Whistleblower Lawyers Use False Claims Act to Target Private Equity Firms Invested in Healthcare and Life Sciences

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Introduction

Recent developments demonstrate that sponsor backed companies in the health care and life sciences sectors, and in some instances private equity firms and professionals, have entered a new era of heightened regulatory scrutiny and enforcement risk. This article addresses the U.S. Department of Justice (DOJ) use of the federal False Claims Act (FCA) to pursue private equity investors and their portfolio companies.[1] While DOJ has been actively investigating private equity portfolio companies, the driver behind the majority of DOJ's investigations are whistleblower plaintiff attorneys who file *qui tam* suits alleging FCA violations. These attorneys have found a receptive audience in both legislative and executive branches of the federal government and are bringing pressure on DOJ to ramp up its focus on the private equity industry, a perceived deep-pocket in FCA cases.

President Biden's recent State of the Union address on March 1, 2022 offers a prominent example of this new era. President Biden said "[A]s Wall Street firms take over more nursing homes, quality in those homes has gone down and costs have gone up."[2] The day prior to the address, the White House released a fact sheet containing allegations that private equity-owned nursing facilities caused cost increases for government payers coupled with a deterioration in the quality of care.[3] Citing an analysis by a progressive think tank, the White House asserted that private equity investment in nursing facilities grew from $5 billion in 2000 to over $100 billion in 2018.[4] That release asserted that "[t]oo often, the private equity model has put profits before people — a particularly dangerous model when it comes to the health and safety of vulnerable seniors and people with disabilities."[5] To combat perceived

failures, the Administration announced a set of reforms intended to improve care by focusing on staffing levels, expanded government inspections, and transparency of ownership by creating a database to track and identify nursing home owners.[6] While focused on nursing homes, the White House pronouncements serve as an admonition to the private equity industry that it will be the subject of heightened governmental scrutiny.

The Broader Political Context

President Biden's recent call-to-arms is not the first governmental effort to focus on private equity investment. On March 25, 2021, the U.S. House of Representatives' Ways and Means Oversight Subcommittee called a hearing to examine private equity's role in healthcare.[7] The subcommittee's Chairman, U.S. Representative Bill Pascrell, Jr. (D-NJ), asserted in a post-hearing editorial that "[t]he time has come to shine a bright beam on how private equity ownership in our healthcare system affects patients. Private equity firms have grown too large and too far-reaching. They must face stricter accounting in their growth."[8] At the hearing, Rep. Pascrell delineated committee Democrats' worries about how private equity "affects patient safety, cost, and jobs," while Republican Ranking Member Mike Kelly (R-PA) made clear that his committee members do not believe that the issue deserves governmental attention.[9]

Much like President Biden's address, the Oversight Subcommittee focused on private equity-owned nursing homes during the COVID-19 pandemic. The hearing featured the testimony of Sabrina Howell, an Assistant Professor from the Stern School of Business at New York University.[10] Professor Howell testified that she estimated that being a patient in a private equity-owned nursing home increased the short-term probability of death by approximately 10 percent, and increased the amount billed to governmental payers by approximately 11 percent.[11] In contrast, utilizing data from the pandemic, Rep. Kelly insisted that Congress should be focused on state and local government actions that required COVID-19 positive patients to return to nursing facilities.[12] The hearing did not include insight from investors in nursing homes, and there was limited discussion of the role that private equity has played in the innovation, expansion, and growth of the nursing home industry. The discussion of investor profit at the expense of quality of care leaves much to be desired, including that many new technologies, discoveries, and time sensitive expansions during the COVID-19 pandemic, including telehealth[13] and vaccine development[14] were made possible with private equity backing.[15]

During the subcommittee hearing, participants also addressed legislative proposals to increase transparency of private equity ownership across healthcare sectors.[16] Chairman Pascrell cited the FCA as a tool being used to root out and punish fraud in private equity owned-companies. Relying on a progressive think tank analysis, Pascrell referred to 25 healthcare companies with some degree of private equity ownership that have resolved FCA cases since 2013 for an aggregate of over $570 million.[17]

