3).
8 31 U.S.C. § 3730.
9 U.S. Dep’t of Justice, Civil Div., “Fraud Statistics—Overview: October 1, 1986–September 30, 2021,” accessed June 1, 2022, https://www.justice.gov/opa/press-release/file/1467811/download.
10 *See* U.S. ex rel. Medrano v. Diabetic Care RX, LLC, Case No. 15-CV-62617, 2018 WL 6978633, at *1 (S.D. Fla. Nov. 30, 2018), report and recommendation adopted in part sub nom., No. 15-CV-62617, 2019 WL 1054125 (S.D. Fla. Mar. 6, 2019).
11 31 U.S.C. § 3729(a)(1).
12 31 U.S.C. § 3729(b)(1).
13 *See* U.S. ex rel. Mandalapu et al. v. Alliance Family of Companies Inc., Civ. Action No. 4:17-cv-00740 (S.D. TX 2017).
14 U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs., 540 F. Supp. 3d 103 (D. Mass. 2021).
15 U.S. Department of Justice, U.S. Attorney’s Office for the Eastern District of Pennsylvania, “Former Owners of Therakos, Inc. Pay $11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients,” news release, November 19, 2020, https://www.justice.gov/usao-edpa/pr/former-owners-therakos-inc-pay-115-million-resolve-false-claims-act-allegations.
16 U.S. ex rel. Mandalapu et al. v. Alliance Family of Companies Inc., Civ. Action No. 4:17-cv-00740; Department of Justice, “EEG Testing and Private Investment Companies Pay $15.3 Million to Resolve Kickback and False Billing Allegations,” news release, July 21, 2021, https://bit.ly/3wYGTvW.
17 U.S. ex rel. Ebu-Isaac, et al. v. Insys Therapeutics, Inc., et al., Case No. 2:16-CV-07937-JLS-AJW, at 5; U.S. Department of Justice, “Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations,” news release, September 18, 2019, https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million.
18 U.S. ex rel. Ebu-Isaac, et al. v. Insys Therapeutics, Inc., et al., Case No. 2:16-CV-07937-JLS-AJW, at 5–7 (emphasis added).