

False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021

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The Department of Justice [announced in a February 1, 2022 press release \(Press Release\)](#) that it obtained more than \$5.6 billion in settlements and judgments from civil cases involving fraud and false claims in the fiscal year ending September 30, 2021 (FY2021) – the second largest annual total recovery in False Claims Act (FCA) history.

Health Care Fraud Dominated the Recovery Landscape

Of the \$5.6 billion, \$5 billion relates to matters involving the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians. Recoveries gained from DOJ's health care fraud enforcement efforts restore funds to federal programs such as traditional Medicare, Medicaid and TRICARE, but DOJ devoted significant efforts to recovering funds defrauded from the Medicare Advantage program (Part C) as well. Medicare Advantage pays a capitated amount to private health insurers based on patients enrolled in the insurers' plans and adjusted for various "risk" factors. DOJ has investigated insurers and healthcare providers that allegedly manipulated the risk adjustment process by submitting claims for reimbursement to federal health care programs that included unsupported diagnosis codes, which made patients appear sicker than they actually were. In FY2021, DOJ entered into settlements with Sutter Health and Kaiser Foundation Health that together provided for the payment of over \$96 million to resolve Medicare Advantage risk adjustment fraud allegations.

DOJ Continues to Prioritize Opioid Fraud Commensurate with the Opioid Crisis

The largest FCA settlements in the past year resulted from settlements with prescription opioid manufacturers: Indivior Inc. and Indivior plc (Indivior), and Purdue Pharma (Purdue). Indivior agreed to pay \$600 million in total to resolve criminal and civil liability, \$209.3 million of which resolved federal civil allegations that Indivior promoted Suboxone, an opioid addiction treatment drug, to physicians who wrote medically unnecessary prescriptions that were often diverted, and made false and misleading statements that Suboxone Film was less likely than other buprenorphine products to be diverted, abused, or result in accidental pediatric exposure.

DOJ announced a \$2.8 billion civil settlement with Purdue and a settlement of \$225 million with members of the Sackler family in October 2021. The \$2.8 billion settlement is in the form of an allowed, unsecured, general unsecured bankruptcy claim, which is now part of the Purdue bankruptcy plan that is on appeal to the U.S. Court of Appeals for the Second Circuit. The settlement resolved allegations that Purdue 1) promoted its opioid drugs to providers it knew were prescribing them for unsafe, ineffective, and medically unnecessary uses that often led to abuse and diversion and 2) paid kickbacks to doctors, specialty pharmacies, and an electronic health records (EHR) developer to increase prescriptions of Purdue's opioids.

DOJ's Health Care Kickback Cases Targeted Manufacturers of Drugs and Devices, EHR Vendors, Hospitals, and Providers of Diagnostic Testing

DOJ netted large recoveries in FY2021 from FCA cases predicated on alleged violations of the Anti-Kickback Statute (AKS). DOJ alleges that claims submitted to the federal healthcare programs for reimbursement are "tainted" if based upon a violation of the AKS, which may arise if a person or entity provides anything of value to someone with the intent to induce them to refer, arrange for, or recommend items or services reimbursable by a federal health care program.

DOJ secured default judgments of \$140 million and \$9 million against urine drug testing laboratories and their owner, Daniel McCollum, respectively, arising from their alleged inducement of providers to refer urine drug tests in exchange for kickbacks. Arriva Medical LLC and its parent, Alere Inc., paid \$160 million to resolve allegations that Arriva paid kickbacks to Medicare beneficiaries by providing them with free diabetic testing glucometers and by routinely waiving beneficiaries' copayments for glucometers and diabetic testing supplies.

OIG cautioned in a 1994 Special Fraud Alert that waiver of beneficiary copayments creates liability under the AKS by inducing the provider to refer items or services reimbursable by federal health care programs. Interestingly, part of the kickback theory leading to DOJ's recovery against Arriva and Alere appears to hinge on allegations that these companies provided kickbacks to beneficiaries themselves in the form of free diabetic testing glucometers.

DOJ has aggressively pursued alleged kickbacks in the EHR industry over the past several years. 2021 brought an \$18.25 million settlement with EHR vendor Athenahealth Inc. arising from Athenahealth's provision of lavish sporting, entertainment, and recreational events, allegedly to generate sales of its EHR product. The government has not explicitly articulated (in publicly available documents) how this remuneration was paid to induce referrals of items or services that were reimbursable by federal health care programs, as required by the AKS.

2021 Revealed a Handful of Civil FCA COVID-19 Fraud Prosecutions Among the Hundreds of Criminal COVID-19 Fraud Cases Brought Since 2020

Historic levels of emergency funding arising from the COVID-19 crisis has resulted in a fair amount of alleged fraud on the various COVID-19 related relief programs. DOJ has focused primarily on criminal prosecutions involving fraud on the Paycheck Protection Program (PPP) created by the Coronavirus Aid, Relief, and Economic Security (CARES) Act in March 2020. In fact, also on February 1, 2022, [DOJ announced](#) that it had charged 22 people in connection with a criminal scheme to defraud the PPP of more than \$3 million. In its Press Release, DOJ highlighted a few PPP civil FCA cases that contributed to the \$5.6 billion recouped.

