Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary Life Science-Focused

January 2021

SUNHAWK

To our Healthcare Management and Compliance Colleagues and Partners:

SunHawk Consulting has produced this free 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 couple of years.

The United States Government requires Corporate Integrity Agreements (CIA) for health care Providers, Payers and Life Science companies when settling allegations of false claims related to quality of care or corporate integrity issues, against various Federal health care programs. Under the terms of a CIA, companies agree to various obligations including, in most cases, the engagement of an Independent Review Organization. The CIA summaries provided herein are extracted from published CIAs and US Department of Justice press releases. For your ease the electronic version of this report includes hyperlinks to the original sources.

After your review, we would appreciate any feedback you believe would make this report more helpful to you or others. Should you find you would like to proactively conduct an audit and/or review of activity within your organization to avoid future adverse findings, SunHawk's team of experts are happy to offer our assistance. Visit us at SunHawkConsulting.com and/or connect with us on LinkedIn for updates to this and other Healthcare Audit and Enforcement Risk Analyses.

Jim Rough
President, SunHawk Consulting, LLC
Jim.Rough@SunHawkConsulting.com

Table of Contents

Contact an Expert

Martin Biegelman
425-213-7344
Martin.Biegelman@SunHawkConsulting.com

James Rose
502-445-7511
James.Rose@SunHawkConsulting.com

Jim Rough
602-334-5522
Jim@SunHawkConsulting.com

SUNHAWK CONSULTING

SUNHAWK CONSULTING

Life Sciences

Pharmaceutical

Pharmaceutical

DUSA Pharmaceuticals To Pay U.S. $20.75 Million To Settle False Claims Act Allegations Relating To Promotion Of Unsupported Drug Administration Process

Company Name: DUSA Pharmaceuticals, Inc; Sun Pharmaceutical industries, Inc
Settlement: $20,750,000

Issue(s): Shortened Intubation Periods

The US DOJ announced that Massachusetts-based DUSA Pharmaceuticals, Inc. (DUSA), a subsidiary of Sun Pharmaceutical Industries, Inc. (Sun Pharma), has agreed to pay the United States $20.75 million and enter into a five-year corporate integrity agreement to resolve allegations that DUSA caused physicians to submit false claims to Medicare and the Federal Employee Health Benefit Program by knowingly promoting an administration process for the drug Levulan Kerastick that contradicted the product instructions approved by the U.S. Food and Drug Administration (FDA) and was unsupported by sufficient clinical evidence.

The DOJ reported allegations that, by January 2014, senior management at both DUSA and Sun Pharma knew that administration of Levulan Kerastick employing short incubation periods ranging from one to three hours resulted in AK clearance rates significantly lower than those achieved in clinical trials using 14 to 18-hour incubation. Nonetheless, between January 2014 and December 2016, DUSA allegedly encouraged physicians to use these demonstrably less effective short incubation periods by using, among other things, paid physician speaker programs, paid physician peer-to-peer discussions, promotion by DUSA's sales force, and the dissemination of incomplete or misleading responses to questions from prescribing doctors.

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

Date: 8/24/2020 **State:** New York **Government Program(s):** Medicare & FEHBP

Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay $600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution

Company Name: Indivior Inc; Indivior PLC; Indivior Solutions
Settlement: $600,000,000

Issue(s): Drug Marketing

The US DOJ announced that Indivior Solutions pleaded guilty to a one-count felony information and, together with its parent companies Indivior Inc. and Indivior PLC, agreed to pay a total of $600 million and enter into a five-year corporate integrity agreement to resolve criminal and civil liability associated with the marketing of the opioid-addiction-treatment drug Suboxone.

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

The DOJ reported allegations that Indivior Solutions made false statements to promote the film version of Suboxone (Suboxone Film) to the Massachusetts Medicaid program (MassHealth) relating to the safety of Suboxone Film around children.

