LAW360

Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

The Hottest FCA Cases & Trends To Watch In 2023

By **Jeff Overley**

Law360 (January 5, 2023, 10:32 PM EST) -- The never-not-busy False Claims Act realm will be extra active in 2023 as the U.S. Supreme Court delivers at least one FCA opinion — and perhaps two or even three — in headliner cases during a year in which attorneys are also eyeing a new circuit split and emerging enforcement frontiers.

To take stock of key FCA themes in the year ahead, Law360 asked lawyers in private practice what they'll be watching most closely in litigation and investigations involving fraud against taxpayer-funded programs. In interviews and correspondence, the lawyers pointed to several Supreme Court dockets, circuit court divisions involving kickback cases, and signs of stronger scrutiny for Medicare Advantage insurers and government contractors with digital troves of sensitive health care information.

Here, Law360 summarizes the hottest topics that FCA practitioners will be tracking over the next 12 months.

'Seminal Legal Issues' in DOJ Dismissal Debate

Briefing and oral arguments at the Supreme Court are already complete in an FCA fight where the justices are contemplating the U.S. Department of Justice's power to torpedo whistleblower-led lawsuits — something the DOJ began doing with unprecedented gusto in recent years amid an unprecedented boom in whistleblower cases.

The high court's forthcoming opinion in Polansky v. Executive Health Resources is expected to answer whether the federal government can deep-six whistleblower cases — which are officially brought on behalf of the government — after initially declining to intervene in them.

In recent decades, the DOJ has declined to join roughly 75% of all cases, and in recent years, it has taken the additional step of unilaterally tossing dozens of nonintervened cases, often because of purported disagreement with fraud theories. But with nearly 700 new whistleblower suits emerging annually, DOJ dismissals remain relatively rare.

If the justices recognize the government's dismissal authority, they are also expected to fashion a framework for judges to apply when assessing dismissal requests. Circuit courts have created several frameworks that differ markedly but also remain deferential to the DOJ.

The dismissal debate has had the FCA bar abuzz for several years, and much of the interest is

intellectual. "Seminal legal issues" are at the core of the debate, Morgan Lewis & Bockius LLP partner Kathleen McDermott, a former DOJ health fraud coordinator, told Law360.

But lawyers are also mindful of practical implications, given that the DOJ has wielded its dismissal sword in monumental cases, including litigation alleging that fraud against the U.S. Food and Drug Administration tainted billions of dollars in Medicare and Medicaid reimbursement.

"It's a powerful tool to defend agency policies and programs, such [as] FDA's authority to determine when a violation of the Federal Food, Drug, and Cosmetic Act has occurred and the appropriate remedy," Morrison & Foerster LLP partner Stacy Cline Amin, former chief counsel of the FDA, said of the government's ability to end fraud suits.

The case is U.S. ex rel. Polansky v. Executive Health Resources Inc. et al., case number 21-1052, before the Supreme Court of the United States.

'Creative Lawyering' Defense in High Court Spotlight

Another FCA tempest on the Supreme Court's radar could dramatically affect efforts to prove that fraud occurred knowingly, as required to create liability. At issue is whether the law covers regulatory violations based on "objectively reasonable" interpretations of compliance obligations, and whether it matters if accused violators never even believed that faulty interpretations were correct.

Four pending petitions are asking those questions, and the justices on Friday will discuss two of those petitions, including one filed in Schutte v. SuperValu Inc. That case is the most advanced of the quartet, and its quest for high court review has won influential allies, including the plaintiffs bar group Taxpayers Against Fraud, the U.S. solicitor general and Sen. Chuck Grassley, R-Iowa, who helped to write the modern FCA.

Advocates of review have fretted that granting FCA immunity to "objectively reasonable" readings of regulations would open a supersized loophole for defense counsel. The DOJ, for example, has **warned** of a scenario in which "a defendant can actually realize that its actions are likely illegal, ignore warnings from attorneys, industry experts, or employees, and yet avoid all consequences through creative lawyering after the fact."

Other observers see the defense as common sense. SuperValu, for example, used an opposition brief to discuss "unclear and complex Medicare and Medicaid provisions, which lower courts have described as among the 'most completely impenetrable texts within human experience.'"

The vast majority of FCA enforcement is directed at companies regulated by the U.S. Department of Health and Human Services, which consistently issues new regulations that frequently span hundreds of pages. As a result, the issue of "objectively held regulatory ambiguity or confusion [is] a real issue in the health industry," Morgan Lewis' McDermott said.

Goldberg Kohn principal Roger A. Lewis, who represents whistleblowers, summed up the situation this way: "At stake is the biggest question for 2023: whether a defendant can ever be liable under the False Claims Act if its regulated conduct, though wrongful, was objectively reasonable."

The cases are U.S. ex rel. Sheldon v. Allergan Sales LLC, case number 22-593, Olhausen v. Arriva Medical LLC et al., case number 22-374, U.S. ex rel. Proctor v. Safeway Inc., case number 22-111, and U.S. ex rel.

Schutte et al. v. SuperValu Inc. et al., case number 21-1326, all before the Supreme Court of the United States.

Kickback Clarity Sought at Supreme Court

The justices could also tee up an FCA blockbuster if they accept a petition from pharmaceutical giant Pfizer Inc., which is challenging government views of the Anti-Kickback Statute. The kickback law is a basis for FCA liability and has spawned numerous settlements with drug companies, often in the eight-figure and nine-figure ranges.

Pfizer's petition — scheduled for the Supreme Court's Friday conference — contends that AKS liability only exists when payments induce government health purchases and are intended to corrupt medical decision-making. The drugmaker's contention — rejected by the Second Circuit and disparaged by HHS — has attracted support at the high court from trade group Pharmaceutical Research and Manufacturers of America, fellow pharmaceutical giant Johnson & Johnson, and the drugmaker-backed National Minority Quality Forum.

