

2021 Significant Settlements

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I. INTRODUCTION

This chapter summarizes a selection of significant settlements in 2021 between members of the food and drug industry and the U.S. Food and Drug Administration (FDA) alongside the U.S. Department of Justice (DOJ). The enforcement authority of FDA and DOJ includes both civil penalties and criminal prosecution.

Consistent with prior years, a majority of these settlements arise from DOJ's use of the False Claims Act (FCA), which imposes liability on persons and companies who defraud governmental programs and contracts. In 2021, the federal government recovered \$5.65 billion in FCA judgements and settlements, roughly \$5.07 billion (90%) of which came from health care and life sciences companies.¹ Total recoveries amount to over \$70 billion since Congress overhauled the FCA in 1986 in order to encourage whistleblower complaints.² Whistleblower, or *qui tam*, actions continued to be a driving force behind DOJ enforcement activity, with 598 whistleblower suits filed in 2021 (as compared to 203 cases filed by the government), which resulted in DOJ recovering over \$1.6 billion from these and earlier filed suits and \$237 million awarded to relators for their role.³

Notably, the amount recovered in 2021 marked the second largest annual total in FCA history, second only to the roughly \$6.2 billion recovered in 2014.⁴ This annual recovery is more than double DOJ's annual recovery amount in 2020 (a ten-year low), suggesting that DOJ has rebounded from the novel coronavirus (COVID-19) pandemic's impact on DOJ's ability to investigate and litigate fraud against the government.

Also, as noted in last year's edition of Significant Settlements, the federal government committed record amounts of money in emergency relief packages during the COVID-19 pandemic. The availability of these federal funds will undoubtedly be a source of healthcare-related fraudulent activity and result in increased fraud-related investigations and prosecutions by DOJ. In fact, the U.S. Attorney General announced in May 2021 the establishment of the COVID-19 Fraud Enforcement Task Force in an effort to foster partnership across government agencies to enforce against COVID-19-

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¹ Fraud Statistics – Overview (DOJ Dec. 2021).

² *Id.*

³ *Id.*; Press Release, U.S. Dep't of Justice, Justice Department's False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021 (Feb. 1, 2022).

⁴ *Id.*

related fraud.⁵ We have not yet seen any settlements in 2021 resulting from healthcare-related FCA allegations arising out of COVID-19 relief programs; however, DOJ is actively pursuing and has announced charges for such violations.⁶ Experts expect that this trend will continue, if not increase, in 2022 and beyond.

While we can expect FCA enforcement related to the COVID-19 pandemic to play a significant role in DOJ activity, DOJ will also continue to prioritize existing efforts more generally. For instance, in 2021, DOJ continued its emphasis on targeting entities that engaged in fraud related to healthcare services provided to patients. This included, for example, fraud involving the payment of kickbacks to referring physicians, whether in cash or in kind, and the provision of medically unnecessary services improperly billed to federal healthcare programs.

This chapter reviews some of the key FCA settlements and other representative settlements and consent decrees between the food and drug industry and the government in 2021.

II. DRUGS

A. *Taro Pharmaceuticals USA, Inc., Sandoz Inc., and Apotex Corporation*⁷

Taro Pharmaceuticals USA, Inc. (“Taro”), Sandoz Inc. (“Sandoz”), and Apotex Corporation (“Apotex”) (collectively, the “Companies”) agreed to pay a total of \$447.2 million to resolve allegations that the Companies conspired to fix the price of various generic drugs in violation of the FCA and Anti-Kickback Statute. Taro agreed to pay \$213.2 million, Sandoz agreed to pay \$185 million, and Apotex agreed to pay \$49 million. The generic drugs involved addressed a variety of health conditions, including nonsteroidal anti-inflammatory drugs used to treat pain and arthritis, corticosteroids used to treat skin conditions, drugs used to treat high cholesterol and triglyceride levels, among others.

The government alleged that Taro, Sandoz, and Apotex paid and received compensation through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for generic drugs manufactured by the Companies. The Anti-Kickback Statute prohibits companies from receiving or making payments in return for selling or purchasing drugs for which payment may be made by a federal healthcare program.

Each of the Companies also entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that includes internal monitoring and price transparency provisions and requires the Companies to implement compliance measures such as risk assessment programs, executive recoupment provisions, and compliance-related certifications for executives and board members.