Indivior Solutions admitted that, in October 2012, it sought to convince MassHealth to expand Medicaid coverage of Suboxone Film in Massachusetts and sent MassHealth false data indicating that Suboxone Film had the lowest rate of accidental pediatric exposure (i.e., children taking medication by accident) of all buprenorphine drugs in Massachusetts, when in fact, it did not. Indivior Solutions further admitted that sending the false and misleading information occurred in the context of marketing and promotional efforts directed at MassHealth, which were overseen by top executives. MassHealth announced it would provide access to Suboxone Film for patients with children under the age of six shortly after Indivior provided the false and misleading information to agency officials.

Date: 7/24/2020 **State:** Virginia **Government Program(s):** Medicaid

---

Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians

Company Name: Novartis Pharmaceuticals Corporation
Settlement: $642,000,000

Issue(s): Anti-Kickback, Medicare Copayments, Speaker Programs

The US DOJ announced that Pharmaceutical company Novartis Pharmaceuticals Corporation (Novartis), based in East Hanover, New Jersey, has agreed to pay over $642 million in separate settlements and enter into a five-year corporate integrity agreement resolving claims that it violated the False Claims Act (FCA). The first settlement pertains to the company's alleged illegal use of three foundations as conduits to pay the copayments of Medicare patients taking Novartis's drugs Gilenya and Afinitor. The second settlement resolves claims arising from the company's alleged payments of kickbacks to doctors.

In the first matter, the DOJ reported allegations that, in October 2012, Novartis learned from the contractor managing Novartis's free drug program for Gilenya that over 300 patients who were receiving free drugs would be eligible for Medicare in 2013. Novartis and the contractor transitioned those patients to Medicare Part D so that, in the future, Novartis would obtain revenue from Medicare when those patients filled prescriptions for Gilenya. Knowing those patients could not afford the copay for Gilenya, Novartis developed a plan with a foundation so that Novartis could cover the copays for those patients. Specifically, at the same time Novartis made a payment to the foundation, Novartis arranged for the foundation to open its MS fund at 6:00 pm on a Friday and for the contractor to have personnel working overtime to submit applications for those patients who had been receiving free Gilenya. Novartis knew that this coordination would result in a disproportionate share of its funding going to Gilenya patients for 2013. Novartis has agreed to pay $51.25 million to resolve these allegations.

Novartis also sells Afinitor, which is a second-line treatment for advanced renal cell carcinoma (RCC) and a treatment for progressive neuroendocrine tumors of pancreatic origin (PNET). The government alleged that Novartis learned that, for the 2010 donation year, it would be the only donor to an RCC copay assistance fund operated by a charitable foundation. The government alleged that Novartis told the foundation that it would be willing to donate to the fund only if the eligibility definition was narrowed in a way that ensured that a greater amount of the copay assistance would support patients

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

taking Afinitor. The government alleged that, as a result of narrowing the fund definition, the fund disproportionately assisted patients taking Afinitor compared to its overall usage rate among RCC drugs.

In the second matter, Novartis will pay $591,442,008 to resolve FCA claims that it paid kickbacks to doctors to induce them to prescribe the Novartis drugs Lotrel, Valturna, Starlix, Tekturna, Tekturna HCT, Tekamlo, Diovan, Diovan HCT, Exforge, and Exforge HCT. In addition, Novartis will forfeit $38.4 million under the Civil Asset Forfeiture Statute. Novartis also made extensive factual admissions in the settlement and agreed to strict limitations on any future speaker programs, including reductions to the amount it may spend on such programs.

In a case pending in the Southern District of New York, the United States alleged that Novartis hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when in fact the events served as nothing more than a means to provide bribes to doctors. Novartis paid physicians honoraria, purportedly as compensation for delivering a lecture regarding a Novartis medication, but, as Novartis knew, many of these programs were nothing more than social events held at expensive restaurants, with little or no discussion about the Novartis drugs. Indeed, some of the so-called speaker events never even took place and the speaker was simply paid a fee in order to induce the speaker to prescribe Novartis drugs.

