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Rounding out 2023: health care enforcement trends in private equity

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Every action has an equal and opposite reaction. Private equity investment in healthcare companies peaked in 2021,[1] and regulatory oversight and enforcement are hot on its heels.[2] Even before this 2021 peak, perceptions of private equity firms' roles in response to information about allegedly improper activity by healthcare providers in portfolio companies have led to multi-million-dollar settlements with the U.S. Department of Justice (DOJ) and state attorneys general.

With even more enforcement activity on the horizon, private equity firms may want to invest early in their portfolio companies' compliance functions, as the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) emphasized in its November 2023 General Compliance Program Guidance.[3]

The False Claims Act[4] (FCA) is a potent enforcement[5] instrument in the healthcare space. Companies and individuals can be held liable under the FCA for treble damages plus significant penalties for knowingly submitting, or causing to be submitted, false claims for payment to the government, falsely certifying compliance with applicable laws to obtain payment from the government, or retaining government payments premised on false claims or false certifications.

In some cases, resolving FCA allegations may be preconditioned on a multi-year corporate integrity agreement that requires compliance reporting to an external monitor. FCA suits may be brought directly by the government or by whistleblowers on the government's behalf, with or without the government's intervention. Around thirty states (and counting) have promulgated FCA statutes modeled after the federal version.

Private equity firms are FCA targets, with government leaders and HHS-OIG[6] voicing concerns,[7] and even suing,[8] over the private equity sector's role in healthcare.[9] But not everyone agrees. Defenders have embraced private equity cash infusions as an alternative to joining a large health system, and touted technological enhancements that improve care and efficiency.[10] Private equity FCA settlements have abounded in recent years. Many of those settlements stem from private equity firms' alleged failures to adequately address practices at their portfolio companies that risk running afoul of healthcare laws.

A recent settlement from June 2023 is *Ebu-Isaac*, where a whistleblower in a non-intervened case alleged that a private equity firm actively promoted and facilitated the widespread off-label use of a fentanyl spray, Subsys, in violation of the Controlled Substances Act; the matter settled after the private equity firm, its three managing partners, and two portfolio pharmacies agreed to pay $9 million.[11]

Another example is *Martino-Fleming*, where in 2021 a private equity sponsor agreed to pay nearly $20 million to settle state FCA allegations brought by the Massachusetts attorney general's office that a portfolio company submitted false claims to the Massachusetts Medicaid program to reimburse for mental health care services rendered by unlicensed and improperly supervised clinic staff.[12]

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Another frequently cited example is *Medrano*, where in 2019 a private equity firm together with its portfolio company agreed to pay the DOJ $21.05 million to resolve accusations that the private equity firm aided its portfolio company in an illegal kickback scheme to prescribe compounded creams and vitamins to military veterans in the TRICARE health program.[13]

Private equity firms defending these and other FCA allegations often argue that they did not "cause" the false claim and lacked "knowledge" of the alleged impropriety, emphasizing their limited role in day-to-day operations. Among other elements, the FCA requires a defendant to have knowingly submitted, or caused to be submitted, a false claim for payment — acting knowingly can be established through actual knowledge, deliberate ignorance, or reckless disregard of the information's falsity.[14]

In denying defendants' motion to dismiss the whistleblower's second amended complaint in *Ebu-Isaac*, the California federal

district court held that the whistleblower had sufficiently pleaded (i) causation, where the private equity firm controlled the portfolio pharmacies and "worked to promote and facilitate the widespread, off-label and medically non-indicated uses of SUBSYS," resulting in government reimbursement, and (ii) knowledge, where the private equity firm proposed distributing Subsys "to a patient population that far outstripped the limited market of opioid-tolerant cancer patients experiencing breakthrough pain."[15]

"No-knowledge" defenses may be difficult to establish to obtain dismissal at the summary judgment[16] or motion to dismiss[17] stages, particularly after the Supreme Court's June 2023 ruling that knowledge under the FCA must be assessed based on *subjective* intent at the time of the alleged misconduct, not based on later assessments of whether the conduct comports with an objectively reasonable interpretation of ambiguous legal requirements.[18]

Consequently, what private equity stakeholders said and thought about their portfolio companies' operations, compliance measures, and applicable law and regulations is of heightened importance. Post-*SuperValu*, specific allegations that a private equity firm had been made aware of, or purposefully avoided being made aware of, potentially troublesome portfolio company practices, will remain critical. But blanket assertions that the firm knew or should have known of such issues likely will remain insufficient to survive a motion to dismiss or summary judgment.[19]

Other private equity FCA actions were settled without a court ruling[20] on the private equity firms' knowledge about alleged portfolio company wrongdoing.[21] To inform the bounds of private equity liability under the FCA post-*SuperValu*, the FCA bar will be closely monitoring the strength of "no-knowledge" defenses in future FCA claims against private equity firms.