⁵ Press Release, U.S. Dep’t of Justice, Attorney General Announces Task Force to Combat COVID-19 Fraud (May 17, 2021).

⁶ See, e.g., Press Release, U.S. Dep’t of Justice, DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19 (May 26, 2021).

⁷ Press Release, U.S. Dep’t of Justice, Pharmaceutical Companies Pay Over \$400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs (Oct. 1, 2021).

These civil settlements follow the Companies' earlier resolution of criminal charges through deferred prosecution agreements. In addition to the total of \$447.2 million in civil settlements, Taro paid a criminal penalty of \$205.6 million, Sandoz paid a criminal penalty of \$195 million, and Apotex paid a criminal penalty of \$24.1 million. Each Company also admitted to conspiring to fix prices on various generic drugs.

B. Kaléo Inc.⁸ and Riad "Ray" Zahr, People's Drug Store, and Ray's Drugs⁹

Kaléo Inc. ("Kaléo") agreed to pay \$12.7 million to resolve allegations that the company caused the submission of false claims for the drug Evzio, an injectable form of naloxone hydrochloride indicated for use to reverse opioid overdose. One month later, a pharmacist in Michigan, Riad "Ray" Zahr, and two specialty pharmacies formerly owned and operated by Zahr agreed to pay \$1 million to resolve allegations that they submitted false claims for Evzio to Medicare.

Insurers often required receipt of prior authorization requests in order to cover Evzio. Kaléo allegedly directed prescribing doctors to send prescriptions to preferred pharmacies that submitted false prior authorization requests for the drug that misrepresented to insurers that the physicians submitted the request (when the pharmacies did so) and/or contained false or misleading information regarding patients' medical histories (for example, false statements that patients had previously tried and failed less costly alternatives to Evzio). The government identified Zahr and his two specialty pharmacies, People's Drug Store and Ray's Drugs, as pharmacies allegedly involved in this scheme.

Additionally, in violation of the Anti-Kickback Statute, the government alleged that 1) Kaléo, Zahr, and the two specialty pharmacies dispensed Evzio without collecting co-payments from government beneficiaries; and 2) Kaléo illegally remunerated prescribing physicians and their office staff to induce and reward the prescription of Evzio.

These settlements with Kaléo, Zahr, and the two specialty pharmacies also resolve claims brought under the *qui tam* provisions by a former employee of Kaléo; the whistleblower will receive roughly \$2.5 million of the settlement amount with Kaléo and \$200,000 of the settlement amount with Zahr and the specialty pharmacies.

C. Incyte Corporation¹⁰

Incyte Corporation ("Incyte") agreed to pay \$12.6 million to resolve allegations that the company paid kickbacks in violation of the FCA. Specifically, Incyte allegedly used an independent foundation as a conduit to cover copayments of federal beneficiaries taking Incyte's drug Jakafi, a drug approved to treat myelofibrosis. Incyte was the sole donor to this fund, which was opened to assist only myelofibrosis patients.

The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying any remuneration—including payment of patients' copay obligations—to induce federal beneficiaries to purchase the company's drugs. The government alleges

⁸ Press Release, U.S. Dep't of Justice, Kaléo Inc. Agrees to Pay \$12.7 Million to Resolve Allegations of False Claims for Anti-Overdose Drug (Nov. 9, 2021).

⁹ Press Release, U.S. Dep't of Justice, Pharmacist and Two Pharmacies Agree to Pay \$1 Million to Resolve Allegations of False Claims for Anti-Overdose Drug (Dec. 8, 2021).

¹⁰ Press Release, U.S. Dep't of Justice, Incyte Corporation to Pay \$12.6 Million to Resolve False Claims Act Allegations for Paying Kickbacks (May 4, 2021).

that, through the fund, Incyte paid the copays of federal beneficiaries taking Jakafi who were ineligible for assistance because they did not have the indicated disease. Consequently, Incyte caused the submission of false claims to Medicare and TRICARE.

This settlement also resolves claims brought under the *qui tam* provisions by a former compliance executive of Incyte; the whistleblower will receive roughly \$3.59 million of the settlement amount.