The government's complaint further alleged that Novartis sales representatives, on the instruction of their managers, selected high-volume prescribers to serve as the paid "speakers" at these events with the intent to induce them to write more — or keep writing many — Novartis prescriptions. The sales representatives then pressured the speakers to increase their prescriptions of Novartis drugs, and often dropped doctors from the speaker program if they failed to do so. Further, the government alleged that this widespread kickback scheme was the result of decisions made by top management at Novartis's North American headquarters in New Jersey.

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

Date: 7/1/2020 **State:** New Jersey **Government Program(s):** Medicare, Medicaid & Other Federally Funded Programs

Manhattan U.S. Attorney Announces Settlement Of Fraudulent Billing And Kickback Lawsuit Against Compounding Pharmacies And Owners

Company Name: Mead Square Pharmacy, Inc
Settlement: $42,600

Issue(s): Anti-Kickback, Compounded Prescription Drugs

The United States Attorney for the Southern District of New York has filed a lawsuit and simultaneously settled civil healthcare fraud claims against Mead Square Pharmacy, Inc. and owner Christopher Casey for their submission of fraudulent claims for reimbursement to federal healthcare programs for compounded prescription drugs in violation of the False Claims Act and the Anti-Kickback Statute. Defendants agreed to pay a total of $426,000, enter into a three-year corporate integrity agreement and admitted to and accepted responsibility for the conduct alleged in the complaint.

The DOJ reported allegations that, from 2011 through 2015, the Pharmacies dispensed a compounded prescription analgesic cream known as Focused Pain Relief from their facility in Victor, New York, to patients around the country.

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

Many of the Pharmacies' patients were beneficiaries of federal healthcare programs such as TRICARE, Medicare, federal employee workers' compensation programs overseen by DOL, and the Federal Employee Health Benefit Program.

The Pharmacies allegedly violated the False Claims Act by dispensing and requesting reimbursement for hundreds of prescriptions of Focused Pain Relief dispensed to federal healthcare program beneficiaries located in states where the Pharmacies were not licensed to operate by the appropriate state authorities, and by failing to disclose that they were not licensed. The Pharmacies also violated the False Claims Act by billing federal healthcare programs for prescriptions dispensed in states in which they had obtained their state licenses under false pretenses, including failing to inform state authorities that they had previously dispensed drugs in the states without a license and by failing to disclose Casey's criminal history on pharmacy license applications.

In addition, it's alleged the Pharmacies violated the Anti-Kickback Statute by engaging in two separate illegal practices. First, the Pharmacies regularly charged federal healthcare program beneficiaries co-payments substantially below program requirements (which often exceeded $100) in order to induce them to purchase expensive prescriptions of Focused Pain Relief, for which the federal healthcare programs paid hundreds and sometimes thousands of dollars each. And second, the Pharmacies often paid illegal kickbacks to their sales representatives in the form of sales commissions tied to the number of Focused Pain Relief prescriptions written by the physicians to whom each representative marketed.

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

Date: 4/2/2020 **State:** New York **Government Program(s):** Medicare, TRICARE & FEHBP

Sanofi Agrees to Pay $11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation

Company Name: Sanofi-Aventis U.S., LLC
Settlement: $11,850,000

Issue(s): Anti-Kickback, Copay Assistance Foundations

The United States Attorney for the District of Massachusetts announced that pharmaceutical company Sanofi-Aventis U.S., LLC ("Sanofi"), has agreed to pay $11.85 million and enter into a five-year corporate integrity agreement to resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation, The Assistance Fund ("TAF").

The government alleged that TAF, an entity claiming 501(c)(3) status for tax purposes, operates funds, including a fund for MS patients, that pay the co-pays of certain patients, including Medicare patients, who were prescribed Lemtrada. TAF allegedly raised its maximum per-patient grant allocation to $20,000 specifically to accommodate Lemtrada patients. During the relevant time period, TAF's MS fund frequently ran out of funding and was closed to new patients. If any patients applied for co-pay assistance at a time when the MS fund was out of funding and closed to new patients, TAF did not maintain a wait list of such patients. As a consequence, whenever TAF's MS fund opened to new patients, the fund provided grants to the patients who applied immediately after the opening and did not provide grants to patients who had sought to apply earlier but at a time when the fund was closed.