Takeaways

With burgeoning federal and state enforcement efforts, private equity firms looking to provide innovative healthcare offerings while also remaining compliant should be aware of the factors on which the DOJ and state attorneys general may focus when evaluating an FCA enforcement action. And HHS-OIG[22] underscores the importance of private equity investors understanding applicable healthcare laws and the role of an effective compliance program.

Tracking these factors pre- and post-transaction may mitigate FCA risk or, at the very least, help size up FCA risk for possible resolution paths in existing investigations or litigations.

- **Pre-transaction diligence**. Consider what information was presented to the private equity firm pre-transaction and the actions it took (pre- and post-transaction) to address possible compliance concerns.
- **Marketing**. Touting a private equity firm's active management to business prospects may challenge later efforts with regulators to downplay the firm's role in day-to-day operations.
- **Knowledge**. Consider whether the private equity firm might be accused of recklessly disregarding or deliberately ignoring red flags that merit investigation and potential operational changes.
- **Compliance**. If diligence or post-transaction operations surface potential issues, enhancing a portfolio company's compliance function — or developing one if it does not exist — may mitigate FCA risk.
- **Government intervention**. Federal declination may leave the door open for state intervention, as in *Martino-Fleming*. This is a potent risk with more than thirty state FCA statutes.

Notes

[1] Condon, Alan. "Private Equity Had 2nd-Highest Year for Healthcare Deal Activity in 2022, Report Finds." Becker's Hospital Review, February 7, 2023, https://bit.ly/3Tc20HU.

[2] Vinluan, Frank. "VC Report: Biotech Financings Fall, M&A Activity Expected to Pick Up." MedCity News, August 16, 2023, https://bit.ly/3Gt7iXB.

[3] https://bit.ly/47IJHhQ

[4] https://bit.ly/3R86CMu

[5] https://bit.ly/3GtZCEB

[6] https://bit.ly/47IJHhQ

[7] "Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya In the Matter of JAB Consumer Fund/SAGE Veterinary Partners Commission File No. 2110140," https://bit.ly/48mdUN, Federal Trade Commission, June 13, 2022 (FTC Chair Khan stating that "Private equity firms have been particularly active in health care" and cautioning that a "focus on short-term profits in the health care context can incentivize practices that may reduce quality of care, increase costs for patients and payors, and generate appalling patient outcomes").

[8] *See FTC v. U.S. Anesthesia Partners, Inc.*, No. 4:23-cv-03560 (S.D. Tex. Sept. 21, 2023) (alleging that private equity fund, its affiliates, and portfolio company engaged in anticompetitive conduct to consolidate and monopolize the anesthesiology market in Texas through a series of "roll up" acquisitions over several years, and price-setting and market allocation arrangements between defendants and certain competitors).

[9] "Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes," https://bit.ly/3TfmaR5. The White House, March 14, 2022 (Biden Administration stating that: "Private equity firms' investment in nursing homes has ballooned from $5 billion in 2000 to more than $100 billion in 2018," "[t]oo often, the private equity model has put profits before people," and promised to "crack down on bad actors" with added funding for CMS to audit nursing homes, expand the instances in which CMS takes enforcement actions against poor-performing facilities, and increase penalties for violations).

[10] Kroin, Michael, and Ezra Simons. "Industry Voices-Private Equity Investment in Healthcare Is Making a Positive Impact ... Especially for Doctors." Fierce Healthcare, April 28, 2023, https://bit.ly/3GxFnpH.

[11] "Fentanyl False Claims Act Qui Tam Case Leads to $9M Settlement." https://prn.to/47H6dHW. Kang Haggerty LLC, June 1, 2023. The settlement resolved allegations in *U.S. ex rel. Ebu-Isaac v. Insys Therapeutics, Inc.*, 16 Civ. 7937-JLS (C.D. Cal.). In 2018, the federal government and seven states intervened in *Ebu-Isaac* (and four other FCA qui tam actions) but only as to claims against Subsys manufacturer Insys Therapeutics and its operating subsidiary; those claims were resolved in a June 2019 global civil and criminal resolution, where Insys agreed to pay $225 million and enter into 5-year corporate integrity agreement.