III. MEDICAL DEVICES

A. *St. Jude Medical Inc.*¹¹

St. Jude Medical Inc. (“St. Jude”) agreed to pay \$27 million to resolve civil allegations that, between November 2014 and October 2016, it knowingly sold defective heart devices to healthcare facilities that then implanted such devices into patients insured by federal healthcare programs.

The government contended that St. Jude failed to provide FDA with material information regarding injuries and deaths resulting from the defective devices that, if communicated at that time, would have led to a product recall. Specifically, St. Jude allegedly withheld information on serious adverse health events in connection with the premature depletion of the battery in certain models of St. Jude’s implantable defibrillators used in patients at risk of cardiac arrest due to an irregular heartbeat.

The devices were ultimately subject to a Class I recall in October 2016, although thousands of defective devices had been implanted into patients since November 2014, during which time the government contended that St. Jude knowingly caused the submission of false claims to federal healthcare programs.

The settlement also resolved claims brought under the *qui tam* provisions by a patient who received one of the devices.

B. *Alere Inc. and Arriva Medical LLC*¹²

Alere Inc. (“Alere”) and Alere San Diego Inc. (“Alere San Diego”) agreed to pay \$38.75 million to resolve civil allegations that the companies violated the FCA by billing, and causing others to bill, the Medicare program for defective rapid point-of-care testing devices.

The government contended that, from 2008 to 2016, the companies knowingly sold defective INRatio blood coagulation monitors used by Medicare beneficiaries. The patients were those individuals taking anticoagulant drugs who used the monitoring device to determine a clinically appropriate and safe dosage for the medications. The Alere companies allegedly knew that the devices’ software algorithm contained a material defect that produced inaccurate and unreliable results for certain patients. The companies allegedly concealed the defect for years, following over a dozen deaths and hundreds of injuries associated with this defect. The devices were ultimately removed from the market after a nationwide Class I product recall.

¹¹ Press Release, U.S. Dep’t of Justice, St. Jude Agrees to Pay \$27 Million for Allegedly Selling Defective Heart Devices (July 8, 2021).

¹² Press Release, U.S. Dep’t of Justice, Medical Device Companies Alere Inc. and Alere San Diego Inc. Agree to Pay \$38.75 Million to Settle False Claims Act Allegations (July 8, 2021); Press Release, U.S. Dep’t of Justice, Mail-Order Diabetic Testing Supplier and Parent Company Agree to Pay \$160 Million to Resolve Alleged False Claims to Medicare (Aug. 2, 2021).

Alere was also the subject of a second settlement for alleged violations of the FCA, along with its subsidiary, Arriva Medical LLC (“Arriva”). Arriva and Alere agreed to pay \$160 million to resolve civil allegations that the companies violated the FCA. Two Arriva founders had previously paid \$1 million to resolve allegations that they participated in the kickback scheme.

The government contended that, from April 2010 to the end of 2016, Arriva (with Alere’s approval) paid kickbacks to Medicare beneficiaries by providing them with “free” or “no cost” glucometers and by routinely waiving, or failing to make reasonable efforts to collect, their copayments. The settlement also resolves allegations that Arriva and Alere caused the submission of false claims to Medicare by providing a meter to all new patients without regard to their eligibility for one and billing Medicare for the new meters. Lastly, the settlement resolves claims that Arriva submitted false claims to Medicare on behalf of deceased beneficiaries.

This settlement also resolves claims brought under the *qui tam* provisions by a former employee at an Arriva call center who will receive more than \$28 million as part of his share of the recovery.

Arriva ceased business operations in 2017.

*C. Arthrex Inc.*¹³

Arthrex Inc. (“Arthrex”) agreed to pay \$16 million to resolve civil allegations that the company violated the FCA by paying kickbacks to a Colorado-based orthopedic surgeon, resulting in the submission of false claims to the Medicare program. Specifically, the government contended that Arthrex provided remuneration to the surgeon in the form of royalty payments supposedly for the surgeon’s contributions to two Arthrex products when, in fact, the remuneration was intended to induce the surgeon’s use of Arthrex products.

Arthrex also entered into a five-year CIA with HHS-OIG that outlined requirements for future compliance. This settlement also resolves claims brought under the *qui tam* provisions; the whistleblower will receive \$2.5 million of the False Claims Act settlement.