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

The United States also alleged that Sanofi made payments to TAF, not with a charitable purpose, but rather with the intention of using TAF as a conduit to pay the financial obligations, including Medicare co-pay obligations, of patients taking Lemtrada, and that Sanofi's payment through TAF of Medicare co-pays for Lemtrada violated the Anti-Kickback Statute. To effectuate its scheme, Sanofi worked with its third-party reimbursement hub to identify Medicare patients for whom physicians had prescribed Lemtrada, but who had not yet received infusions of the drug because they lacked sufficient funds to afford the co-pays for Lemtrada.

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

Date: 2/28/2020 **State:** Massachusetts **Government Program(s):** Medicare

Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients

Company Name: Chronic Disease Fund, Inc d/b/a Good Days from CDF, Patient Access Network Foundation
Settlement: $2,000,000 and 4,000,000

Issue(s): Anti-Kickback

The US Attorney's for the District of Massachusetts announced that two foundations, Chronic Disease Fund, Inc. d/b/a Good Days from CDF ("CDF"), and Patient Access Network Foundation ("PANF"), have agreed to pay $2 million and $4 million, respectively, and enter into a three-year corporate integrity agreement to resolve allegations that they violated the False Claims Act by enabling pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.

The government alleged that CDF and PANF worked with various pharmaceutical companies to design and operate certain funds that funneled money from the companies to patients taking the specific drugs the companies sold. These schemes enabled the pharmaceutical companies to ensure that Medicare patients did not consider the high costs that the companies charged for their drugs. The schemes also minimized the possibility that the companies' money would go to patients taking competing drugs made by other companies.

Additionally, the United States alleged that, from 2010 through 2014, CDF conspired with five pharmaceutical companies – Novartis, Dendreon, Astellas, Onyx, and Questcor – to enable them to pay kickbacks to Medicare patients taking their drugs. It is further alleged that, from 2011 through 2014, PANF permitted four pharmaceutical companies – Bayer, Astellas, Dendreon, and Amgen – to use PANF as a conduit to pay kickbacks to Medicare patients taking their drugs. Details of the conduct can be found in attached addendum.

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

Date: 10/25/2019 **State:** Texas **Government Program(s):** Medicare

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations

Company Name: Avanir Pharmaceuticals
Settlement: $95,000,000

Issue(s): Anti-Kickback, Drug Marketing, Speaker Programs

The US DOJ announced that Avanir Pharmaceuticals (Avanir), a pharmaceutical manufacturer based in Aliso Viejo, California, was charged for paying kickbacks to a physician to induce prescriptions of its drug Nuedexta. The Northern District of Ohio also announced indictments of four individuals, including former Avanir employees and one of the top prescribers of Nuedexta in the country, who were involved in the kickback scheme. Avanir has also agreed to pay over $95 million and enter into a five-year corporate integrity agreement to resolve civil False Claims Act allegations of kickbacks as well as its false and misleading marketing of Nuedexta to providers in long term care facilities to induce them to prescribe it for behaviors commonly associated with dementia patients, which is not an approved use of the drug.

As alleged in a one-count Information filed in the United States District Court for the Northern District of Georgia, Avanir violated the Anti-Kickback Statute by paying a doctor to induce him to become a high prescriber of Nuedexta to beneficiaries of federal healthcare programs, offering him financial incentives to write additional Nuedexta prescriptions for beneficiaries of federal healthcare programs, and inducing him to recommend that other physicians prescribe Nuedexta to beneficiaries of federal healthcare programs. The Northern District of Georgia also announced a deferred prosecution agreement resolving the charge, under which Avanir admits that it paid the doctor to induce him to not only maintain, but increase his prescription volume. Under the agreement's terms, Avanir will pay a monetary penalty in the amount of $7,800,000, and a forfeiture in the amount of $5,074,895.