[12] "Private Equity Firm and Former Mental Health Center Executives Pay $25 Million Over Alleged False Claims Submitted for Unlicensed and Unsupervised Patient Care." https://prn.to/47H6dHW. Office of the Attorney General of Massachusetts, October 14, 2021. The settlement resolved allegations in *U.S. ex rel. Martino-Fleming and Commonwealth of Mass. v. South Bay Mental Health Ctrs.*, Co. 15-cv-13065-PBS (D. Mass.).

[13] "Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations." https://bit.ly/3GuWLLC. Department of Justice, September 18, 2019. The settlement resolved allegations in *U.S. ex rel. Medrano and Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America.*, No. 15-CV-62617 (S.D. Fla.).

[14] *See United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391, 1400-01 (2023).

[15] *U.S. ex rel. Ebu-Isaac v. Insys Therapeutics, Inc.*, 16 Civ. 7937-JLS, 2021 WL 3619958, at *10 (C.D. Cal. June 9, 2021). The *Ebu-Isaac* court denied defendants' motion to dismiss relators' second amended complaint against private equity firm BelHealth Investment Partners, its three principals, and its two mail-order specialty pharmacies. The court held that relator sufficiently pleaded that between 2013–2016, the pharmacies — under the control of and at the direction of BelHealth and its principals — dispensed and shipped thousands of prescriptions of Subsys nationwide to participants of Medicare, Medicaid, and TRICARE for widespread off-label, illegitimate, and non-medically accepted or necessary uses, in violation of the Controlled Substances Act.

[16] *See, e.g., U.S. ex rel. Martino-Fleming and Commonwealth of Mass. v. South Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 129-30 (D. Mass. 2021) (largely denying defendants' motion for summary judgment because, among other reasons, a factual question existed about whether the private equity firm recklessly disregarded reports of lacking supervision where the firm was aware of applicable government billing procedures and received pre- and post-acquisition diligence reports documenting clinical supervision issues).

[17] *United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America*, No. 15-CV-62617, 2018 BL 445241, at *13-14 (S.D. Fla. Nov. 30, 2018) (denying defendants' motion to dismiss and holding that the complaint adequately alleged that the private equity firm had knowledge of its portfolio company's marketing kickback scheme by funding the portfolio company's commission payments to marketers, who were allegedly paying telemedicine doctors to prescribe a pharmacy's products without a proper review of patients' needs).

[18] *SuperValu Inc.*, 143 S. Ct. at 1404 (declining to adopt an "objective reasonableness" standard for FCA knowledge and holding that petitioners can establish *scienter* by showing that "respondents believed that their claims were not accurate"). The *SuperValu* Court noted that the evidentiary record established defendants' subjective belief that usual and customary pricing of prescription drugs refers to the post-rebate price through emails, among other records, that said "[w]e may have some issues with U&C [usual and customary]" and "if you [match a] price offer, that becomes your usual and customary [price] for that day." *Id*. at 1398.

[19] *See, e.g., Medrano*, 2018 BL 445214, at *15 (holding that plaintiff failed to allege that private equity firm had requisite knowledge of a prescriber-patient scheme where the complaint merely alleged that the firm "knew or should have known" of the scheme's existence and, otherwise, was devoid of allegations that the firm "was aware of any patient complaints regarding unauthorized prescriptions" or other allegations from which the firm's knowledge of the alleged scheme could be "inferred").

[20] *See U.S. ex rel. Mandalapu, et al. v. Alliance Family of Companies LLC, et al.*, No. 4:17-cv-00740 (S.D. Tex.) (DOJ announcing in July 2021 that private equity firm defendant agreed to pay $1.8 million to resolve FCA kickback allegations across six qui tam complaints that the firm discovered misconduct at its portfolio company during diligence but took no actions to stop it despite its ability to exercise control over the portfolio company where it held a management services agreement and a minority of board seats; DOJ also settled allegations with the portfolio company for $13.5 million).

[21] *U.S. ex rel. Johnson, et al. v. Therakos, Inc. et al.*, No. 12-cv-01454 (E.D. Pa.) (DOJ announcing (https://bit.ly/3RtGX29) in November 2020 that private equity defendant agreed to pay $1.5 million of a total $11.5 million settlement to resolve FCA allegations that fraudulent claims were submitted to federal healthcare programs because of improper sales and promotion practices that continued at its portfolio company (a pharmaceutical and medical device entity) after the private equity firm acquired the company — which settled its own FCA claims for the additional $10 million amount).

[22] https://bit.ly/47lJHhQ

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