THE FALSE CLAIMS ACT AND HEALTHCARE: 2021 RECOVERIES AND 2022 OUTLOOK

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US Healthcare Fraud and Abuse Alert

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In a significant departure from the general downward trend in False Claims Act[1] (FCA) civil fraud recoveries over the past half-decade[2] —and as predicted last year[3] —recoveries in Fiscal Year (FY) 2021 drastically increased compared to those in FY 2020. The US$5.6 billion in recoveries reported by the United States Department of Justice (DOJ) in its 1 February 2022 press release is more than double the US$2.2 billion recovered in FY 2020, and is the second largest total recovery ever recorded.[4] Yet again, the healthcare industry was far and away the primary driver of civil fraud enforcement activity, accounting for 90% of total recoveries—over US$5 billion.[5] Notably, healthcare civil fraud recoveries in FY 2021 were the highest ever in a single year by a large margin, representing nearly US$2 billion more than the previous high reported in FY 2012 (and over US$3 billion more than FY 2020).[6] As expected, aggregate recoveries were much greater in *qui tam* matters in which the DOJ participated, either by filing its own complaint, intervening in relators' *qui tam* actions, or otherwise pursuing a recovery.[7] This fact held true for all *qui tam* activity generally, and for healthcare matters in particular.[8]

The substantial increase in civil fraud recoveries in FY 2021 is due, in large part, to the highly publicized US$2.8 billion settlement with Purdue Pharma in connection with the opioid manufacturer's marketing and sales practices.[9] However, even setting aside the latter recovery, by virtually any measure, FY 2021 was marked by heavy heath care-related FCA activity. The government did not discriminate in its enforcement across the healthcare industry, as it targeted insurers,[10] healthcare systems,[11] medical suppliers,[12] pain clinics,[13] clinical laboratories,[14] substance abuse centers,[15] pharmaceutical companies,[16] psychiatric facilities,[17] home health agencies,[18] and hospitals[19] (among others) with its enforcement efforts. The DOJ has, again, expressed its intent to pursue healthcare fraud diligently, touting its “vigorous pursuit of healthcare fraud” as instrumental in “restor[ing] funds to federal programs such as Medicare, Medicaid, and TRICARE” and “prevent[ing] billions more in losses by deterring others who might try to cheat the system for their own gain,” as well as “protect[ing] patients from medically unnecessary or potentially harmful actions.”[20]

Looking ahead to FY 2022, K&L Gates LLP perceives three areas to be particularly worthy of attention. First, Congress appears primed to consider legislation that would significantly amend the FCA to make it more difficult for defendants to assert materiality defenses pursuant to *Escobar*[21] and its progeny and for the government to dismiss *qui tam* actions over relators' objections.[22] Second, FCA actions predicated on the use of Electronic Health Record systems (EHRs) against vendors and providers are likely to substantially increase. And, third, industry participants should expect the DOJ to accelerate its pursuit of fraud in the Medicare Advantage arena against both insurers and providers. This article will first examine the statistics underlying FCA activity in FY 2021, and will then explore these three areas in depth.

To read the full alert, click here.

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FOOTNOTES

[1] 31 U.S.C. §§ 3729 - 3733.

[2] Civil fraud recoveries dropped from a high of US$5 billion in FY 2016 to US$2.3 billion in FY 2020. U.S. Dep't of Just., Fraud Statistics Overview (Feb. 1, 2022), https://www.justice.gov/file/1467871/download.

[3] Mark A. Rush, Mary Beth F. Johnston, John H. Lawrence, Nora E. Becerra, & Laura A. Musselman, The False Claims Act and Health Care: 2020 Recoveries and 2021 Outlook, K&L Gates (Feb. 22, 2021),https://www.klgates.com/The-False-Claims-Act-and-Health-Care-2020-Recoveries-and-2021-Outlook-2-22-2021.

[4] Press Release, U.S. Dep't of Just., 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. Recoveries in FY 2021 were exceeded only by those in FY 2014, which saw US$6.2 billion in civil fraud recoveries. *See* Note 2, *supra*.

[5] *See* U.S. Dep't of Just., Fraud Statistics Overview (Feb. 1, 2022), https://www.justice.gov/file/1467871/download. Importantly, this sum reflects only federal recoveries; Medicaid recoveries are not accounted for in this figure. *Id*.

[6] *Id*.

[7] *See id*.

[8] *See id*. Of the US$1.7 billion in recoveries in qui tam actions in FY 2021, US$1.2 billion (71%) resulted from matters in which the DOJ intervened or otherwise pursued. *See id*. For healthcare *qui tam* matters, US$1.5 billion was recovered, of which US$1 billion was attributable to cases in which the DOJ intervened/otherwise pursued. *See id*.

[9] Press Release, U.S. Dep't of Just., Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020), https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.