The FCA permits DOJ, and certain whistleblowers, to pursue fraud when materially false claims are knowingly submitted to government payers.[18] On February 1, 2022, DOJ announced that it recovered over $5.6 billion in settlements and judgments involving the FCA in fiscal year 2021, $5 billion of which came from companies accused of defrauding Medicare and Medicaid.[19] In its press release, the Acting Assistant Attorney General touted that annual FCA recoveries are "one of the most important tools available to the department to deter and to hold accountable those who seek to misuse public funds."[20] The FCA creates liability, including treble damages and

significant per claim penalties for anyone that knowingly presents, or *causes* to be presented, a false claim for payment to the government, or that knowingly makes or uses, or *causes* to be made or used, a false record or statement in connection with a claim.[21] The FCA requires that DOJ or the whistleblower establish that a defendant acted with either (a) actual knowledge, (b) deliberate ignorance, or (c) reckless disregard.[22] These seemingly simple standards have led to conflicting circuit court decisions because, among other things, FCA cases often involve an assessment of whether a defendant's interpretation of a rule or regulation was "objectively reasonable" and whether the government has provided notice that the defendant's interpretation was incorrect.[23]

Examples abound showing how executive and legislative branch pressure on DOJ have led to a focus on private equity investment in healthcare and life sciences. In June of 2020, the former Acting Assistant Attorney General said that DOJ would pursue FCA cases against private equity firms, especially where firms take an "active role" in illegal conduct by a portfolio company.[24] But the warning extends well beyond those taking an "active role," as DOJ has been pursuing FCA liability against private equity investors even where allegations that the companies took an "active role" are absent. In these cases, it is not clear what theory of liability exists.

Against this background, private equity firms can expect whistleblower lawyers to increase the number of FCA *qui tams* across healthcare sectors. This article provides an overview of how the FCA is being used by the whistleblower bar and DOJ to investigate and penalize private equity firms for portfolio company conduct. The article then discusses recent FCA settlements that involve private equity firms, and provides recommendations for firms and their portfolio companies to mitigate the risk of potential FCA liability.

False Claims Act

The federal FCA allows DOJ or whistleblowers, known as relators, to file lawsuits to recover treble damages, per claim penalties, as well as legal fees and costs from companies that defraud the government.[25] When FCA suits are filed by relators, the cases are filed under seal and called *qui tam* suits. Any time a *qui tam* suit is filed, DOJ is required to investigate the allegations.[26] Thereafter, DOJ has the option of intervening in the *qui tam* suit and assuming responsibility for the litigation.[27] In over two-thirds of *qui tams,* DOJ declines to intervene; in these cases, the relator maintains responsibility for prosecuting the case.[28] When DOJ declines to intervene, the United States remains the real party in interest and receives at least seventy percent of any recovery, with the relator receiving a percentage of the total.[29] If a relator wins a case where the government has not intervened, then the relator may be entitled to a larger share of the recovery.[30] As most companies that operate in the healthcare and life sciences sectors know well, the FCA's whistleblower provisions and financial incentives spur hundreds of lawsuits each year.[31]

The most frequently utilized sections of the FCA impose liability for any individual or entity that knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval by the government.[32] 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.[33] Companies and individuals also can be liable for conspiring to violate the FCA, and conspiracy claims are analyzed under traditional civil conspiracy precedent.[34] A "claim" is any request or demand for money that may be made directly or through an intermediary, such as a vendor. In the FCA context, the term "knowingly" has three standards:

(a) actual knowledge; (b) deliberate ignorance; or (c) reckless disregard.[35]

Use of False Claims Act to Target Private Equity

Healthcare companies have been in the FCA cross-hairs for decades. In the last three fiscal years, FCA recoveries in the healthcare sectors came from pharmaceutical and device manufacturers, managed care providers, hospitals, pharmacies, clinical laboratories, and physicians, among others. Until recently, private equity firms and their principals have avoided FCA scrutiny because the law does not provide a direct avenue to pierce the corporate veil. Now, relators' counsel are increasingly targeting private equity firms and their principals as a potential deep pocket for FCA recovery, on the theory that they may be responsible for *causing* the submission of false claims made by their portfolio companies. Driven by whistleblower complaints and now buoyed by decrees from the White House and Congress, DOJ is also pursuing private equity firms and their owners with vigor.