Two of the three settlements – \$287,055 from Seth Bernstein, the owner of All in Jets LLC dba JetReady, and \$30,000 from Sextant Marine Consulting LLC – arose from qui tam or whistleblower lawsuits brought by private parties on behalf of the federal government. The settlement agreement between DOJ and Bernstein alleges that Bernstein made a false statement in connection with the submission of the PPP loan application; specifically, that funds would be used for payroll expenses. According to the qui tam relator – a former JetReady employee – Bernstein misappropriated PPP funds received to cover personal, non-company related expenses instead of the payroll expenses for which they were intended. The whistleblower in the matter involving Sextant alleged that Sextant unlawfully applied for and received two PPP loans after falsely certifying that it would receive only one. Similarly, in a third FCA settlement brought by the government in the first instance, rather than a whistleblower, Dr. Sandeep Walia agreed to repay a second PPP loan he received after certifying, in connection with the application for that second PPP loan, that his medical practice had not received one previously.

We expect to see more FCA enforcement arising from misrepresentations in CARES Act relief program applications and misappropriation of these funds, as harkened by Deputy Assistant Attorney General [Michael D. Granston](#) at the ABA Civil False Claims Act and Qui Tam Enforcement Institute on December 2, 2020.

The FCA Remains a Powerful Tool for the Government to Deploy Across Multiple Arenas

The lion's share of DOJ's FY2021 recovery came from settlements involving actors in the health care industry, but the Press Release showcased the diversity of fraud recoveries under multiple theories targeting myriad industries. DOJ attributed additional FCA settlements to: 1) procurement fraud related to defense contracts and the government's contract with a provider of office furniture; 2) kickbacks and medically unnecessary services provided by hospitals, home health care agencies, pharmaceutical manufacturers, diagnostic testing entities, medical device manufacturers, and government contractors; 3) underpaying and underreporting royalties on the value of natural gas produced on federal lands leased to private entities; 4) underpaying customs duties; 5) engaging in non-competitive bidding practices; 6) fraudulently obtaining federal funds for tutoring services; and 7) failure to maintain quality control programs over loans insured by the Federal Housing Administration.

Trends and Takeaways

The recovery of \$5.6 billion under the FCA is an enormous leap from the \$2.2 billion of recoveries in FY2020, and is exceeded only by the \$6.1 billion recovery in FY2014, and in only two prior years since 1986 have recoveries exceeded \$5 billion. The \$5 billion in FCA recoveries DOJ attributes to the health care industry sets a new record, over the \$3.1 billion in health care recoveries in FY 2012, and an almost three-fold increase from FY 2021 with \$1.8 billion in health care recoveries.

The \$5.6 billion includes over \$1.6 billion attributed to lawsuits filed under the qui tam provisions. In FY2020, DOJ recovered only \$2.2 billion under the FCA, \$1.7 billion of which was credited to qui tam actions. In FY2021, the government paid out \$237 million to the individuals who filed qui tam actions, a decrease from a payout of \$309 million the year before. DOJ reports that in FY2021, 598 lawsuits were filed under the qui tam provisions, a decline from the 672 filings in FY2020, and the lowest number of qui tam filings since FY2010. This reflects the increase we have observed in DOJ-initiated actions, and a remarkable year for DOJ recoveries in these matters.

Notably, DOJ counted as part of its \$5.6 billion in FCA recoveries the \$2.8 billion agreement with Purdue, but a federal district court judge unraveled the settlement in December 2021 because it released the Sackler shareholders, who are not debtors in the bankruptcy, from liability in civil opioid-related cases. It is unclear if the Purdue bankruptcy plan will survive following the district court's decision, and if so, how much DOJ might actually recover on the basis of this claim. Without counting this claim, DOJ FCA recoveries would be \$2.2 billion, the same amount as in FY2020.

We predict that government-initiated cases will continue to be a strong driver of investigations, but we expect that qui tam actions, which have been waning, will surge. DOJ's fiscal year 2022 FCA enforcement results will likely reflect outsize recoveries related to the health care industries, but may also include settlements involving misrepresentations by cybersecurity vendors in connection with government procurement, given the discussion involving President Biden's May 2021 Executive Order prioritizing cybersecurity protection for federal government networks and the October 2021 announcement of the Civil Cyber-Fraud Initiative. We also anticipate that the momentum will shift with increased civil enforcement, as well as core criminal prosecutions, of COVID-19 fraud, driven by [DOJ's robust data analytics](#) and by qui tam relators.

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