The Northern District of Ohio also announced indictments of four individuals who paid or received kickbacks from Avanir. Named in the 83-count indictment are: Deepak Raheja, Gregory Hayslette, Frank Mazzucco, and Bhupinder Sawhny, 70. All four are charged with conspiracy to solicit, receive, offer and pay health care kickbacks. Avanir has agreed to cooperate in the prosecution of these individuals.

In a separate civil resolution, Avanir has agreed to pay $95,972,017 to the United States to resolve allegations under the False Claims Act related to its marketing of Nuedexta. The government alleged that between October 29, 2010, and December 31, 2016, Avanir provided remuneration in the form of money, honoraria, travel, and food to certain physicians and other health care professionals to induce them to write prescriptions for Nuedexta. One form of remuneration included Avanir's payment to certain health care professionals to give talks (commonly known as "speaker's programs") about Nuedexta based on their willingness to prescribe Nuedexta. These events were primarily social, with no educational value.

The government further alleged that Avanir implemented a strategy to market Nuedexta in long-term care (LTC) facilities for uses other than PBA that had not been approved by the FDA and were not medically accepted indications as defined by the statutes and regulations governing the Federal health care programs. In particular, Avanir sought to capitalize on efforts by the Centers for Medicare and Medicaid Services to reduce the use of anti-psychotics on dementia patients in LTC facilities, based in part on CMS's concern that anti-psychotics can be and have been used as a form of chemical restraint for residents. Avanir did so by instructing its sales force to initiate discussions in LTCs regarding anti-psychotic use and how Nuedexta could be used to reduce a LTC facility's reliance on anti-psychotics even though Avanir's own studies demonstrated that the actual population of patients with PBA is limited. In order to counter the objection by certain

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

physicians that they had few, if any, patients that exhibited signs of PBA in their facilities, Avanir instructed sales representatives to provide false and misleading information that PBA patients could be exhibiting a wide variety of "behaviors" such as crying without tears, moaning, or making other inarticulate sounds, when, in fact, those symptoms are commonly observed in patients who have dementia but do not have a diagnosis of PBA. This strategy worked, and Nuedexta utilization in LTC facilities increased.

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

Date: 9/26/2019 **State:** California **Government Program(s):** Medicare & Medicaid

Insys Therapeutics Agrees to Enter into $225 Million Global Resolution of Criminal and Civil Investigations

Company Name: Insys Therapeutics
Settlement: $225,000,000

Issue(s): Anti-Kickback, Speaker Programs

The US Attorney's for the District of Massachusetts announced that Opioid manufacturer Insys Therapeutics agreed to a global resolution to settle the government's separate criminal and civil investigations. As part of the criminal resolution, Insys will enter into a deferred prosecution agreement with the government, Insys's operating subsidiary will plead guilty to five counts of mail fraud, and the company will pay a $2 million fine and $28 million in forfeiture. As part of the civil resolution, Insys agreed to pay $195 million and enter into a five-year corporate integrity agreement to settle allegations that it violated the False Claims Act.

The DOJ reported allegations that, from August 2012 to June 2015, Insys began using "speaker programs" purportedly to increase brand awareness of Subsys through peer-to-peer educational lunches and dinners. However, the programs were actually used as a vehicle to pay bribes and kickbacks to targeted practitioners in exchange for increased Subsys prescriptions to patients and for increased dosage of those prescriptions. One practitioner targeted by Insys was a physician's assistant who practiced with a pain clinic in Somersworth, N.H. During the first year that Subsys was on the market, the physician's assistant did not write any Subsys prescriptions for his patients. In May 2013, the physician's assistant joined Insys's sham speaker program knowing that it was a way to receive kickbacks for writing Subsys prescriptions. After joining the sham speaker program, the physician's assistant wrote approximately 672 Subsys prescriptions for his patients – many of which were medically unnecessary – and in turn, received $44,000 in kickbacks from Insys.

