Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary - Life Science Reports

March 1, 2022 - March 31, 2025

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To our Healthcare Management and Compliance Colleagues and Partners:

SunHawk Consulting produces this complimentary Report in an effort to promote the value of shared learnings, as well as to provide focused insights into healthcare related Corporate Integrity Agreements (CIA) settled over the last two years.

The United States Government may impose a Corporate Integrity Agreement (CIA) upon an entity when settling cases related to false claims submitted for services paid for by federally funded health care programs, The CIA establishes terms companies must meet including, in most cases, the engagement of an Independent Review Organization (IRO).

The Summary Reports included here provide focused insights into recently settled healthcare-related CIAs. The Summary Reports extract key data from published CIAs and US Department of Justice press releases to guide providers, payers, and life sciences companies in designing and refining their compliance programs. For your convenience and ease of use, the electronic version of this report includes hyperlinks to the original sources. The Report is updated regularly and new settlement matters are highlighted in orange to facilitate your review.

We appreciate feedback you believe would make this report more helpful to you or others. Should you wish to proactively audit or review your organizational activities as a result of these learnings, SunHawk's team of experts are happy to offer our assistance. Visit us at SunHawkConsulting.com and connect with us on LinkedIn for updates to this and other Healthcare Audit and Enforcement Risk Analyses.

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Justice Department Announces Resolution of Criminal and Civil Investigations into McKinsey & Company's Work with Purdue Pharma L.P.; Former McKinsey Senior Partner Charged with Obstruction of Justice

Company Name: McKinsey & Company, Inc. United States
Settlement: $650,000,000

Issue(s): False Claims Act, Anti-Kickback, Obstruction of Justice, Opioid Consulting
CIA Term: Five Years

The US DOJ announced that McKinsey & Company Inc. (McKinsey), a global management consulting firm based in New York, has agreed to pay $650 million to resolve a criminal and civil investigation into the firm's consulting work with opioids manufacturer Purdue Pharma L.P. (Purdue). The resolution pertains to McKinsey's advice to Purdue concerning the sales and marketing of Purdue's extended-release opioid drug, OxyContin, including a 2013 engagement in which McKinsey advised on steps to "turbocharge" sales of OxyContin.

Today's resolution marks the first time a management consulting firm has been held criminally responsible for advice resulting in the commission of a crime by a client and reflects the Justice Department's ongoing efforts to hold actors accountable for their roles in the opioid crisis. The resolution is also the largest civil recovery for such conduct.

Additionally, a former McKinsey senior partner who worked on Purdue matters has been charged with obstruction of justice in federal court in Abingdon, Virginia. Martin E. Elling, 60, a U.S. citizen currently residing in Bangkok, Thailand, has been charged with one count of knowingly destroying records, documents and tangible objects with the intent to impede, obstruct and influence the investigation and proper administration of a matter within the jurisdiction of the Justice Department. Elling has agreed to plead guilty and is expected to appear in federal court in Abingdon to enter his plea and for sentencing at later dates.

As part of the government's resolution with McKinsey, the company has entered into a five-year deferred prosecution agreement (DPA) (part one and part two) in connection with a criminal Information filed in U.S. District Court for the Western District of Virginia against McKinsey's U.S. subsidiary (McKinsey & Company Inc. United States, "McKinsey U.S."). The information charges McKinsey U.S. with one felony count of knowingly destroying records, documents and tangible objects with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of the Justice Department; and one misdemeanor count of knowingly and intentionally conspiring with Purdue and others to aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid prescriptions.

McKinsey has agreed to pay a penalty of over $231 million, a forfeiture amount of over $93 million (reflecting all money it was paid by Purdue from 2004 to 2019) and a payment of $2 million to the Virginia Medicaid Fraud Control Unit to resolve the criminal allegations. McKinsey also has entered into a civil settlement agreement in which it will pay over $323 million to resolve its liability under the False Claims Act for allegedly providing advice to Purdue Pharma L.P. that caused the submission of false and fraudulent claims to federal healthcare programs for medically unnecessary prescriptions of OxyContin, as well as allegedly failing to disclose to the U.S. Food and Drug Administration (FDA) conflicts of interest arising from McKinsey US's concurrent work for Purdue and the FDA. This brings the total payments under the global resolution to $650 million.

