

DOJ Recoveries for False Claims Act Cases Doubled in 2021

On February 1, 2022, the U.S. Department of Justice (DOJ) announced their recovery of \$5.6 billion in settlements and judgments from civil cases involving fraud and false claims for *fiscal year* (FY) 2021.¹ Over \$5 billion was recouped from the healthcare industry for federal losses alone, and included recoveries from drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.² This figure is more than double the amount of healthcare-related recoveries secured in FY 2020, which totaled \$1.8 billion.³ Settlements received from the healthcare industry (approximately 93% of the total recovery amount) far outstripped recoveries from defense, energy, construction, and other industries.⁴ In addition to the \$5 billion recovered for federal losses, the DOJ also recovered tens of millions of dollars for state and Medicaid programs in FY 2021.⁵

The largest healthcare recoveries were related to settlements from opioid litigation. In the year's largest settlement, \$2.8 billion was recovered from Purdue Pharma as part of its global resolutions of criminal and civil liability related to allegations that the company "promoted its opioid drugs to health care providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion."⁶ In addition to the \$2.8 billion, individual Purdue shareholders and board members agreed to pay \$225 million to resolve allegations "that they approved a new marketing program that intensified marketing of OxyContin to extreme, high-volume prescribers, causing opioid prescriptions for uses that were unsafe, ineffective and medically unnecessary, and that often led to abuse and diversion."⁷ In another settlement, \$209 million was recovered from Indivior, as part of its global resolutions of criminal and civil liability related to allegations that the company "promoted the opioid-addiction-treatment drug Suboxone to physicians who were writing prescriptions that were not for a medically accepted indications and were often diverted."⁸ These two cases accounted for nearly 75% of 2021 healthcare recoveries.

In addition to pursuing cases related to opioids, the DOJ settled two cases related to their Medicare Advantage (also known as Medicare Part C) plans. Because Medicare Advantage pays providers a set amount per

enrolled patient, which amount is then adjusted by a number of risk factors that affect expected healthcare expenditures (i.e., a plan with more higher-risk patients would receive more reimbursement), the government has a strong interest in ensuring that providers do not manipulate the risk adjustment process. Sutter Health paid \$90 million to resolve allegations that it "submitted invalid diagnoses and received inflated payments as a result."⁹ Further, Kaiser Foundation Health Plan of Washington paid \$6.3 million to resolve allegations that it submitted invalid diagnoses, which resulted in the receipt of inflated payments.¹⁰ In addition to these settlements, the government intervened in lawsuits against Independent Health Corporation and against members of the Kaiser Permanente consortium alleging that they submitted inaccurate information about the health status of enrolled beneficiaries in order to receive inflated Medicare reimbursement.¹¹

Several lawsuits were resolved in 2021 related to unlawful kickbacks. For example:

- (1) Arriva Medical LLC, a mail-order diabetic testing supply company, paid \$160 million to settle allegations that Arriva paid kickbacks to Medicare beneficiaries via "free" or "no cost" glucometers and frequently waived or did not collect copayments for glucometers and diabetic testing supplies;¹²
- (2) An individual who owned and operated pain management clinics and urine drug testing laboratories paid \$9 million, and his clinic and laboratories paid \$140 million to resolve allegations that the clinics and laboratories paid unlawful kickbacks to providers to induce referrals of urine tests;¹³
- (3) Athenahealth Inc., an electronic health records technology (EHR) vendor, paid \$18.35 million to resolve allegations that it "invited customers and prospective customers to lavish all-expense-paid sporting, entertainment, and recreational events to generate sales of its EHR product,"¹⁴ and,
- (4) Three generic pharmaceutical manufacturers paid in excess of \$400 million to resolve allegations that they paid and received illegal remuneration "through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers as part of a conspiracy to fix the price of certain generic drugs."¹⁵

Several other lawsuits brought or resolved by the DOJ in 2021 were related to billing for medically unnecessary services or services not rendered as billed. SavaSeniorCare LLC paid \$11.2 million to resolve claims that it submitted false claims for rehabilitation therapy services in pursuit of corporate targets, rather than in accordance with a patient’s medical needs.¹⁶ Alere paid \$38.75 million to resolve allegations of billing for “defective rapid point-of-care testing devices used by Medicare beneficiaries to monitor blood coagulation when taking anticoagulant drugs.”¹⁷ Apria Healthcare LLC paid \$40.5 million to resolve allegations that it submitted false claims related to the provision of non-invasive ventilators to beneficiaries who had no need or use for the devices.¹⁸ St. Jude Medical paid \$27 million to resolve allegations that it “knowingly sold defective, implantable heart devices and failed to disclose serious adverse health events in connection with premature battery depletion in those devices.”¹⁹ Regency (and its owner) paid \$20.3 million to resolve allegations of falsifying documentation in order to bill federal healthcare programs for medically unnecessary durable medical equipment.²⁰

As in 2019 and 2020, the DOJ’s FY 2021 press release included an additional section entitled, “*Holding Individuals Accountable*,” wherein it reviewed several

cases in which the DOJ obtained substantial judgments from individuals, illustrating its continued commitment to the 2015 memorandum authored by then-Deputy Attorney General Sally Yates regarding holding individuals accountable for corporate wrongdoing (often referred to as the “Yates Memo”).²¹

Money recovered by the DOJ through healthcare fraud enforcement is crucial in returning assets back to federally-funded programs such as Medicare, Medicaid, and TRICARE.²² Since 1986, recoveries made under civil FCA suits total more than \$70 billion.²³ Over the past five years, there has been a significant uptick in the number of FCA suits brought on by both *whistleblowers* (also known as *qui tam* lawsuits) and the DOJ, with 598 *qui tam* cases and 203 *non-qui tam* cases initiated in FY 2021 alone.²⁴ The number of *qui tam* cases in 2020 was the lowest it had been since 2009, potentially indicating the government’s decreasing reliance on whistleblower activity.²⁵ However, the total amount recovered in FY 2021 was the second largest ever recorded and the most since 2014.²⁶ However, if the \$2.8 billion settlement with Purdue was removed, the total amount of recoveries would be more in line with past years. Nevertheless, the DOJ’s continued active interest and involvement in fraud and abuse cases in 2021 suggests that FCA enforcement will remain high going forward.

1 “Justice Department’s False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021” Department of Justice, Office of Public Affairs, Press Release, February 1, 2022, <https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year> (Accessed 2/7/22).
2 *Ibid.*
3 *Ibid.*
4 *Ibid.*
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
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18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*; “Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020” Department of Justice, Office of Public Affairs, Press Release, January 14, 2021, <https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020> (Accessed 1/19/21); “Individual Accountability for Corporate Wrongdoing” By Sally Quillian Yates, Letter to Assistant U.S. Attorneys General and All United States Attorneys, September 9, 2015.
22 Department of Justice, Office of Public Affairs, Press Release, February 1, 2022.
23 *Ibid.*
24 “Fraud Statistics – Overview” Department of Justice, <https://www.justice.gov/opa/press-release/file/1467811/download> (Accessed 2/7/22).
25 *Ibid.*
26 Department of Justice, Office of Public Affairs, Press Release, February 1, 2022.



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