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FCA Trends To Watch For Health, Life Sciences Cos.

By **George Breen, Erica Bahnsen and Daniel Fundakowski** (March 7, 2022, 6:01 PM EST)

This article takes a look at the U.S. Department of Justice's 2021 health care fraud stats, as well as key False Claims Act trends to watch throughout the rest of this year.

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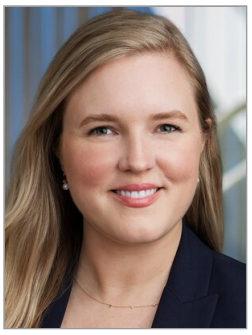

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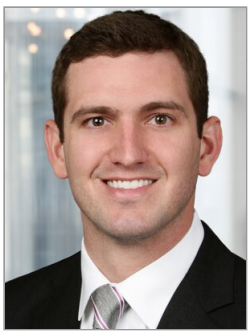

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False Claim Act Stats

While the number of new False Claims Act actions filed in fiscal year 2021 decreased, government recoveries reached a record high, particularly from the health care and life sciences sectors.

With collections amounting to $5.6 billion, fiscal year 2021 marks the U.S. Department of Justice's largest annual total FCA recovery since fiscal year 2014, and more than twice the $2.3 billion received in fiscal year 2020.

Fiscal year 2021 was also a record-shattering year for the DOJ as it relates to health care fraud enforcement — more than $5 billion, 90% of the total, was obtained from cases pursued against individuals and entities in the health care and life sciences industries, eclipsing the $1.9 billion recovered in fiscal year 2020.[1]

While high recoveries in 2021 are largely due to settlements with prescription opioid manufacturers, including a $2.8 billion resolution with one opioid manufacturer, the continued focus on health care and life sciences companies, by both DOJ and qui tam relators, is telling.

Relator actions and awards reached a decade low in fiscal year 2021. There were 598 new actions brought under the qui tam provisions of the FCA in fiscal year 2021, a decrease from the 675 actions filed in fiscal year 2020, and the lowest number of filings since fiscal year 2010. Of the 598 qui tam cases filed in fiscal year 2021, 388 were health care-related (65%), the lowest number of health care-related qui tam cases filed since fiscal year 2010.

The enforcement statistics suggest increasing provider exposure in declined qui tam cases where relators pursue FCA cases without the DOJ's intervention.[2] The $452 million collected in those cases from the health care and life sciences industries is the largest recovery since fiscal year 2015 and the second largest recovery in reported history.

The Garland Memo

On July 1, 2021, shortly after beginning his tenure as attorney general, Merrick Garland issued an internal memo rescinding the prior administration's actions limiting the utility of guidance documents in enforcement actions.

The Garland memo explains that while guidance documents alone cannot form the basis for an enforcement action, they "may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements."[3]

The memo further states that to "the extent guidance documents are relevant to claims or defenses

in litigation, Department attorneys are free to cite or rely on such documents as appropriate."

In line with the DOJ's actions, in October 2021, the U.S. Department of Health and Human Services issued a proposed rule that would withdraw two regulations issued during the prior administration that were directed at HHS' issuance of guidance documents and processes around enforcement actions.

The first rule is the good guidance practice rule, which required that each guidance document issued by HHS include a statement clarifying that the guidance does not have the force and effect of the law and is not binding unless incorporated in a contract.

The second rule is the transparency and fairness in civil administrative enforcement actions rule, which limits how HHS may use guidance documents in administrative enforcement actions.[4]

The practical effect of these departures from the practices of the prior administration is unclear, as the DOJ and HHS remain subject to the limitations set forth by the U.S. Supreme Court's 2019 decision in Azar v. Allina Health Services.

In Allina, the Supreme Court held that any Medicare issuance that establishes or changes a substantive legal standard governing Medicare eligibility, benefits or payments for services must go through notice-and-comment rulemaking to be valid.[5]

While the release of the Garland memo is likely to bolster enforcement that emphasizes alleged noncompliance with subregulatory guidance, the Supreme Court's Allina decision should temper those efforts.

DOJ's Cybersecurity Initiative

On Oct. 6, 2021, the DOJ announced the launch of its Civil Cyber-Fraud Initiative through which it will leverage the FCA to pursue cybersecurity-related fraud by government contractors and grant recipients.[6]

Specifically, the new initiative will target individuals and entities that are "knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches."

Beyond enhanced government enforcement in this arena, this initiative is expected to spur an uptick in whistleblower activity in cases of suspected noncompliance with cybersecurity requirements or misrepresentations made to the government.

Given the stated intent to use the FCA to address these issues, rigorous and ongoing monitoring and auditing of cybersecurity policies and practices for compliance in these areas — and ensuring understanding of contractual obligations — will be key in mitigating this enforcement risk.