Many of the cases involving private equity firms have been resolved without an admission of liability and before evidentiary discovery regarding the firms' involvement (or lack thereof). In cases that are farther along or where the claims are more detailed, the allegations typically follow a common pattern. The allegations begin by focusing on information that the private equity firm and its representatives receive during the diligence process. Ignoring corporate form and management's role, relator's attorneys allege that private equity firms have implicit control over operations and compliance once invested.

Whether the relator's allegations are viable, or whether what was learned during diligence provided sufficient notice of wrongdoing to the firm, DOJ seems to be taking the position that compliance issues raised during diligence are enough to hold private equity firms liable under the FCA. In seeking to do so, DOJ is required only to establish that the firm "caused" the submission of false claims. Notably, this type of standard does not require that the firm file or encourage the filing of false claims, and failing to stop such conduct could be deemed sufficient. Recently, a Massachusetts federal judge allowed a case to proceed to trial on the basis that causing the submission of a false claim can be met where there is evidence that a private equity firm "rejected recommendations" to bring a portfolio company into compliance, even without evidence that the firm took any affirmative step toward filing false claims.[36] The following sections provide an overview of recent FCA cases involving private equity firms that contain fact patterns that suggest pro-active steps for firms to take to avoid FCA liability.

U.S. ex rel. Ebu-Isaac, et al. v. Insys Therapeutics, Inc., et al.

On June 9, 2021, U.S. District Judge Josephine Staton in the Central District of California denied a private equity firm's motion to dismiss a FCA case against it and its portfolio companies.[37] Keeping in mind that the court treats the allegations in the complaint in a light most favorable to DOJ and the relator, the court's analysis is instructive.[38]

The complaint alleged "cooperation" among private equity investors and a specialty pharmacy "to carry out a *joint business venture*" where "separate business entities were managed and used to varying degrees to carry out a *common goal*."[39] In the order, the first issue addressed by the court was whether a private equity firm could be liable for the acts of a portfolio company under the FCA. The Court noted that the FCA "imposes liability on 'any person who … knowingly presents, *or causes to* be presented, a false or fraudulent claim for payment or approval.'"[40] The court ruled that "where an entity 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."[41] The Court took note that the complaint alleged that the private equity firm claimed to provide "management, oversight, and strategic guidance for the operations of"[42] its portfolio company, and that "communications from the top officials of" the private equity investor did not "distinguish among the various entities and suggest cooperation by all the entities . . . ."[43]

The Court noted that the complaint contained allegations that the managing partner of the firm sent e-mails that failed to "distinguish among the [private equity] entities, and he appears to speak on behalf of them all."[44] In the referenced e-mail, the partner used "the collective pronoun 'we' to discuss volumes of drugs to be acquired and rebates to be paid" to the portfolio company.[45] The Court opined that "[i]n context, this email is one voice speaking collectively for" the private equity investor and its portfolio company.[46] In addition to the e-mail, the Court referenced "a press release announcing the acquisition of" the portfolio company and quoted its chief operating officer as saying that the private equity investor "is the perfect partner to accelerate [the portfolio company's] growth from a regional company to a national platform."[47] Finally, the Court referred to the "overlap of officers and board members for the various entities."[48] Based on these allegations, the Court found the complaint sufficiently alleged that the private equity defendants "worked with or through other entities and thereby caused false claims to be presented for payment."[49]

While not a decision on the merits, the order provides several constructive points to consider. First, make sure that corporate forms are respected by having the management of portfolio companies operate independently and report to the board of directors, not directly to any investor. Second, be mindful that communications from private equity investors, whether e-mail, text, or oral, may be easy misinterpreted. Lastly, when promoting investments in press releases, investors and portfolio companies should carefully evaluate the language they use to describe their relationship.

U.S. ex rel. Medrano, et al. v. Diabetic Care RX, LLC, et al.