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

Date: 6/5/2019 **State:** Arizona **Government Program(s):** Medicare & TRICARE

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations

Company Name: Astellas Pharma US Inc; Amgen Inc
Settlement: $124,750,000

Issue(s): Copay Assistance Foundations

The US DOJ Office of Public Affairs announced that two more pharmaceutical companies – Astellas Pharma US Inc. (Astellas) and Amgen Inc. (Amgen) – have agreed to pay a total of $124.75 million and enter into a five-year corporate integrity agreement to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare copays for their own products, through purportedly independent foundations that the companies used as mere conduits.

Astellas

Astellas sells Xtandi, an androgen receptor inhibitor (ARI) used to treat certain prostate cancer. The government alleged that, in May 2013, Astellas asked two foundations about the creation of copay assistance funds to cover the copays for Medicare patients taking ARIs, but not for other types of prostate cancer drugs. In July 2013, both foundations opened ARI-only copay funds, and Astellas was the sole donor to both funds. The government alleged that Astellas knew that Xtandi would likely account for the vast majority of utilization from each fund, and, in fact, Medicare patients taking Xtandi received nearly all of the copay assistance from the two ARI funds. The government further alleged that, during the time that the ARI funds were open, Astellas promoted the existence of the ARI funds as an advantage for Xtandi over competing drugs in an effort to persuade medical providers to prescribe Xtandi. Astellas has agreed to pay $100 million to resolve the government's allegations.

Amgen

Amgen sells the secondary hyperparathyroidism drug Sensipar and the multiple myeloma drug Kyprolis. Amgen acquired Kyprolis as part of its acquisition of Onyx Pharmaceuticals Inc. in 2013. With respect to Sensipar, the government alleged that, in late 2011, Amgen stopped donating to a foundation that provided financial support to patients taking any of several secondary hyperparathyroidism drugs and approached a new foundation about creating a "Secondary Hyperparathyroidism" fund that would support only Sensipar patients. Amgen allegedly worked with the new foundation to determine the fund's coverage parameters and, in November 2011, the foundation launched a "Secondary Hyperparathyroidism" fund with Amgen as its sole donor. Until June 2014, the fund covered only Sensipar. Amgen allegedly made payments to the fund even though the cost of these payments exceeded the cost to Amgen of providing free Sensipar to financially needy patients. However, by enabling the fund to cover the copays of Medicare beneficiaries, Amgen caused claims to be submitted to Medicare and generated revenue for itself.

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

Date: 4/25/2019 **State:** California **Government Program(s):** Medicare

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

Astellas Pharma US, Inc. To Pay $7.3 Million To Resolve False Claims Act Allegations

Company Name: Astellas Pharma US, Inc
Settlement: $7,300,000

Issue(s): Drug Marketing

The US Attorney's for the Eastern District of Pennsylvania announced that Pharmaceutical company Astellas Pharma US, Inc., will pay $7.3 million and enter into a five-year corporate integrity agreement to resolve allegations that it violated the False Claims Act in connection with its marketing and promoting of the drug Mycamine for pediatric use.

The DOJ reported allegations that, between 2005 and 2010, Astellas knowingly marketed and promoted the sale of Mycamine for pediatric use, which was not a medically accepted indication and, therefore, not covered by federal health care programs. During this time period, the FDA approved Mycamine to treat adult patients suffering from serious and invasive infections caused by the fungus Candida, including infections in the esophagus, the blood and the abdomen, and to prevent Candida infections in adults undergoing stem cell transplants. From 2005 until June 2013, however, Mycamine was not approved to treat pediatric patients for any use.

The allegations resolved by the settlement arose from a lawsuit filed by Frank Smith, a former Astellas sales representative, under the False Claims Act's whistleblower provisions, which permit private parties to sue for false claims on behalf of the government and to share in any recovery. Smith will receive $708,852.