*D. Neurosurgeon Wilson Asfora, M.D., Medical Designs LLC, and Sicage LLC*¹⁴

Neurosurgeon Wilson Asfora, M.D. and two medical device distributors owned by Asfora, Medical Designs LLC and Sicage LLC, agreed to pay a combined total of \$4.4 million to resolve civil allegations that the companies made illegal payments to Asfora to induce the use of certain medical devices in violation of the Anti-Kickback Statute and that Asfora submitted claims for medically unnecessary surgeries in violation of the FCA.

Specifically, the government contended that for nearly a decade, Asfora, Medical Designs, and Sicage knowingly and willfully engaged in three kickback schemes: 1) Medical Designs and Sicage allegedly paid Asfora profit distributions in exchange for Asfora’s use of the companies’ devices in his spine surgeries; 2) Medical Designs resold other manufacturers’ spinal devices and split the profits with Asfora when

¹³ Press Release, U.S. Dep’t of Justice, Medical Device Company Arthrex to Pay \$16 Million to Resolve Kickback Allegations (Nov. 8, 2021).

¹⁴ Press Release, U.S. Dep’t of Justice, Neurosurgeon and Two Affiliated Companies Agree to Pay \$4.4 Million to Settle Health Care Fraud Allegations (May 3, 2021).

Asfora used those devices in surgeries; and 3) Asfora received kickbacks from medical device manufacturer Medtronic USA Inc. in exchange for using Medtronic's infusion pumps. These kickbacks were allegedly paid in the form of lavish meals and alcohol to Asfora through a restaurant he owned with his wife.

The government also contended that Asfora knowingly submitted false claims to federal health care programs for medically unnecessary procedures using devices in which he had financial interests, despite receiving warnings from physician colleagues that such procedures were medically unnecessary. Other settlements related to the provision of unnecessary medical procedures are discussed in the following section.

Asfora and his two distribution companies are excluded from participation in federal health care programs for a term of six years. This settlement also resolves claims brought under the *qui tam* provisions by two doctors who will receive \$800,000 as part of their share of the recovery.

Medical Designs and Sicage also agreed to pay \$100,000 in penalties for alleged violations of the Center for Medicare and Medicaid Services' (CMS) Open Payments Program in that they failed to report to CMS Asfora's ownership interests and payments made to Asfora. This program, established by the Affordable Care Act, requires medical device companies to disclose to CMS physician ownership interests and certain transfers of value to a physician.

IV. HEALTHCARE SERVICES

Settlements related to healthcare services generally concerned one of two categories of alleged activities: 1) the provision of medically unnecessary or medically substandard services resulting in the submission of false claims to federal healthcare programs in violation of the FCA; and/or 2) the payment or receipt of remuneration in violation of the Anti-Kickback Statute, which may also give rise to FCA violations if such activity resulted in the submission of false claims to a federal healthcare program.

A. Medically Unnecessary or Medically Substandard Services

1. SavaSeniorCare LLC¹⁵

SavaSeniorCare LLC and related entities ("Sava") agreed to pay \$11.2 million (plus additional amounts if certain financial contingencies occur) to resolve allegations that Sava caused its skilled nursing facilities (SNFs) to bill Medicare programs for rehabilitation therapy services that were not reasonable, necessary, or performed skillfully and that Sava billed Medicare and Medicaid programs for grossly substandard skilled nursing services.

The government alleged that Sava:

- Knowingly engaged in a systemic effort to increase Medicare billing and pressured its SNFs to meet unrealistic financial goals that resulted in the provision of unreasonable, unnecessary, or unskilled services to Medicare patients and, ultimately, the submission of false claims for such services;

¹⁵ Press Release, U.S. Dep't of Justice, SavaSeniorCare LLC Agrees to Pay \$11.2 Million to Resolve False Claims Act Allegations (May 21, 2021).

- Delayed patient discharge from its facilities in order to increase its Medicare payments;
- Knowingly submitted false claims to Medicaid for coinsurance amounts for beneficiaries eligible for both Medicaid and Medicare and for which Sava had also submitted false claims to Medicare;
- Knowingly submitted false claims to Medicare and Medicaid for grossly substandard nursing services (e.g., failing to have sufficient staffing, failing to follow appropriate pressure ulcer protocols and appropriate falls protocols, and failing to appropriately administer medications to patients).