Today's filing includes a 71-page Agreed Statement of Facts, which provides a detailed account of McKinsey's work with Purdue relating to OxyContin. As part of the resolution, McKinsey has agreed to implement a significant compliance program, including a system of policies and procedures designed to identify and assess high-risk client engagements. As part of this compliance program, McKinsey will implement new document retention procedures and training for all partners, officers and employees who provide or implement advice to clients. This compliance program is in addition to the provisions negotiated between McKinsey and the Department in a concurrent resolution with McKinsey & Company Africa that was announced on Thursday, Dec. 5.

McKinsey has also agreed that it will not do any work related to the marketing, sale, promotion or distribution of controlled substances during the five-year term of the DPA. The resolution requires McKinsey's Managing Partner to certify, on an annual basis, the firm's compliance with its obligations under the DPA and federal law.

As described in the DPA, McKinsey received credit for its cooperation with the United States in connection with the criminal investigation, including providing updates regarding information obtained through is internal investigation; highlighting documents of interest in voluminous productions; and facilitating interviews. McKinsey also engaged in extensive remedial measures, including voluntarily stopping all work in 2019 on any opioid-specific business issues; terminating two senior partners, including Elling, who communicated about deleting opioid-related documents concerning Purdue; hiring a new chief legal officer and chief ethics and compliance officer; significantly enhancing its new client selection framework; and deploying a formalized diligence review and intake process for all clients. McKinsey has agreed to continue to cooperate with the United States.

McKinsey's Criminal Liability for Misbranding

The criminal misbranding charge was based on McKinsey's advice to Purdue Pharma L.P. as set forth in the Agreed Statement of Facts filed today. Between 2004 and 2019, McKinsey contracted with Purdue on 75 different engagements in the United States. In 2007, a Purdue affiliate pleaded guilty to misbranding OxyContin, from 1996 through 2001, by falsely marketing it as less addictive, less subject to abuse and diversion, and less likely to cause dependence and withdrawal than other pain medications, and Purdue entered into a five-year corporate integrity agreement (CIA) with HHS-OIG. After the 2007 guilty plea, McKinsey partners maintained close contact with Purdue, and in 2009, worked with Purdue to enhance "brand loyalty" for OxyContin and protect market share. In 2010 McKinsey worked with Purdue to obtain FDA approval for a version of OxyContin that was reformulated with abuse-deterrent properties. Following the introduction of reformulated OxyContin in August 2010, OxyContin sales immediately began to decline. Purdue studied the drivers for this decline and attributed it, in large part, to a drop in prescriptions for individuals abusing OxyContin and increases in regulatory safeguards intended to hinder medically unnecessary prescribing of OxyContin.

In May 2013, Purdue retained McKinsey to conduct a rapid assessment of the underlying drivers of OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities. This 2013 effort was called Evolve to Excellence, or "E2E," and included McKinsey advising Purdue on how to "turbocharge" the sales pipeline for OxyContin by, among other strategies, intensifying marketing to High Value Prescribers, included prescribers who were writing opioid prescriptions for uses that were unsafe, ineffective, and medically unnecessary. McKinsey consultants spoke with Purdue about the concerns and increasing reluctance of pharmacists and pharmacy chains to fill prescriptions for OxyContin as abuse of the drug rose. McKinsey consultants also went on several "ride-alongs" with Purdue sales representatives in the field, as these sales representatives called on prescribers and pharmacists. In notes about one of these ride-alongs, a McKinsey consultant wrote, in part, "Pharmacist; [had] a gun and was shaking; abuse is definitely a huge issue[.]"

In August 2013, McKinsey partners met with certain members of the Purdue Board of Directors (members of the family that controlled Purdue) to present McKinsey's findings and proposal; as one McKinsey partner reported afterwards, "[b]y the end of the meeting the findings were crystal clear to everyone and they gave a ringing endorsement of 'moving forward fast.'" McKinsey also described for Purdue the financial value at stake: "hundreds of millions, not tens of millions."