[10] *E.g.,* Press Release, U.S. Dep't of Just., Medicare Advantage Provider to Pay $6.3 Million to Settle False Claims Act Allegations (Nov. 16, 2020), https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-63-million-settle-false-claims-act-allegations.

[11] *E.g.*, Press Release, U.S. Dep't of Just., Northern Ohio Health System Agrees to Pay Over $21 Million to Resolve False Claims Act Allegations for Improper Payments to Referring Physicians (July 2, 2021), https://www.justice.gov/opa/pr/northern-ohio-health-system-agrees-pay-over-21-million-resolve-false-claims-act-allegations; Press Release, U.S. Dep't of Just., Prime Healthcare Services and Two Doctors Agree to Pay $37.5 Million to Settle Allegations of Kickbacks, Billing for a Suspended Doctor, and False Claims for Implantable Medical Hardware (July 19, 2021), https://www.justice.gov/opa/pr/prime-healthcare-services-and-two-doctors-agree-pay-375-million-settle-allegations-kickbacks; Press Release, U.S. Dep't of Just., Sutter Health and Affiliates to Pay $90 Million to Settle False Claims Act Allegations of Mischarging the Medicare Advantage Program (Aug. 30, 2021), https://www.justice.gov/opa/pr/sutter-health-and-affiliates-pay-90-million-settle-false-claims-act-

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allegations-mischarging; Press Release, U.S. Dep't of Just., United States Intervenes and Files Complaint in False Claims Act Suit Against Health Insurer for Submitting Unsupported Diagnoses to the Medicare Advantage Program (Sept. 14, 2021), https://www.justice.gov/opa/pr/united-states-intervenes-and-files-complaint-false-claims-act-suit-against-health-insurer.

[12] *E.g.,* Press Release, U.S. Dep't of Just., Mail-Order Diabetic Testing Supplier and Parent Company Agree to Pay $160 Million to Resolve Alleged False Claims to Medicare (Aug. 2, 2021), https://www.justice.gov/opa/pr/mail-order-diabetic-testing-supplier-and-parent-company-agree-pay-160-million-resolve-alleged.

[13] *E.g.*, Press Release, U.S. Dep't of Just., United States Obtains $140 Million in False Claims Act Judgments Against South Carolina Pain Management Clinics, Drug Testing Laboratories and a Substance Abuse Counseling Center (Sept. 3, 2021).

[14] *See, e.g., id*.

[15] *See, e.g., id*.

[16] *E.g.*, Press Release, U.S. Dep't of Just., Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

[17] *E.g.,* Press Release, U.S. Dep't of Just., Ohio Treatment Facilities and Corporate Parent Agree to Pay $10.25 Million to Resolve False Claims Act Allegations of Kickbacks to Patients and Unnecessary Admissions (March 5, 2021), https://www.justice.gov/opa/pr/ohio-treatment-facilities-and-corporate-parent-agree-pay-1025-million-resolve-false-claims.

[18] *E.g.*, Press Release, U.S. Dep't of Just., Home Health Agency Operator BAYADA to Pay $17 Million to Resolve False Claims Act Allegations for Paying Kickback (Sept. 8, 2021), https://www.justice.gov/opa/pr/home-health-agency-operator-bayada-pay-17-million-resolve-false-claims-act-allegations-paying.

[19] *E.g.*, Press Release, U.S. Dep't of Just., Texas Heart Hospital and Wholly-Owned Subsidiary THHBP Management Company LLC to Pay $48 Million to Settle False Claims Act Allegations Related to Alleged Kickbacks (Dec. 18, 2020), https://www.justice.gov/opa/pr/texas-heart-hospital-and-wholly-owned-subsidiary-thhbp-management-company-llc-pay-48-million.

[20] U.S. Dep't of Just., Fraud Statistics Overview (Feb. 1, 2022), https://www.justice.gov/file/1467871/download.

[21] Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 579 U.S. 176, 195 136 S. Ct. 1989, 2003 (2016) ("[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material").

[22] *Compare* U.S. ex rel. Borzilleri v. Bayer Healthcare Pharms. Inc., 24 F.4th 32 (1st Cir. Jan. 21, 2022) (government's motion to dismiss will be granted unless the relator can establish "the government is transgressing constitutional limitations or perpetrating a fraud on the court") *with* U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc., 970 F.3d 835, 848 (7th Cir. 2020) (in order for the government to dismiss relator's complaint after its automatic intervention rights have expired, it must first intervene by showing "good cause"), U.S. v. Everglades Coll., Inc., 855 F.3d 1279, 1285-86 (11th Cir. 2017) (the government may dismiss relator's complaint at any point and need

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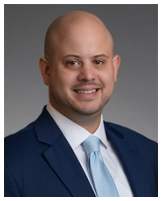
not intervene to do so), Swift v. U.S., 318 F.3d 250, 252 (D.C. Cir. 2003) (government has “unfettered right” to dismiss), and U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139, 1145 (9th Cir. 1998) (government must articulate “valid government purpose” rationally related to dismissal).

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