COVID-19 Enforcement Efforts

Congress has appropriated $178 billion to the provider relief fund to reimburse eligible providers for health care-related expenses or lost revenues attributable to COVID-19.

As a condition of receiving the relief funds, eligible providers are required to comply with the provider relief fund's terms and conditions, which are extensive and include representations to the government that the funds would be used only to prevent, prepare for or respond to the coronavirus, or that the funds would reimburse providers for health care-related expenses, or lost revenues, attributable to COVID-19.

Throughout 2021, the DOJ was consistent in its messaging, as evidenced by the establishment of a COVID-19 fraud enforcement task force, that COVID-19-related fraud is a top priority and that misuse of provider relief funds could lead to FCA exposure for providers and regulated entities.[7]

Moreover, the complex and evolving provider relief fund guidance issued by the government — and

the sweeping nature of the required certifications — will make FCA cases predicated on alleged misuse of provider relief funds fertile ground for relators.

Looking ahead in 2022, we expect a wave of DOJ COVID-19 enforcement, especially with the billions in new funding recently distributed from the provider relief fund — more than $2 billion to over 7,600 providers in late January — and the troves of data that have recently been submitted to the government by recipients of the provider relief funds.[8]

Consistent with the DOJ's swift FCA enforcement in connection with Paycheck Protection Program funds, we expect the DOJ to move quickly in investigating perceived fraud in connection with provider relief funds, and we encourage providers and regulated entities to be prepared for enhanced government scrutiny in connection with the receipt, distribution and expenditure of those funds.[9]

FCA Actions Against Private Equity Stakeholders

Significant settlements with private equity stakeholders were announced in 2021.

By way of example, the private equity owners and former executives of South Bay Mental Health Center agreed to pay $25 million to resolve allegations that they knew that the center was providing unlicensed, unqualified and unsupervised services in violation of regulatory requirements and caused fraudulent claims to be submitted to MassHealth.[10] The private equity firm held a majority of seats on the center's board of directors and one of the firm's executives served as CEO of the center.[11]

Similarly, Alliance Family of Companies LLC, a national electroencephalography testing company based in Texas, and its minority private equity investor agreed to pay a combined $15.3 million to resolve allegations that it submitted or caused to be submitted false claims to federal health care programs that resulted from kickbacks to referring physicians, or that sought payment for work not performed, or for which only a lower level of reimbursement was justified.

According to the DOJ, the private equity investor became aware of the alleged kickbacks during the due diligence phase of its investment and allowed the conduct to continue once it commenced management of Alliance.[12]

These settlements suggest that private equity companies will continue to be an area of focus in FCA enforcement and underscore the need for effective review of compliance issues in diligence and correction of problems identified post-acquisition.

Clinical Judgment in FCA's Falsity Requirement

While the FCA requires that claims be false or fraudulent in order to give rise to liability, the statute does not define those terms, and this has become a contentious issue for FCA cases predicated on the propriety of clinical judgments.

In the landmark 2019 ruling of U.S. v. AseraCare, the U.S. Court of Appeals for the Eleventh Circuit held that FCA liability must be based on an objective falsehood, not a subjective difference of opinion.[13]

The Eleventh Circuit recently reapplied its logic in U.S. ex rel. Bell v. Cross, holding that "in order for a clinical judgment to be 'false' in the context of the FCA, it must be objectively false."[14]

Without evidence establishing a verifiable, factual flaw in clinical judgment, the district court held that the relator's testimony regarding her beliefs that therapy was unnecessary established nothing more than a difference of opinion, which "falls short of establishing objective falsity."

The U.S. Court of Appeals for the Ninth Circuit took another approach in U.S. ex rel. Winter v. Gardens Regional Hospital & Medical Center, where it considered whether an objective falsehood is required at the pleading stage to avoid dismissal.[15]

The Ninth Circuit held that the broad language of the FCA "does not distinguish between 'objective' and 'subjective' falsity or carve out an exception for clinical judgments and opinions," and thus held that a physician's clinical judgment could be false under the FCA "if the opinion is not honestly held,

or if it implies the existence of facts ... that do not exist." The Supreme Court denied certiorari on Feb. 22, 2021.

While the circuits remain divided on the issue of falsity in FCA cases, the practical effects of the circuit split and the differing standards are likely to become more apparent in 2022 as courts continue to apply them.

Ramifications of Government's Continued Payment in Evaluating FCA Materiality

The FCA requires that a defendant's statement or conduct be material to the government's decision to pay the claim. In accordance with the Supreme Court's 2016 decision in Universal Health Services Inc. v. Escobar, the touchstone of materiality is whether the government would have paid the claim in question if it had known of the defendant's noncompliance with an applicable law or regulation.[16]

In the latest decision addressing this issue, U.S. ex rel. Prose v. Molina Healthcare of Illinois, the relator alleged that Molina falsely certified that it was providing skilled nursing facility services to its riskiest, and most expensive, patients, yet failed to actually do so one year into its capitation contract with the state of Illinois, where Molina was paid fixed amounts for each beneficiary at specific tiers.