On September 18, 2019, DOJ announced a $21.36 million settlement with compounding pharmacy Diabetic Care Rx, LLC d/b/a Patient Care America (PCA), two PCA officers, and PCA's private equity investor.[50] The settlement marked the end of a case where DOJ intervened against a private equity investor defendant. DOJ described the resolution as demonstrating its "continuing commitment to hold all responsible parties to account for the submission of claims to federal health care programs that are tainted by unlawful kickback arrangements."[51] In the settlement, the private equity firm defendant did not admit liability.

When the case was filed under seal in 2015, the relators alleged that the private equity owner directed PCA to enter into an illegal kickback scheme.[52] The complaint contained claims that the private equity owner provided funds to pay commissions to marketers, who were paying telemedicine physicians a "kickback" to prescribe PCA's products without regard to medical necessity. The relator claimed that the private equity investor's funding of these commissions was the direct cause of fraudulent billing. Based upon its investigation, DOJ intervened in the case. In 2018, DOJ filed its complaint in intervention against the pharmacy and its private equity controlling investor.[53] 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.[54] In particular,

DOJ focused on two partners of the private equity firm who served as officers of the pharmacy and exerted significant control over the alleged scheme.[55]

DOJ alleged that the private equity firm, which acquired PCA two years before the company entered into the marketing agreements at issue, initiated PCA's entry into the allegedly fraudulent scheme. Specifically, DOJ alleged that the private equity firm approved the decision to use marketers to generate referrals knowing that TRICARE was the primary source of PCA's revenue.[56] DOJ accused the private equity investor of hiring a CEO to "launch" the alleged scheme, which allegedly earmarked money for kickback payments.[57] In addition, DOJ alleged that the private equity firm received regular financial reports showing PCA's revenue and commissions paid to marketers, and that the private equity firm funded $2 million of the payments to marketers. The complaint contained allegations that the firm's purported focus on profit—including its plans to sell the pharmacy in the near term—had propelled it to enter the unlawful business at issue. The private equity firm moved to dismiss the allegations. The court initially dismissed the FCA claim, but granted leave to amend. Notably, nothing in the court's decisions or DOJ's filings suggest that a company's conduct can be imputed to a private equity investor merely by virtue of their investment; rather, in *dicta*, the magistrate judge wrote that an investor can be liable under the FCA if the investor "devises or implements unlawful business practices" that would not have otherwise existed.[58] DOJ subsequently filed an amended complaint and the case settled prior to argument on the renewed motions to dismiss.

U.S. ex rel. Johnson, et al. v. Therakos, Inc., et al.

On November 19, 2020, DOJ announced an FCA settlement with a private equity firm in *U.S. ex rel. Johnson v. Therakos, Inc.*[59] Therakos and its private equity investor agreed to pay a combined $11.5 million to resolve FCA allegations.[60] DOJ alleged that between 2006 and 2015, Therakos engaged in off-label marketing to promote its cancer treatment for use in pediatric patients. Therakos was a J&J subsidiary from 2006 to 2012, at which point it was acquired by a private equity firm.

Unlike *Medrano*, there were no allegations as to the private equity firm's involvement in the alleged off-label promotion. Instead, the complaint contained allegations that the improper off-label promotion continued after the private equity firm acquired Therakos, and that the firm hired a former Therakos employee as the company's new CEO. These allegations stand in stark contrast to other cases and appear to border on piercing the corporate veil due to the lack of the private equity investor's involvement. Given that the settlement was reached prior to DOJ filing a complaint in intervention, however, DOJ may have made additional allegations had the case proceeded. The private equity firm denied the allegations against it, as part of an agreement to settle its involvement in the case for $1.5 million, out of the combined settlement amount of $11.5 million.

U.S. ex rel. Mandalapu, et al. v. Alliance Family of Companies LLC, et al.