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

Date: 4/16/2019 **State:** Illinios **Government Program(s):** Medicare & Medicaid

Pharmaceutical Company Agrees to Pay $17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians

Company Name: US WorldMeds LLC
Settlement: $17,500,000

Issue(s): Anti-Kickback, Copay Assistance Foundations

The US DOJ Office of Public Affairs announced that US WorldMeds LLC (USWM) has agreed to pay $17.5 million and enter into a five-year corporate integrity agreement to resolve allegations that it violated the False Claims Act by paying kickbacks to patients and physicians to improperly induce prescriptions of its drugs, Apokyn and Myobloc.

The DOJ reported allegations that USWM substantially increased the price of Apokyn in or around January 2012, a decision that resulted in a corresponding increase to Medicare patients' copays — which for many patients exceeded $5,000 per year. The United States alleged that, from the time of the price increase through June 30, 2013, USWM illegally paid Medicare patients' Apokyn copays through a third-party foundation. During the relevant time period, USWM allegedly knew it was the only donor to the foundation's Parkinson's Disease fund and that virtually all of the fund's

donations were spent on Medicare Apokyn patients. The United States alleged that these payments represented illegal inducements to patients in violation of the Anti-Kickback Statute and False Claims Act.

The United States also alleged that USWM paid kickbacks to two physicians to induce prescriptions of Apokyn and Myobloc. Specifically, the United States alleged USWM paid these physicians excessive speaking and consulting fees and provided impermissible entertainment, such as lavish meals, private plane rides, and all-expense paid trips with their spouses (including trips to the Kentucky Derby).

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

Date: 4/30/2019 **State:** Kentucky **Government Program(s):** Medicare

Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations

Company Name: Jazz Pharmaceuticals plc; Lundbeck LLC; Alexion Pharmaceuticals Inc
Settlement: $122,600,000

Issue(s): Anti-Kickback, Copay Assistance Foundations

The US DOJ Office of Public Affairs announced that three pharmaceutical companies – Jazz Pharmaceuticals plc (Jazz), Lundbeck LLC (Lundbeck), and Alexion Pharmaceuticals Inc. (Alexion) – have agreed to pay a total of $122.6 million and enter into a five-year corporate integrity agreement to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare or Civilian Health and Medical Program (ChampVA) copays for their own products, through purportedly independent foundations that the companies used as mere conduits.

Jazz

Jazz sells Xyrem, a narcolepsy medication with Gamma Hydroxybutyrate (GHB)—a central nervous system depressant and controlled substance—as its main active ingredient. The government alleged that, in 2011, Jazz asked a foundation to create a fund that would pay the copays of Xyrem Medicare patients and that the foundation agreed to establish a "Narcolepsy Fund," to which Jazz became the sole donor. The government alleged that Jazz knew that, although Xyrem accounted for a small share of the overall narcolepsy market, the fund almost exclusively used Jazz's donations to pay copays for Xyrem and required non-Xyrem patients on competing products to obtain a denial letter from another assistance plan before helping them. The government further alleged that, in conjunction with establishing this fund, Jazz made Medicare patients ineligible for Jazz's free drug program and instead referred Xyrem Medicare patients to the foundation, enabling Jazz to generate revenue from Medicare and induce purchases of the drug, rather than continuing to provide these patients with free drugs. Meanwhile, Jazz raised the price of Xyrem by over 150 percent from 2011 through the end of the relevant time period.

Jazz also sold Prialt, an injectable severe chronic pain medication. The government alleged that Jazz asked the same foundation to create a fund ostensibly to assist patients with the co-pays of any severe chronic pain drugs, but which, in practice, almost exclusively paid Prialt Medicare copays. Shortly after creating the fund, the foundation allegedly told Jazz that when severe chronic pain patients seeking assistance with other drugs contacted the foundation, it would refer them

elsewhere. The government alleged that Jazz was also aware that the fund did not appear on the foundation's website, thereby minimizing the number of non-Prialt patients seeking assistance from the fund. Jazz has agreed to pay $57 million to resolve the government's allegations.