For Purdue and McKinsey, E2E was a financial success. Their targeting of High Value Prescribers slowed OxyContin's declining sales and kept Purdue's profits flowing at the expense of public health. After the conclusion of McKinsey's work for Purdue on E2E, McKinsey performed additional work with Purdue that also sought to maximize OxyContin sales by further targeting sales efforts to High Value Prescribers.

Obstruction of Justice by Former McKinsey Senior Partner

According to the charging documents filed today, Elling served as the Director of the client services team for approximately 30 of McKinsey's engagements with Purdue. He had a senior, relationship-focused role with respect to the E2E engagement and was involved in securing the engagement for McKinsey. On July 4, 2018, Elling allegedly emailed another senior partner: "Just saw in the FT that [Purdue board member] is being sued by states attorneys general for her role on the [Purdue] Board. It probably makes sense to have a quick conversation with the risk committee to see if we should be doing anything other [than] eliminating all our documents and emails. Suspect not but as things get tougher there someone might turn to us." According to court documents, forensic analysis of Elling's McKinsey-issued laptop found that Elling in fact removed materials related to McKinsey's work for Purdue from the laptop, as well as a Purdue-related folder from his Outlook email account.

Elling faces a maximum penalty of 20 years in prison, three years of supervised release and a fine up to $250,000 for the obstruction of justice charge. A federal district court judge will determine any sentence after considering the U.S. Sentencing Guidelines and other statutory factors.

False Claims to Federal Healthcare Programs

The department's civil False Claims Act settlement resolves allegations that, from 2013 to 2014, McKinsey US, by advising Purdue to turbocharge OxyContin marketing to High Value Prescribers, some of whom were already prescribing very large quantities of OxyContin, as a means to increase OxyContin sales, and despite its awareness of the opioid crises, thereby knowingly caused false and fraudulent claims for OxyContin to be submitted to Medicare, Medicaid, TRICARE, the Federal Employees Health Benefit Program and the Veterans Health Administration.

Along with the civil settlement, McKinsey US entered into a five-year Corporate Integrity Agreement with HHS-OIG. The CIA, HHS-OIG's first with a management consulting firm, contains novel obligations regarding risk assessment and quality control. First, the CIA requires McKinsey's Compliance Committee to establish a robust risk evaluation process, evaluating engagement risks and providing quality oversight for certain client deliverables. Second, it requires McKinsey to establish a Quality Review Program to assess the quality of McKinsey's advice to certain life sciences and health care clients with the dual goals of ensuring that McKinsey complies with applicable laws and does not provide or assist clients with plans, advice, or strategies that violate the law. HHS-OIG will select an independent Compliance Expert to review McKinsey's systems and processes under the Quality Review Program and to review a sample of McKinsey client engagements, including the advice provided to those clients.

False Claims to FDA

The department's civil False Claims Act settlement also resolves allegations that, from 2014 to 2017, McKinsey US knowingly misled the FDA by assigning consultants to concurrently work on both FDA projects and competitively sensitive Purdue projects, contrary to McKinsey US' conflict of interest policy. While soliciting a contract from the FDA, McKinsey US represented to the FDA that it had a conflict-of-interest policy in which its consultants serving the FDA would not be assigned to a competitively sensitive project for a significant period of time following an assignment for FDA. The FDA then awarded McKinsey US the first in a series of contracts on a project relating to the monitoring of the safety of FDA-regulated products. McKinsey US admitted that it did not inform the FDA that its consultants worked on the Purdue projects around the same time those consultants also worked on the FDA project.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 12/11/2024 **Entity Location:** Texas **Government Program(s):** Medicare, Medicaid, TRICARE, Federal Employees Health Benefit Program, Veterans Health Administration, FDA

Pharmaceutical Company QOL Medical and CEO Agree to Pay $47M for Allegedly Paying Kickbacks to Induce Claims for QOL's Drug Sucraid

Company Name: QOL Medical, LLC, and Others
Settlement: $47,000,000

Issue(s): False Claims Act, Anti-Kickback, Pharmaceutical
CIA Term: Five Years

The US DOJ announced that pharmaceutical company QOL Medical LLC (QOL) and its co-owner and CEO, Frederick E. Cooper, have agreed to pay $47 million to resolve allegations that they caused the submission of false claims to federal health care programs, in violation of the False Claims Act and similar state statutes, by offering kickbacks in the form of free Carbon-13 breath testing services to induce claims for QOL's drug Sucraid.