On July 21, 2021, DOJ announced a $15.3 million settlement with Alliance Family of Companies LLC (Alliance), a national ambulatory EEG testing company, and a private equity firm that had invested in Alliance in 2017.[61] The settlement resolved claims brought in five sealed *qui tams* that had been consolidated before U.S. District Court for the Southern District of Texas.[62] In addition to claims against Alliance, several of the *qui tams* contained allegations against one of the private equity firms that had invested in Alliance.[63] The relators alleged

that Alliance submitted false claims to federal healthcare programs for EEG tests that were incorrectly coded to increase reimbursement, and the relators asserted that claims were false because they resulted from improper kickbacks paid by Alliance to ordering physicians.[64] The alleged kickback scheme involved "allowing" ordering physicians to independently bill for interpreting the EEG tests even though a contracted neurologist had already performed the EEG interpretation.[65]

In addition to Alliance, relators alleged that a private equity investor discovered the alleged improper activity during the due diligence process that it undertook pursuing its investment in the company. Like the *Therakos* case discussed above, there were no specific allegations as to the private equity firm's involvement in the alleged schemes. Instead, and once again, DOJ asserted that the alleged schemes continued after the private equity firm invested in Alliance. Alliance and its private equity investors denied all wrongdoing but agreed to resolve the cases to avoid the cost of protracted litigation. Unlike the other cases discussed in this article, the private equity firms in these cases sued the founders of Alliance for fraud during the diligence process, claiming that they actively misled investors about the alleged schemes.

U.S. ex rel. Martino-Fleming v. South Bay Medical Health Centers, et al.

In October 2021, DOJ reached the largest FCA settlement yet with a private equity firm.[66] The firm paid nearly $20 million to settle claims under the FCA and the Massachusetts false claims statute that a mental health company it owned allegedly billed Medicaid for services provided by individuals who were not supervised in accordance with Massachusetts Medicaid regulations.[67] The private equity firm did not admit wrongdoing in the settlement. Like the *Therakos* and *Alliance* cases, this conduct was alleged to have pre-dated the firm's investment in the company. DOJ declined to intervene in the case, but the relator pursued the federal claims and the Massachusetts Attorney General's Office pursued the state claims.

This was the first FCA case against a private equity firm in which the court ruled on summary judgment motions. In its summary judgment decision, the District Court held that there was a sufficient factual dispute on the question of the private equity firm's potential liability to allow the case to proceed. In the decision, the Court found that there was evidence that the firm "rejected recommendations" to bring the portfolio company into compliance. The Court held that this amounted to "knowing ratification" of a pre-acquisition "policy" of submitting false claims.[68]

Diligence Process & Compliance

For private equity firms looking to invest in healthcare and life science companies, the goal is to avoid DOJ investigations, spurious whistleblower claims, financial losses, devotion of time to governmental investigations and litigation, reputational damage, and adverse disclosure requirements during fund raising. While effective compliance is an important factor, nothing can stop relators from filing cases and, once filed, DOJ has the statutory obligation to investigate when they do. The expected cost of conducting an internal investigation, producing documents to DOJ, defending DOJ interviews of employees, executives, and board members alone is enough to end many proposed investments—not to mention the reputational risks that are associated with being in DOJ's crosshairs.

To limit exposure, private equity firms should assure that the investment team and board representatives are well trained in compliance and FCA risk. The team should conduct comprehensive due diligence focused on regulatory areas that are specific to the business in question.

Firms should be particularly cautious when dealing with companies in high risk sectors of the healthcare market, including companies that bill Medicare Part B (which is at issue in many healthcare fraud cases) and companies whose business entails promotion of products or services to prescribers.

If allegations come to light prior to closing, buyers should consider requesting that the seller investigate and, if necessary, remedy the situation and utilize the HHS-OIG self-disclosure protocol to report the problem prior to close. Self-disclosure before there is a pending FCA case can result in more favorable resolution terms. Additionally, the sooner firms are able to identify compliance issues that may lead to FCA liability, the sooner the value of the problem can be quantified and addressed in the deal through appropriately tailored indemnification provisions or other means. After closing, assure that compliance is operating optimally and invest in seasoned compliance officers. Robust compliance processes and procedures including with respect to handling compliance complaints is key.

When portfolio companies implement new business strategies, assure that counsel has evaluated and determined that the new strategies fall squarely within the heartland of common practices for the industry. New avenues that drive sales and promotion in healthcare can be high risk. Any time an employee interacts with an ordering physician or referral source, there are potential risks, including under the Anti-Kickback Statute and Stark Act, in addition to the FCA. Investors can focus on improving performance and do so with the direct involvement of compliance personnel.