Molina had subcontracted with a provider to cover the skilled nursing facility services and the relator alleged that, even after that subcontract was terminated and no skilled nursing facility services were being provided, Molina continued to collect money from the state on the contract that included skilled nursing facility services.[17]

Molina argued that the government had actual knowledge that Molina could no longer provide these skilled nursing facility services because the government continued paying after the relator's FCA complaint was filed, and the state renewed its contract with Molina twice during that time.

Although Molina prevailed in the district court, a split panel at the U.S. Court of Appeals for the Seventh Circuit reversed, finding Molina's certifications to be material, notwithstanding continued payment of claims after learning that Molina did not provide the relevant services. Molina filed a certiorari petition on Feb. 14 this year.

This decision represents one of many approaches courts take to evaluating continued payment in the context of materiality. Circuits remain split on how much leeway to grant the government in light of continued payment despite knowledge of noncompliance.

Safeco's Interpretation of the Reckless-Disregard Scienter Standard

To satisfy the FCA's scienter element, a defendant must either have actual knowledge of the falsity of information, act in deliberate ignorance of its truth or falsity, or act in reckless disregard of its truth or falsity.

In Safeco Insurance Co. v. Burr in 2007, the Supreme Court held that a defendant who acts under an incorrect interpretation of a relevant statute or regulation does not act with reckless disregard if the interpretation is objectively reasonable and no authoritative guidance cautioned the defendant against it.[18]

In U.S. ex rel. Schutte v. SuperValu last year, the Seventh Circuit joined the U.S. Courts of Appeals for the Third, Eighth and Ninth Circuits in applying the Supreme Court's reasoning in Safeco to interpret "reckless disregard" in the FCA context.[19]

The relator alleged that SuperValu violated the FCA by reporting that the usual and customary price of certain drugs it sold was the retail cash price, not the lower price reflecting discounts SuperValu offered to customers who requested a price match based on a competitor's lower price.

In affirming the district court's order granting summary judgment, the Seventh Circuit, while agreeing with relator that SuperValu should have included the deeper discounts in its U&C prices, held that SuperValu's interpretation of the regulations was objectively reasonable and there was no authoritative guidance that warned SuperValu away from its interpretation.

The U.S. Court of Appeals for the Fourth Circuit followed suit in U.S. ex rel. Sheldon v. Allergan Sales this year, extending Safeco to legally false claims, which turn on whether a defendant correctly interpreted and complied with its legal obligations, but not to factually false claims where, for example, a defendant billed the government for goods or services it never provided.[20]

These cases suggest growing adoption of Safeco's reckless-disregard scienter standard among the circuits, and we expect this will continue to be a focal issue in FCA cases.

The Unsettled Standard for Government Dismissal of FCA Cases

Section 3730(c)(2)(A) of the FCA gives the DOJ the express authority to seek dismissal of an FCA case, even over the relator's objection, if the relator is provided notice and an opportunity for a hearing. Courts remain divided on what standard to apply when the government exercises that statutory dismissal authority.

The DOJ's efforts to dismiss qui tam cases have generally been analyzed under two standards: the U.S. Court of Appeals for the D.C. Circuit's Swift standard and the Ninth Circuit's Sequoia Orange standard.[21]

The Swift standard is the most deferential and provides the government with an unfettered right to dismiss qui tam cases. By contrast, the Sequoia Orange standard applies a rational-relation standard that requires the government to show (1) a valid government purpose and (2) a rational relation between dismissal and accomplishment of the purpose, before the court can grant the dismissal.

In Borzilleri v. Bayer Healthcare Pharmaceuticals this year, the U.S. Court of Appeals for the First Circuit adopted yet another standard for Section 3730(c)(2)(A) dismissals.[22] In a case where the government declined and later moved to dismiss, the court held that

> (i) although the government does not bear the burden of justifying its motion to the court, the government must provide its reasons for seeking dismissal so that the relator can attempt to convince the government to withdraw its motion at the hearing; and (ii) if the government does not agree to withdraw its motion, the district court should grant it unless the relator can show that, in seeking dismissal, the government is transgressing constitutional limitations or perpetrating a fraud on the court.

The First Circuit affirmed the district court's dismissal, as the relator merely presented disagreements with the government's conclusions about the sufficiency of its investigation and the qui tam action's potential for success — failing to demonstrate any constitutional infirmities or fraudulent motives underlying the government's motion to dismiss.