Sucraid is an FDA-approved therapy for the rare genetic condition Congenital Sucrase-Isomaltase Deficiency (CSID). CSID patients have difficulty digesting sucrose (table sugar) and suffer from gastrointestinal symptoms such as diarrhea, abdominal pain, bloating and gas.

Beginning in 2018, QOL, with Cooper's approval, distributed free Carbon-13 breath test kits to health care providers and asked providers to give the kits to patients with common gastrointestinal symptoms. QOL claimed that the test could "rule in or rule out" CSID. In fact, the test does not specifically diagnose CSID. Conditions other than CSID can cause a patient to test "positive" for low sucrase activity on a Carbon-13 breath test. Approximately 30% of the Carbon-13 breath tests from QOL were positive for low sucrase activity.

QOL paid a laboratory to analyze the breath tests, report the results to health care providers and also provide the results to QOL. The results provided to QOL did not contain patient names, but did contain the name of the health care provider who ordered the test, along with the patient's age, gender, symptoms and test result. Between 2018 and 2022, QOL disseminated this information to its sales force with instructions to make sales calls for Sucraid to health care providers whose patients had positive Carbon-13 breath test results. QOL tracked whether sales representatives converted "positive" Carbon-13 breath tests into Sucraid prescriptions. As QOL's CEO, Cooper was aware of and approved the implementation and continuation of this marketing program.

Some QOL sales representatives also made claims to health care providers regarding the Carbon-13 test's ability to definitively diagnose CSID that were not supported by published scientific literature. For example, in slides at a 2019 national sales training, which Cooper reviewed, QOL suggested that sales representatives tell health care providers, "If you have a positive breath test, the patient will not improve unless you treat with Sucraid."

As part of the settlement, QOL and Cooper admitted and accepted responsibility for certain facts providing the basis of the settlement.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 11/01/2024 **Entity Location:** Florida **Government Program(s):** federal health care programs

Two Jacksonville Compounding Pharmacies and Their Owner Agree to Pay at Least $7.4 Million to Resolve False Claims Act Allegations

Company Name: Balotin, Gregory H.
Settlement: $7,400,000

Issue(s): False Claims Act, Compounded Pain Creams
CIA Term: Three Years

The US DOJ announced that Smart Pharmacy, Inc., SP2, LLC, and owner Gregory Balotin have agreed to pay at least $7.4 million to resolve lawsuits filed in Jacksonville, Florida, alleging they violated the False Claims Act by adding the antipsychotic drug aripiprazole to topical compounded pain creams to boost reimbursement and by routinely waiving patient copayment obligations. The settlement amount is based on the defendants' ability to pay.

Aripiprazole, which is sold under the brand names Abilify, Abilify Maintena, and Aristada, is approved by the U.S. Food and Drug Administration to treat a number of psychological conditions such as schizophrenia and Tourette's disorder. The United States alleged that the defendants crushed aripiprazole pills approved for oral use and included them in compounded creams used topically for pain treatment, while knowing that there was not an adequate clinical basis to do so. The defendants allegedly included the drug in the pain creams to increase their profits on prescriptions paid for by Medicare Part D and TRICARE, the federal health care program for active duty military personnel, retirees, and their families. Both Medicare Part D and TRICARE reimburse pharmacies for the individual ingredients included in compounded drugs, thus defendants increased their reimbursement by adding aripiprazole to the combination of drugs used in their pain creams.

The government also alleged that the defendants improperly waived patient copayments to induce patients to accept the pain cream prescriptions. Although copayments may be waived in certain unique circumstances, such as on the basis of an individualized assessment of a patient's financial hardship, the defendants allegedly routinely waived copayments without regard to patient need.