Finally, 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.

Conclusion

Private equity firms should expect increasing DOJ scrutiny of investments in healthcare and life sciences. Given the costly and time-consuming nature of FCA investigations, the best defense is a good offense: firms should be careful to respect corporate formalities and bolster their processes to identify and remediate any compliance issue when it arises, both in terms of pre-acquisition diligence and post-acquisition compliance programs. To the extent FCA investigations do arise, firms should retain experienced counsel to advise on this evolving area of law.

Endnotes

1. The False Claims Act, 31 U.S.C. §§ 3729-33.
2. Transcript of President Joseph R. 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/*.
3. *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/* ("Private equity firms have been buying up struggling nursing homes, and research shows that private equity-owned nursing homes tend to have significantly worse outcomes for residents. Private equity firms' investment in nursing homes has ballooned from $5 billion in 2000 to more than $100 billion in 2018, with about 5% of all nursing homes now owned by private equity firms. Too often, the private equity model has put profits before people—a particularly dangerous model when it comes to the health and safety of vulnerable seniors and people with disabilities. Recent research has found that resident outcomes are significantly worse at private equity-owned nursing homes**: . . .**").
4. *Id.*
5. *Id.* ("One working paper examining 18,000 nursing home facilities over a seventeen-year period found that private equity ownership increased excess mortality for residents by 10%, increased prescription of antipsychotic drugs for residents by 50%, decreased hours of frontline nursing staffing by 3%, and increased taxpayer spending per resident by

11%. That suggests an additional 20,150 lives lost as a result of private equity ownership.")(*citing* Gupta, A., *et al*., *Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes*, Bureau of Economic Research, Working Paper 28474 *https://www.nber.org/papers/w28474* (Feb. 2021)).

6. *Id.*
7. *https://waysandmeans.house.gov/legislation/hearings/oversight-subcommittee-hearing-examining-private-equity-s-expanded-role-us* (March 25, 2021); Hearing transcript: *https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/OV-3%20Hearing%20Transcript.pdf*.
8. 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*.
9. *Id.*
10. Statement of Sabrina T. Howell, Ph.D., Asst. Prof. NYU Stern School of Business, *Private Equity in Healthcare*, U.S. House of Representatives Ways and Means Oversight Subcommittee. (March 25, 2021) *https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/S.%20Howell%20Testimony.pdf*.
11. *Id.* ("We find that going to a private equity owned nursing home increases the probability of death during the stay and the following 90 days by about 10% of the mean of 17%, implying about 20,150 lives lost due to private equity ownership of nursing homes during our sample period. In turn, we calculate a mortality cost of about $21 billion in 2016 dollars. This is about twice the total payments – $9 billion – made by Medicare to private equity facilities during our after sample period.").
12. *https://waysandmeans.house.gov/legislation/hearings/oversight-subcommittee-hearing-examining-private-equity-s-expanded-role-us* (March 25, 2021); Hearing transcript: *https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/OV-3%20Hearing%20Transcript.pdf*.
13. In 2021, telehealth use increased to a stabilized 38 times that seen before the early COVID-19 spike in 2020. Further, investment in virtual care and digital health skyrocketed, fueling innovation, with three times the level of investment in 2020 than it had in 2017. 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*.
14. 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*.
15. Stanford, J., Stat News, Opinion, *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/*.
16. *Id.* at *infra* fn. 8.
17. *See* Private Equity Stakeholder Project, *Money for Nothing: How Private Equity has Defrauded Medicare, Medicaid, and Other Government Health Programs, and How that Might Change* (Feb. 22, 2021*), https://pestakeholder.org/report/money-for-nothing-how-private-equity-has-defrauded-medicare-medicaid-and-other-government-health-programs-and-how-that-might-change/*.
18. *United States ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 388 (5th Cir. 2008) (*citing Avco Corp. v. U.S. Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989)).
19. Press Release*, Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021*, Feb. 1, 2022*, https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year*.
20. *Id.*
21. 31 U.S.C. § 3729(a)(1), 15 C.F.R. § 6.3(a)(3). For 2022, per claim FCA penalties can range up to $23,607. This inflation adjusted per claim number is facially excessive. For example, if a FCA suit involved the submission of a single claim for 10,000 patients, then the maximum statutory penalty for that year would exceed $236 million (on top of treble damages of the amount billed). In most cases, the mandatory penalty provisions effectively end any opportunity to litigate a dispute before a finder of fact. This is one reason the FCA case law is sparse given that rational companies are forced to settle even spurious claims rather than risk bankruptcy. Congress should rethink these penalty and damage provisions in order to allow those wrongly accused to have their day in court.
22. 31 U.S. Code § 3729(b)(1); *See United States v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013) (reckless disregard is "the most capacious of the three" standards).
23. *See United States ex rel. Sheldon v. Allergan Sales*, LLC, 24 F.4th 340, 347–48 (4th Cir. 2022)(citing *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 127 S. Ct. 2201 (2007)).
24. Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform (June 26, 2020*), https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims*.
25. 31 U.S.C. §§ 3729-33.
26. 31 U.S.C. § 3730.
27. *Id.* For the most up-to-date aggregated 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.
28. *Id.*
29. *Id.*
30. *Id.*
31. 31 U.S.C. § 3730(d).