Sava also entered into a five-year chain-wide CIA with the HHS-OIG that requires an independent review organization to annually review patient stays and associated paid claims by Medicare. The CIA also requires an independent monitor to review the quality of resident care. This settlement also resolves four claims brought under the *qui tam* provisions.

2. *Interface Rehab*¹⁶

Interface Rehab (“Interface”) agreed to pay \$2 million to resolve allegations that Interface submitted Medicare claims for medically unreasonable or unnecessary rehabilitation therapy services. This settlement resolves Interface’s role in a July 2020 DOJ settlement with Longwood Management Corporation and twenty-seven affiliated SNFs in which those parties agreed to pay \$16.7 million to resolve similar allegations.

Specifically, the government alleged that Interface submitted false claims for “Ultra High” levels of therapy at eleven SNFs. The amount of Medicare reimbursement varies depending upon the skilled therapy and nursing needs for qualifying patients; the “Ultra High” level is the highest level of Medicare reimbursement. Interface allegedly pressured therapists to increase the amount of therapy provided to patients and to bill patients at the “Ultra High” level in order to meet Interface’s pre-planned Medicare revenue targets.

This settlement also resolves claims brought under the *qui tam* provisions by a former Director of Rehab at Interface; the whistleblower will receive \$360,000 of the settlement amount.

3. *Ascension Michigan and Related Hospitals*¹⁷

Ascension Michigan and related hospitals, Providence Park Hospital, St. John Hospital and Medical Center, St. John Macomb Oakland Hospital, and Ascension Crittenton Hospital (collectively, “Ascension”) agreed to pay \$2.8 million to resolve allegations that Ascension submitted false claims to federal healthcare programs for medically unnecessary procedures performed by a gynecologic oncologist.

Specifically, the government alleged that Ascension knew such claims were falsely submitted and improperly kept payment for fees related to unnecessary hysterectomies that the doctor performed, chemotherapy services that the doctor administered or

¹⁶ Press Release, U.S. Dep’t of Justice, Interface Rehab to Pay \$2 Million to Resolve False Claims Act Allegations (July 23, 2021).

¹⁷ Press Release, U.S. Dep’t of Justice, Ascension Michigan to Pay \$2.8 Million to Resolve False Claims Act Allegations (Aug. 5, 2021).

ordered, and evaluation and management services by the doctor that were either not performed or not rendered as represented.

Ascension allegedly had concerns about this doctor's quality of care, based upon patient complaints and higher-than-average rates of pulmonary embolisms and surgical infections and, in fact, hired a third party doctor to conduct a peer review of the doctor's patients. The peer reviewer found that for a majority of the doctor's services, a less aggressive surgery or medical intervention would have been consistent with the standard of care. In 2018, Ascension made a self-disclosure to HHS-OIG related to the professional and facility fees it billed to federal healthcare programs for the doctor's services and ultimately ended its contractual relationship with the doctor.

This settlement also resolves claims brought under the *qui tam* provisions in which the whistleblowers will receive a total of \$532,000 of the settlement amount.

B. Payment of Kickbacks

1. Prime Healthcare Services, Dr. Prem Reddy, and Dr. Siva Arunasalam¹⁸

In a joint resolution with the DOJ and the California Department of Justice, one of the largest hospital systems in the country and two of its doctors agreed to pay \$37.5 million to resolve alleged FCA and California False Claims Act violations. Specifically, the settlement involved Prime Healthcare Services ("Prime"), Prime's Founder and Chief Executive Officer Dr. Prem Reddy, and California interventional cardiologist Dr. Siva Arunasalam. Arunasalam agreed to pay \$2 million, Reddy agreed to pay \$1.775 million, and Prime agreed to pay \$33.725 million. Notably, Prime and Reddy previously paid a combined total of \$65 million in 2018 related to allegations of false claims and overbilling.

Specifically, the government alleged that:

- Prime paid Arunasalam kickbacks in its purchase of Arunasalam's physician practice and surgery center in that the purchase price exceeded fair market value and was not commercially reasonable. Such payments were made to induce Arunasalam to refer patients to one of Prime's hospitals;
- One of Prime's entities, High Desert Heart Vascular Institute, and Arunasalam used Arunasalam's billing number to bill Medicare and Medi-Cal for services provided by a different doctor whose Medicare and Medi-Cal billing privileges had been revoked;
- Certain Prime hospitals billed Medi-Cal and federal benefit programs for false claims based upon inflated invoices.