In connection with the settlement, Gregory Balotin has agreed to enter into a three-year integrity agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG), which includes an annual claims review by an independent review organization.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 06/14/2023 **Entity Location:** Florida **Government Program(s):** Medicare Part D, TRICARE

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Mallinckrodt Agrees to Pay $260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks

Company Name: Mallinckrodt plc
Settlement: $260,000,000

Issue(s): False Claims Act, Anti-Kickback Statute, Medicaid Rebates, Copay Subsidies
CIA Term: Five Years

The US DOJ announced that pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. (Questcor)) (collectively Mallinckrodt), has agreed to pay $260 million to resolve allegations that Mallinckrodt violated the False Claims Act by knowingly: 1. underpaying Medicaid rebates due for its drug H.P. Acthar Gel (Acthar); and 2. using a foundation as a conduit to pay illegal co-pay subsidies in violation of the Anti-Kickback Statute for Acthar. In 2019 and 2020, respectively, the government filed separate complaints detailing these allegations. The settlement, which is based on Mallinckrodt's financial condition, required final approval of the U.S. Bankruptcy Court for the District of Delaware, which approved the settlement on March 2.

In connection with the settlement, Mallinckrodt also entered a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA contains unique drug price transparency provisions and monitoring provisions focused on Medicaid rebate and patient assistance program activities. The CIA also requires Mallinckrodt to establish a risk assessment program, implement executive recoupment provisions, and obtain compliance related certifications from company executives and board members.

Medicaid Drug Rebate Claims

Pursuant to the Medicaid Drug Rebate Program, drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The statute requires manufacturers to pay inflation-based rebates for drugs, which are designed to insulate the Medicaid program from drug price increases outpacing inflation. These rebates are calculated by comparing the drug's Base Date Average Manufacturer Price (AMP), which is the drug's price on the date that the "dosage form and strength" of the drug was first marketed or 1990, whichever is later, to its current price.

In its complaint filed on March 3, 2020, the government alleged that Mallinckrodt knowingly underpaid rebates due for Acthar from 2013 until 2020. According to the complaint, Mallinckrodt and its predecessor Questcor began paying rebates for Acthar in 2013 as if Acthar was a "new drug" first marketed in 2013, rather than a drug that had been approved since 1952. Allegedly, this practice meant the companies ignored all pre-2013 price increases when calculating and paying Medicaid rebates for Acthar from 2013 until 2020. In particular, the government alleged that Acthar's price had already risen to over $28,000 per vial by 2013, and therefore ignoring all pre-2013 price increases for Medicaid rebate purposes significantly lowered Medicaid rebate payments for Acthar. Under the settlement agreement, Mallinckrodt admitted that Acthar was not a new drug as of 2013 but rather was approved by the U.S. Food and Drug Administration and marketed prior to 1990, and agreed to correct Acthar's base date AMP and that it will not change the date in the future.

Kickback Claims

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, which may take the form of a copayment. Congress included copay requirements in the Medicare program, in part, to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can

demand for their drugs. The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration -- which includes money or any other thing of value -- to induce Medicare patients to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations.

In its complaint filed on June 5, 2019, the government alleged that Mallinckrodt knowingly used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as "free" to doctors and patients while increasing its price. Mallinckrodt allegedly paid these illegal subsidies through three funds that Mallinckrodt had a foundation set up to induce Medicare-reimbursed purchases of Acthar, and used the subsidies to counteract doctor and patient concerns about the drug's high cost.