In Polansky v. Executive Health Resources last year, the Third Circuit held that the government must intervene before it can move to dismiss and that Federal Rules of Civil Procedure 41(a)(1)(A)(i) governs such motions.[23] The court construed the government's motion to dismiss as a motion to intervene and dispensed the case on the basis of Federal Rules of Civil Procedure 41(a)(1)(A)(i). The relator in Polansky filed a certiorari petition on Jan. 26.[24]

For now, the circuits remain split on the standard for Section 3730(c)(2)(A) dismissals. With certiorari sought in the Polansky case, it is possible that the Supreme Court will resolve the split in 2022.

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Epstein Becker law clerk Chloe Hillard contributed to this article.

[1] Department of Justice, Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021, February 1, 2022, available at https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year.

[2] Total awards to relators fell in FY 2021 to the lowest number in over a decade. According to DOJ's statistics, the government paid out $238 million to relators in FY 2021, the lowest number since FY 2008.

[3] Department of Justice, Issuance and Use of Guidance Documents by the Department of Justice, July 1, 2021, available at https://www.justice.gov/opa/page/file/1408606/download.

[4] Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures, 86 Fed. Reg. 58042-53 (Oct. 20, 2021), available at https://www.federalregister.gov/documents/2021/10/20/2021-22503/department-of-health-and-human-services-proposed-repeal-of-hhs-rules-on-guidance-enforcement-and.

[5] Azar v. Allina Health Services , 139 S. Ct. 1804 (2019).

[6] Department of Justice, Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative, October 3, 2021, available at https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative.

[7] See, e.g., Department of Justice, Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference, February 17, 2021, available at https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar; Memorandum for the Deputy Attorney General, Heads of Department Litigating Components, United States Attorneys, Executive Office for United States Attorneys, Federal Bureau of Investigation, Office of the Inspector General, Organized Crime Drug Enforcement Task Force, and Interpol Washington from the Attorney General, at 2 (May 17, 2021), available at https://www.justice.gov/opa/press-release/file/1394721/download.

[8] Health Resources & Services Administration, Important Dates for Reporting, available at https://www.hrsa.gov/provider-relief/reporting-auditing/important-dates; Department of Health & Human Services, HHS Distributing $2 Billion More in Provider Relief Fund Payments to Health Care Providers Impacted by the COVID-19 Pandemic, January 25, 2022, available at https://www.hhs.gov/about/news/2022/01/25/hhs-distributing-2-billion-more-provider-relief-fund-payments-health-care-providers-impacted-covid-19-pandemic.html.

[9] Department of Justice, Justice Department Takes Action Against COVID-19 Fraud, March 26, 2021, available at https://www.justice.gov/opa/pr/justice-department-takes-action-against-covid-19-fraud.

[10] Mass.gov, Private Equity Firm and Former Mental Health Center Executives Pay $25 Million Over Alleged False Claims Submitted for Unlicensed and Unsupervised Patient Care, Oct. 14, 2021, available at 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.

[11] The center, for its part, agreed in 2018 to pay $4 million to resolve allegations emanating from the same activity.

[12] Department of Justice, EEG Testing and Private Investment Companies Pay $15.3 Million to Resolve Kickback and False Billing Allegations, July 21, 2021, available at https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-kickback-and-false.

[13] United States v. AseraCare, Inc. , 938 F.3d 1278 (11th Cir. 2019).

[14] U.S. ex rel. Bell v. Cross , No. 21-11064, 2021 WL 5544685 (11th Cir. Nov. 26, 2021).

[15] U.S. ex rel. Winter v. Gardens Regional Hospital and Medical Center , 953 F.3d 1108 (9th Cir. 2021), cert. denied, 114 S.Ct. 1380 (U.S. 2021).

[16] Universal Health Services Inc. v. Escobar , 136 S. Ct. 1989 (2016).

[17] U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc. , 17 F.4th 732 (7th Cir. 2021).

[18] Safeco Insurance Company of America v. Burr , 551 U.S. 47 (2007).

[19] U.S. ex rel. Schutte v. SuperValu, Inc. , 9 F.4th 455 (7th Cir. Aug. 12, 2021).

[20] U.S. ex rel. Sheldon v. Allergan Sales, LLC , __ F.4th ___, 2022 WL 211172 (4th Cir. 2022).

[21] Swift v. United States , 318 F.3d 250 (D.C. Cir. 2003); U.S. ex rel. Sequoia Orange Co. v Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998).

[22] Borzilleri v. Bayer Healthcare Pharmaceuticals , Case No. 20-1066, __ F.4th ___ (1st Cir. 2022).

[23] Polansky v. Executive Health Resources , 17 F.4th 376 (3d Cir. Oct. 28, 2021). Fed. R. Civ. P. 41(a)(1)(A)(i) provides that a plaintiff has an absolute right to dismiss an action without prejudice any time "before the opposing party serves either an answer or a motion for summary judgment."

[24] Petition for Writ of Certiorari, Polansky v. Executive Health Resources, 21-1052 (Jan. 26, 2022).