Prime and Reddy entered into a five-year CIA with HHS-OIG that requires, among other things, that Prime maintain a compliance program and engage an Independent Review Organization to review arrangements entered into or on behalf of its affiliates. This settlement also resolves claims brought in two lawsuits under the *qui tam* provisions by a former Prime executive and a former employee in the billing office at

¹⁸ Press Release, U.S. Dep't of Justice, 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).

a Prime hospital. The former executive will receive nearly \$10 million of the False Claims Act settlement.

2. *Akron General Health System*¹⁹

Akron General Health System (AGHS) agreed to pay \$21.25 million to resolve allegations of improper relationships with referring physicians which resulted in the submission of false claims to Medicare in violation of the FCA. The Cleveland Clinic Foundation acquired AGHS in 2015 and, upon learning of these practices, voluntarily disclosed its concerns to the government.

The government alleged that AGHS compensated area physician groups substantially in excess of fair market value in exchange for patient referrals in violation of the Anti-Kickback Statute and the Physician Self-Referral Law. The Physician Self-Referral Law (commonly called the Stark Law) prohibits hospitals from submitting claims to Medicare for certain services referred by physicians with whom the hospital has an improper financial arrangement. Further, AGHS then submitted claims to federal healthcare programs for services rendered to these unlawfully referred patients in violation of the FCA.

This settlement also resolves claims brought under the *qui tam* provisions by the former Director of Internal Audit at AGHS.

3. *Alliance Family of Companies LLC and Acor Holdings LLP*²⁰

Alliance Family of Companies LLC (“Alliance”), a national electroencephalography (EEG) testing company, and Acor Holdings LLP (“Acor”), a private investment company and investor of Alliance, agreed to pay a combined total of \$15.3 million to resolve allegations of misconduct that resulted in the submission of false claims to federal healthcare programs. Specifically, Alliance agreed to pay \$13.5 million to resolve allegations that it caused the submission of false claims resulting from kickbacks to referring physicians and sought payment for work not performed or for which Alliance was entitled to a lesser reimbursement. Acor agreed to pay \$1.8 million to resolve allegations that, through its management agreement with Alliance, Acor caused false billings as a result of the kickback scheme.

The government alleged that Alliance induced physicians to order its EEG tests by providing kickbacks in the form of free EEG test-interpretation reports, allowing certain physicians who were not specialized in the testing area to submit claims to the government as though they interpreted the results. The government also alleged that Alliance received increased reimbursements as a result of its use of inaccurate billing codes for certain EEG testing and billed for specialized digital analysis it did not perform. Of the \$13.5 million payable by Alliance, roughly \$13 million is payable to the federal government and \$475,000 is payable to state Medicaid programs. However, Alliance must pay additional amounts if certain financial events occur and must forego claims to \$390,000 in suspended payments otherwise owed by Medicare. Alliance also entered into a five-year CIA with the HHS-OIG.

The government alleged that Acor learned of Alliance’s kickback scheme during due diligence Acor performed prior to its investment in Alliance and that Acor

¹⁹ Press Release, U.S. Dep’t of Justice, 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).

²⁰ Press Release, U.S. Dep’t of Justice, EEG Testing and Private Investment Companies Pay \$15.3 Million to Resolve Kickback and False Billing Allegations (July 21, 2021).

caused the submission of false claims when it allowed such conduct to continue after entering into a management contract with Alliance. Of the \$1.8 million payable by Ancor, \$1.78 million is payable to the federal government and \$64,000 is payable to state Medicaid programs.

This settlement also resolves claims brought in six lawsuits under the *qui tam* provisions.

V. CONCLUSION

These settlements illustrate DOJ's commitment to enforcing the FCA against not only offending corporate entities but also individuals and entities connected to and aware of the activities of offending entities (for instance, investors or successors-in-interest following a change in ownership).

More broadly, the 2021 settlements illustrate FDA's and DOJ's commitment to medical product safety, as well as their continued emphasis on ensuring patient safety by holding accountable those who compromise the medical care given to patients. DOJ also expects its enforcement practices to serve as a deterrent against others who may seek to misuse public funds.