The settlement provides for Mallinckrodt's payment of approximately $234.7 million to resolve the Medicaid rebate allegations and approximately $26.3 million to resolve the kickback allegations. Of the amount allocated to the Medicaid rebate claims, Mallinckrodt will pay approximately $123.6 million to the United States and approximately $110.1 million to the participating Medicaid States, pursuant to the terms of separate settlement agreements Mallinckrodt has or will enter into with those states. In October 2020, Mallinckrodt filed for bankruptcy protections and this settlement with the government has been approved for payment by the U.S. Bankruptcy Court for the District of Delaware.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 03/03/2022 **Entity Location:** Missouri **Government Program(s):** Medicaid, Medicare

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Medical Devices

Advanced Bionics LLC to Pay Over $12 Million for Alleged False Claims for Cochlear Implant Processors

Company Name: Advanced Bionics LLC
Settlement: $12,600,000

Issue(s): False Claims Act, Cochlear Implants
CIA Term: Five Years

The US DOJ announced that Advanced Bionics LLC, a Valencia, California-based manufacturer of cochlear implant system devices, has agreed to pay more than $12 million to resolve allegations that it misled federal health care programs regarding the radio-frequency (RF) emissions generated by some of its cochlear implant processors.

The tests at issue measured the extent to which cochlear implant systems generate RF emissions that can potentially interfere with other devices that use the RF spectrum. Such other devices may include telephones, alarm and security systems, televisions and radios.

The settlement resolves allegations that Advanced Bionics, in submitting pre-market approval applications to the Food and Drug Administration (FDA) for Advanced Bionics' Neptune and Naida cochlear implant processors, made false claims regarding the results of its RF emissions tests. Advanced Bionics allegedly represented that its processors satisfied an internationally recognized emissions standard when, in fact, Advanced Bionics did not comply with that standard. More specifically, Advanced Bionics allegedly failed to honor the standard's requirements to test processors using "worst-case" configurations, and improperly shielded certain emissions-generating system components during emissions testing. Advanced Bionics then allegedly sought reimbursement from Medicare, Medicaid, and other federally funded healthcare programs for these devices.

In addition to the civil settlement, Advanced Bionics entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG. The CIA requires an independent review of activities and processes relating to the preparation or submission of Premarket Approval Applications (PMAs) to the FDA and performance standards relevant to those PMAs. Advanced Bionics must also implement a robust compliance program that includes, among other things, a risk assessment program and compliance certifications from key managers and from the Board of Directors.

The settlement provides that Advanced Bionics will pay roughly $11.36 million to the United States, and in addition, will pay approximately $1.24 million to the participating Medicaid States, pursuant to the terms of separate settlement agreements that Advanced Bionics has, or will enter into, with those states.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 12/19/2022 **Entity Location:** California **Government Program(s):** Medicare, Medicaid, other federally funded healthcare programs

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Medical Device Manufacturer Biotronik Inc. Agrees To Pay $12.95 Million To Settle Allegations of Improper Payments to Physicians

Company Name: Biotronik, Inc.
Settlement: $12,950,000

Issue(s): False Claims Act, Anti-Kickback Statute, Cardiac Devices
CIA Term: Five Years

The US DOJ announced that Biotronik Inc. (Biotronik), a medical device manufacturer based in Oregon, has agreed to pay $12.95 million to resolve allegations that it violated the False Claims Act by causing the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce their use of Biotronik's implantable cardiac devices, such as pacemakers and defibrillators.

The Federal Anti-Kickback Statute prohibits offering or paying anything of value to induce referrals of items or services covered by Medicare and other federally funded programs. The statute is intended to ensure that medical providers' judgments are not compromised by improper financial incentives.

The settlement announced today resolves allegations that Biotronik engaged in a kickback scheme to pay certain favored physicians to induce and reward their use of Biotronik's pacemakers, defibrillators and other cardiac devices. In particular, Biotronik allegedly abused a new employee training program by paying physicians for an excessive number of trainings and, in some cases, for training events that either never occurred or were of little or no value to trainees. Biotronik allegedly made these payments despite concerns raised by its own compliance department, which warned that salespeople had too much influence in selecting physicians to conduct new employee training and that the training payments were being over-utilized. The settlement also resolves allegations that Biotronik violated the Anti-Kickback Statute when it paid for physicians' holiday parties, winery tours, lavish meals with no legitimate business purpose and international business class airfare and honoraria in exchange for making brief appearances at international conferences.