32. 31 U.S.C. § 3729 (a)(1)(A).
33. 31 U.S.C. § 3729 (a)(1)(B).
34. *See U.S. ex rel. Westmoreland* v. *Amgen, Inc.*, 738 F. Supp. 2d 267, 280 (D. Mass. 2010).
35. *Id.* at fn. 25.
36. *U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center*, Civ. Action No. 15-13065 (D. Mass. May 19, 2021)(In this declined qui tam, the relator alleged that South Bay submitted false claims to Medicaid because the underlying services were not appropriately supervised by licensed personnel).
37. *See 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, at 5 (C.D.Cal. June 9, 2021).
38. *Id.* at 2021 WL 3619958.
39. *Id.* at 5-7 (emphasis added).
40. *Id.* at 6 (*citing* 31 U.S.C § 3729 (a)(1)(A) and *United States v. Mackby*, 261 F.3d 821, 827-28 (9th Cir. 2001) ("[A] person need not be the one who actually submitted the claim forms in order to be liable.")).
41. *Id.* at 5 (emphasis added).
42. The Court also 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 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." *Id.* Further, the court noted that the private equity firm allegedly "negotiated with INSYS on behalf of" its portfolio company. *Id.*
43. *Id.* at 7.
44. *Id.*
45. *Id.*
46. *Id.*
47. *Id*.
48. *Id*.
49. *Id.*
50. DOJ Press Release (Sept. 18, 2019), *https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million*.
51. *Id.*
52. *Id.*
53. *United States ex rel. Medrano v. Diabetic Care Rx, LLC d/b/a Patient Care America, et al.* (S.D. Fla. No. 15-62617).
54. *Id.*
55. *Id.*
56. *Id.*
57. *See Medrano*, 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).
58. *See Id.* at *10, *13 (finding that the investor in *Medrano* was accused of advancing a "marketing kickback scheme that ultimately led to the presentment of claims to TRICARE," nevertheless the court recommended that the FCA claim be dismissed because it fell "short of Rule 9(b)'s heightened pleading standard"); *Medrano*, No. 15-CV-62617, 2019 WL 1054125, at *6 (S.D. Fla. Mar. 6, 2019) (declining to review this finding because "the Court agrees that the FCA claim should be dismissed").
59. 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*.
60. *Id.*
61. DOJ Press Release (July 21, 2021), *https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-kickback-and-false*.
62. *Id.*
63. *Id.*
64. *Id.* (all qui tams in this matter remain under seal as of April 2022).
65. *Id.*
66. Mass AG Press Release (Oct. 14, 2021), *https://www.mass.gov/news/private-equity-firm-and-former-mental-health-center-executives-pay-25-million-over-alleged-false-claims-submitted-for-unlicensed-and-unsupervised-patient-care*.
67. *Id.*
68. *Martino-Fleming*, Civ. Action No. 15-13065 (D. Mass. May 19, 2021).