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False Claims Act Enforcement Risk For Private Equity Investors

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Introduction

The U.S. Department of Justice ("DOJ") is using the False Claims Act ("FCA") to pursue private equity investors for alleged violations committed by portfolio companies.[1] While several case resolutions have become public, there are multiple on-going that 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 of private equity plays in the health care 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 and vaccine development.[2] While investors may be rewarded, casting private equity investors in a negative light is misguided. While some criticize private equity for profit-taking,[3] 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[4] and executive[5] branches of government, 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.[6] Any time a *qui tam* suit is filed, DOJ must investigate the allegations.[7] 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 whistleblower every year.[8] 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.[9] 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.[10] 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.[11] "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: that is, 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 assure 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 (for example, policy revisions, enhanced training, corrective actions, revisions to existing commercial or other contracts, or even using the HHS-OIG self-disclosure protocol (if appropriate)), not to mention incorporating specifically tailored indemnification provisions in the relevant investment agreements.

Corporate Form & 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 report 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.[19]

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 e-mail, text, or oral – can easily be misconstrued. When promoting investments in press 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."[20] In one recent decision, a Court noted that the managing partner of an investment firm sent e-mails that failed to "distinguish among the entities, and he appears to speak on behalf of them all."[21] In e-mails 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.[22] The Court held that the "email is one voice speaking collectively for" the private equity investor and its portfolio company.[23] In addition, the Court referenced a portfolio company press 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."[24]

Conclusion

For private equity firms invested in health care 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.

Key Takeaways

- ✓ DOJ 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] The False Claims Act, 31 U.S.C. §§ 3729-33; *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); *U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center*, Civ. Action No. 15-13065 (D. Mass. May 19, 2021); *United States ex rel. Medrano v. Diabetic Care Rx, LLC d/b/a Patient Care America, et al.*, Case No. 15-CV-62617, 2019 WL 1054125 (S.D. Fla. Mar. 6, 2019); *U.S. ex rel. Mandalapu, et al., v. Alliance Family of Companies, and Ancor Holdings, L.P., et al.*, Civil Action No. 4:17-cv-00740 (S.D. TX 2017).

[2] Cooper, L., *Covid-19 Vaccine: How Private-Equity Portfolio Companies Played a Role*, Wall Street Journal, ("Private-equity portfolio companies have been involved in nearly every step of the process from drug development to vaccine transportation"), https://graphics.wsj.com/glider/behind-the-scenes-of-the-covid-19-vaccine-rollout-c5ffacbe-1007-4cb7-a739-2803699f6ed4; Stanford, J., Stat News, *Thank Private Risk-Taking, Not Public Funding, for COVID-19 Vaccines, Therapies* (April 5, 2021), https://www.statnews.com/2021/04/05/thank-private-risk-taking-not-public-funding-for-covid-19-vaccines-therapies/; *See McKinsey Insights Report* (July 9, 2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality (In 2021, telehealth utilization increased to a stabilized 38 times that seen before the first COVID-19 spike. Private investment in virtual and digital health skyrocketed, fueling innovation, with three times the level of investment in 2020 than in 2017).

[3] Transcript of President Biden's State of the Union, delivered March 1, 2022; https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/03/01/remarks-of-president-joe-biden-state-of-the-union-address-as-delivered/ ("[A]s Wall Street firms take over more nursing homes, quality in those homes has gone down and costs have gone up."); *Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes*, released by the White House on Feb. 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/ ("[R]esearch shows that private equity-owned nursing homes tend to have significantly worse outcomes for residents).

[4] Hearing transcript: https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/OV-3%20Hearing%20Transcript.pdf; U.S. Rep. Bill Pascrell, *Private Equity's Growing Control of Health Care Endangers the Underserved*, April 12, 2021, https://pascrell.house.gov/news/documentsingle.aspx?DocumentID=4682

[5] *Id.* at fn. 3.

[6] 31 U.S.C. §§ 3729-33. For 2022, FCA penalties can range up to $23,607 per claim. *Id.* at § 3729(a)(1), 15 C.F.R. § 6.3(a)(3).

[7] 31 U.S.C. § 3730.

[8] 31 U.S.C. § 3730(d). For the most up-to-date statistics on *qui tam* filings and recoveries, see Civil Div., U.S. Dep't of Justice, Fraud Statistics—Overview: October 1, 2021–September 30, 2022.

[9] *See Medrano*, 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) (DOJ alleged that the pharmacy paid kickbacks to marketing firms to target TRICARE beneficiaries for medically unnecessary pain cream prescriptions, and that the private equity firm played a key role in initiating the scheme. In particular, DOJ focused on two partners of the private equity firm who served as officers of the pharmacy and were accused of exerting significant control over the alleged scheme).

[10] 31 U.S.C. § 3729 (a)(1)(A).

[11] 31 U.S.C. § 3729 (a)(1)(B).

[12] 31 U.S.C. §§ 3729-33.

[13] *See Mandalapu*, Civil Action No. 4:17-cv-00740 (S.D. TX 2017).

[14] *Martino-Fleming*, Civ. Action No. 15-13065 (D. Mass. May 19, 2021)(In this declined *qui tam*, the relator alleged that portfolio company and private equity firm submitted false claims to Medicaid because the underlying services were not appropriately supervised by licensed personnel).

[15] DOJ Press Release (Nov. 19, 2020), https://www.justice.gov/usao-edpa/pr/former-owners-therakos-inc-pay-115-million-resolve-false-claims-act-allegations (DOJ alleged that between 2006 and 2015, a pharmaceutical manufacturer engaged in off-label promotion of a cancer treatment for use in pediatric patients. In 2012, a private equity firm bought the company. There were no allegations that the private equity firm was involved in the alleged off-label promotion. The complaint simply alleged that the improper off-label promotion continued after the private equity firm acquired the company. DOJ appeared to take the position that the firm recklessly disregarded its obligations as an investor by not identifying and stopping the off-label promotion).

[16] *Mandalapu,* Civil Action No. 4:17-cv-00740 (S.D. TX 2017); DOJ Press Release (July 21, 2021), https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-15.3-million-resolve-kickback-and-false

[17] *Ebu-Isaac*, Case No. 2:16-CV-07937-JLS-AJW, 2021 WL 3619958, at 5 (C.D.Cal. June 9, 2021); *see also Medrano,* Case No. 15-CV-62617, 2018 WL 6978633 (S.D. Fla. No. 15-62617)(DOJ announced a $21.36 million settlement with compounding pharmacy Patient Care America ("PCA"), two PCA officers, and PCA's private equity investor -- Press Release (Sept. 18, 2019), https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million).

[18] *Ebu-Isaac* at 5 (emphasis added) (On June 9, 2021, U.S. District Judge Josephine Staton in the Central District of California denied the private equity firm's motion to dismiss a FCA case against it and its portfolio companies. Bear in mind that Judge Staton treated the allegations in the complaint in a light most favorable to DOJ and the relator).

[19] *Id.* (The Court referenced allegations that the private equity firm (a) promoted the use of its portfolio company to facilitate "the large scale distribution SUBSYS," (b) directed its portfolio company to "dispense SUBSYS for contraindicated use and off-label use," (c) directed its portfolio

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company "to dispense the incorrect initial dosages" of SUBSYS, and (d) directed the portfolio company "to submit claims based on the widespread off-label use of SUBSYS.").

[20] *Id.* at 7.

[21] *Id.* at 5-6.

[22] *Id.*

[23] *Id.*

[24] *Id.* (emphasis added).