Medicaid is funded jointly by the states and the federal government. The States of Arizona, California, Illinois, Missouri and Nevada paid for a portion of the Medicaid claims at issue and will receive a total of approximately $933,400 from the settlement with Biotronik.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 08/26/2022 **Entity Location:** Oregon **Government Program(s):** Medicare, Medicaid

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Stockton Doctor and Medical Practice Agree to Pay Nearly $2 Million to Resolve Allegations of Health Care Fraud

Company Name: Kamali, M.D., Azizulah (Aziz) D/B/A Aziz Kamali, M.D., Inc., and Others
Settlement: $1,963,953

Issue(s): False Claims Act, Anti-Kickback Statute, Neurostimulators
CIA Term: Three Years

The US Attorney for the District of Eastern California announced that Azizulah "Aziz" Kamali and his medical corporation, Aziz Kamali, M.D. Inc., have agreed to pay $1,963,953 to resolve allegations that they violated the False Claims Act by submitting millions of dollars of false claims to Medicare for surgically implanted neurostimulators and paying kickbacks to sales marketers, U.S. Attorney Phillip A. Talbert announced today.

According to the settlement, Dr. Kamali and his medical corporation admitted that they submitted claims to Medicare for surgically implanted neurostimulator devices even though they did not perform surgery or implant neurostimulators. Dr. Kamali and Kamali Inc. admitted that they instead taped a disposable electroacupuncture device called "Stivax" to their patients' ears. Stivax devices do not require surgical implantation and are not reimbursable by Medicare. The government alleges that this conduct violated the False Claims Act.

Dr. Kamali and his medical corporation also admitted that they paid a marketing company a percentage of the reimbursements they received from Medicare for billing implantable neurostimulators, in return for the marketing company arranging for and recommending that patients order Stivax from them. The United States alleges that this conduct violated the Anti-Kickback Statute and the False Claims Act.

In addition to paying the civil settlement, Dr. Kamali and Kamali Inc. have agreed to enter into an Integrity Agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The Integrity Agreement requires that Dr. Kamali and Kamali Inc. implement specific compliance measures, including training on applicable health care fraud laws and contracting with an Independent Review Organization that will conduct third-party audits of the medical necessity of their Medicare claims.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 08/12/2022 **Entity Location:** California **Government Program(s):** Medicare

Essilor Agrees to Pay $16.4 Million to Resolve Alleged False Claims Act Liability for Paying Kickbacks

Company Name: Essilor of America, Inc., and Others
Settlement: $16,400,000

Issue(s): False Claims Act, Anti-Kickback Statute, Optical Lenses
CIA Term: Five Years

The US DOJ announced that Essilor International, Essilor of America Inc., Essilor Laboratories of America Inc. and Essilor Instruments USA (collectively, "Essilor"), headquartered in Dallas, have agreed to pay $16.4 million to resolve allegations that the company violated the False Claims Act by causing claims to be submitted to Medicare and Medicaid that resulted from violations of the Anti-Kickback Statute.

Essilor manufactures, markets and distributes optical lenses and equipment used to produce optical lenses. The United States alleged that between Jan. 1, 2011, and Dec. 31, 2016, Essilor knowingly and willfully offered or paid remuneration to eye care providers, such as optometrists and ophthalmologists, to induce those providers to order and purchase Essilor products for their patients, including Medicare and Medicaid beneficiaries, in violation of the Anti-Kickback Statute. The Anti-Kickback Statute prohibits offering or paying anything of value to induce the referral of items or services covered by Medicare, Medicaid and other federally-funded programs. The statute is intended to ensure that medical providers' judgments are not compromised by improper financial incentives.

In connection with the settlement, Essilor entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG. The CIA requires, among other things, that Essilor hire an independent review organization to review its systems, policies, processes and procedures for ensuring that any discounts, rebates, or other reductions in price offered to providers comply with the Anti-Kickback Statute. The CIA also requires Essilor to implement a new written review and approval process to ensure all existing and new discount arrangements comply with the Anti-Kickback Statute.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 04/04/2022 **Entity Location:** Texas **Government Program(s):** Medicare, Medicaid