Lundbeck

Lundbeck sells Xenazine, the only drug that was approved to treat chorea associated with Huntington's disease until a generic version became available until 2015. The government alleged that Lundbeck was the sole donor and made millions in payments to a fund at a foundation that ostensibly provided financial support only for patients with Huntington's Disease. However, Lundbeck allegedly referred Xenazine patients with many other conditions to this foundation, which then paid the Xenazine copays for these unapproved uses from its Huntington's Disease fund. The government further alleged that, in June 2014, after the foundation determined that its Huntington's Disease fund would no longer pay the copays of patients taking Xenazine for non-Huntington's disease uses, Lundbeck agreed to repurpose some of its prior donations to the Huntington's Disease fund to a "general fund" at the foundation for the purpose of paying these patients' Xenazine copays, and made subsequent "unrestricted" payments to the foundation with the understanding that the foundation would use these payments to pay Xenazine copays for these same patients. Lundbeck allegedly asked the foundation whether there was a "risk" that this practice would be viewed as not compliant with the foundation's HHS-OIG Advisory Opinion, and the foundation allegedly replied that "[t]hey don't know what we use the general fund for."

The government also alleged that, at the time it was engaged in the foregoing conduct, Lundbeck had a policy of not permitting Medicare or ChampVA patients to participate in its free drug program for Xenazine, which was open to other financially needy patients, even if those Medicare or ChampVA patients could not afford their copays for Xenazine. Instead, in order to generate revenue from Medicare and ChampVA and to induce purchases of Xenazine, Lundbeck allegedly referred financially needy non-Huntington's Disease Xenazine patients to the foundation, which resulted in claims to Medicare and ChampVA to cover the cost of the drug. Lundbeck has agreed to pay $52.6 million to resolve the government's allegations.

Alexion

Alexion sells Soliris, which, from Jan. 1, 2010, through June 30, 2016, was indicated for certain uses to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The cost of Soliris, based upon its list price and indicated dosing recommendation, can be approximately $500,000 per year. The government alleged that Alexion made donations to a "Complement-Mediated Disease" (CMD) fund at a foundation to pay the Medicare copay obligations of patients taking Soliris and to induce those patients' purchases of Soliris. Alexion allegedly knew that the price it set for Soliris could pose a barrier to patients' purchases of it. In particular, the government alleged that Alexion approached the foundation in January 2010 to request that it create a fund to provide financial assistance to Soliris patients, including by paying patients' Soliris Medicare copays and other medical expenses for Soliris patients. Over the next several months, Alexion and the foundation allegedly discussed the coverage parameters for the fund, including Alexion's desire that the foundation "not support a patient with any of these [CMD] diagnoses for other reasons tha[n] Soliris therapy." After the fund opened, Alexion—the sole donor to the fund—allegedly understood that the foundation's provision of financial assistance to a patient was contingent on the patient taking Soliris. Alexion allegedly noted internally that it needed to be diligent in letting the foundation know if a patient had stopped taking Soliris so that Alexion's donations would not be used on patients who were not starting or maintaining Soliris therapy.

Meanwhile, the government alleged that Alexion had a general practice of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not

SUNHAWK CONSULTING

Life Sciences

Pharmacuetical

afford their copays for Soliris. Instead, in order to generate revenue from Medicare and induce purchases of Soliris, Alexion allegedly referred Medicare patients prescribed Soliris to the foundation, through the foundation's "referral portal" software. Allegedly, the "referral portal" reported information back to Alexion confirming those Soliris patients who were approved for copay or other financial assistance from the foundation, and detailed the foundation's payments to them, which resulted in claims to Medicare to cover the cost of Soliris. Alexion has agreed to pay $13 million to resolve the government's allegations.The claims resolved by the settlement are allegations only; there has been no determination of liability.

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

Date: 4/4/2019 **State:** Philadelphia **Government Program(s):** Medicare & ChampVA