There's no circuit split to boost Pfizer's chances of a cert grant, but there also haven't been many circuit court decisions regarding the AKS and corrupt intent. There's a dearth of decisions because "the penalties for violating the AKS are too draconian to fight in most instances," which is why "pharmaceutical manufacturers have acquiesced in billions of dollars in FCA settlements," Pfizer wrote in its petition.

Many of those settlements have involved the types of payments that Pfizer wants to make: ostensibly charitable assistance to help patients afford expensive drugs that are covered by Medicare. Despite past FCA settlements involving similar payments, Pfizer and other drugmakers keep trying to offer financial assistance — arguably because there's a lucrative return on investment that would be even more lucrative without AKS concerns.

"The industry is fearful, because they're going to continue to engage in AKS violations," Tycko & Zavareei LLP partner Eva Gunasekera, a former DOJ health fraud lawyer, told Law360. "They're continuing to support business practices that violate the Anti-Kickback Statute, and they want to continue in that vein without the fear of the law enforcement gavel coming down on them."

Even if the justices turn down Pfizer's petition, the intent standard of the AKS is likely to remain a hot topic. That's partly because Pfizer has started a serious conversation about the issue, and partly because a new case advancing the same argument is playing out in Virginia federal court.

"Is some kind of corrupt intent required? ... That's certainly what I would argue," Covington & Burling LLP partner Matthew F. Dunn told Law360, stipulating that he was not specifically addressing Pfizer's petition. "We expect that [question] to continue to be a key issue in investigations related to alleged AKS violations and related False Claims Act litigation."

The cases are Pfizer Inc. v. HHS et al., case number 22-339, before the Supreme Court of the United States, and Pharmaceutical Coalition for Patient Access v. U.S. et al., case number 3:22-cv-00714, in the U.S. District Court for the Eastern District of Virginia.

AKS Ruling Raises Prospect of 'Powerful Defenses'

One rung below the Supreme Court, circuit courts are suddenly split on a separate Anti-Kickback Statute question that could carry considerable consequences for the False Claims Act. The question is about an AKS provision that creates FCA liability when improper billing includes items or services "resulting from" kickback violations.

In mid-2022, the Eighth Circuit created the cleavage by finding that the provision establishes a "but-for causal requirement" — meaning that many FCA cases "must prove that a defendant would not have included particular items or services but for the illegal kickbacks."

The Eighth Circuit's opinion in Cairns v. D.S. Medical LLC acknowledged that the Third Circuit reached a different conclusion a few years earlier in a case called Greenfield v. Medco Health Solutions Inc. In that case, the Third Circuit explored the FCA and the AKS and found that "neither requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider."

Dunn, the Covington partner, told Law360 that the meaning of "resulting from" is something that carries "significant importance" and "would be an issue in any False Claims Act case that's premised on an underlying violation of the AKS."

The debate is likely to continue percolating in other courts, and if the Eighth Circuit's reading were to ultimately become the dominant interpretation, it "would present opportunities for powerful defenses for defendants in these types of cases," Dunn added.

Cybersecurity, Medicare Advantage Seen as Prime Targets

In comments shared with Law360, lawyers also singled out several business sectors and legal theories as probable hotbeds of False Claims Act attention. One oft-cited area was cybersecurity, which the DOJ has formally prioritized in the FCA context since the October 2021 debut of its Civil Cyber-Fraud Initiative.

Andrew O'Connor, a partner at Ropes & Gray LLP, told Law360 that "health care and life sciences companies that contract with or receive grants from the federal government may be subject to scrutiny under the initiative," particularly if they contract with the U.S. Department of Veterans Affairs.

The initiative's first FCA settlement, made public in March 2022, involved a medical services contractor that served the U.S. Air Force and settled for nearly $1 million because it "had not consistently stored patients' medical records on a secure [electronic] system," according to a DOJ announcement. Later in 2022, an aerospace contractor inked a $9 million FCA deal after "misrepresenting its compliance with cybersecurity requirements," the DOJ said.

Companies accused of flouting cybersecurity requirements are likely to have "strong arguments in response, including regarding whether such requirements are material," O'Connor said. But, he added, "The cost of defending such cases can be significant."

Looking ahead, Morrison & Foerster partner Nathaniel R. Mendell predicted that "2023 may be the year we see enforcers use the False Claims Act to punish inadequate cybersecurity protections that leave confidential patient information vulnerable to hacking."

"Prosecutors will be increasingly drawn to this area," Mendell said, because of "the importance of patient privacy and the increasing threat of sophisticated ransomware and cyberattacks on the health care industry."

Several FCA attorneys also cited Medicare Advantage as a litigation locus in 2023. The privately administered program offers plenty of FCA fodder: Enrollment has ballooned to almost 30 million beneficiaries — roughly half of the total Medicare population — and spending last year exceeded $400 billion, according to the Kaiser Family Foundation.

"Medicare Advantage has been on DOJ's short list of False Claims Act priorities for the past few years and is mentioned frequently in speeches and at conference appearances by DOJ officials," O'Connor said.

The DOJ has sued some of the program's leading insurance plans, including Cigna Corp. and Anthem Inc., and has generally accused companies of exaggerating patient illnesses in order to extract more money from Uncle Sam.

"Fraud in the Medicare Advantage program will continue to be a big-ticket, high-impact focus of FCA activity in 2023," Goldberg Kohn's Lewis said, adding that the program's size will probably keep FCA cases "in the headlines for years to come."

--Editing by Jay Jackson Jr. and Jill Coffey.
