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QUI TAM QUARTERLY

ENFORCEMENT TRENDS IN FALSE CLAIMS ACT LIABILITY FOR PATIENT ASSISTANCE PROGRAMS

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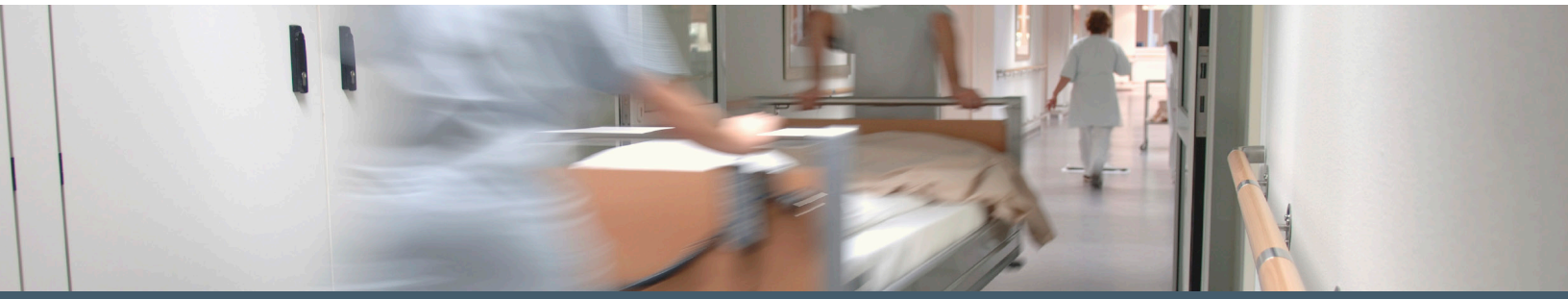

Qui Tam Quarterly is a quarterly publication authored by members of the K&L Gates Health Care Fraud & Abuse team highlighting emerging and pressing issues in health care fraud and abuse, including litigation and governmental investigations involving the False Claims Act, the Stark Law, the Anti-Kickback Statute, and other health care fraud related statutes.

Patient assistance programs (PAPs) provide financial assistance to patients of limited financial means in a variety of forms, including free or discounted products, product coupons, cost-sharing assistance, and in some cases, financial support to pay health insurance premiums, cost of living expenses, and travel reimbursement related to the receipt of medical care. The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) has continually acknowledged that properly structured PAPs can provide important "safety net assistance" to patients with limited financial means who cannot afford necessary drugs, particularly those with chronic illnesses and high drug costs. Independent charitable organizations or foundations bolstered by donations from drug and medical device manufacturers generally administer these programs pursuant to OIG guidance. However, in recent years, federal and state regulators have subjected PAPs to intense scrutiny and increased enforcement, particularly those programs that assist patients with drug costs. In particular, government regulators have alleged that several independent charity PAPs were functioning merely as a conduit for payments by drug manufacturers to patients and impermissibly influencing beneficiaries' drug choices in violation of the federal Anti-Kickback Statute (AKS).

In light of the continued scrutiny of PAPs and the government's increased enforcement actions in recent years, PAPs and the pharmaceutical companies that donate to them face significant compliance risk and uncertainty in an area dominated by OIG guidance documents and advisory opinions. This article provides (i) a review of applicable law and OIG's evolving guidance regarding PAPs, (ii) a review and analysis of recent enforcement actions taken by the OIG and Department of Justice (DOJ) against pharmaceutical manufacturers under the False Claims Act (FCA), and (iii) key insights regarding the legal landscape surrounding FCA cases involving PAPs.[1]

Applicable Law and Government Guidance

The AKS prohibits individuals and entities from knowingly and willfully soliciting, receiving, offering, or paying—directly or indirectly—any remuneration to induce or reward the referral, order, lease, or recommendation of an item or service payable by a federal health care program.[2] For purposes of the AKS, remuneration includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly.[3] The AKS is intent-based, which means remuneration for referrals is only subject to liability if there is the requisite intent to induce or provide referrals; however, a defendant is not required to have actual knowledge of, or a specific intent to commit, a violation of the AKS in order to be found liable.[4] Further, multiple federal circuit courts have held that the AKS is violated if one purpose (as opposed to a primary or sole purpose) of a payment or remuneration to a provider is to induce referrals.[5]

Most notably, the AKS specifically provides that a claim for items and services provided in violation of the AKS constitutes a false claim under the FCA.[6]

Through the advisory opinion process, the OIG has approved certain independent charitable programs that can help financially needy beneficiaries with health care expenses. At the same time, the OIG has had long-standing concerns regarding patient assistance programs, generally, and particularly with regard to drug manufacturers' involvement in PAPs. Such advisory opinions have primarily focused on charities that provide assistance to patients who cannot afford cost-sharing obligations for prescription drugs. The opinions have addressed whether the charities are sufficiently independent from drug manufacturer donors so as to not violate fraud and abuse laws.

In 2005, the OIG issued a Special Advisory Bulletin (2005 Special Advisory Bulletin) that analyzed fraud and abuse concerns associated with PAPs.[7] The 2005 Special Advisory Bulletin provided that certain cost-sharing subsidies provided by bona fide, independent PAPs unaffiliated with drug manufacturers do not raise AKS concerns, even if the PAPs receive manufacturer contributions, provided the following factors are satisfied:

- Neither the pharmaceutical manufacturer nor any affiliate exerts any direct or indirect influence or control over the charity or the PAP.
- The charity awards assistance in an independent manner that severs any link between the pharmaceutical manufacturer's funding and the patient (i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer).
- The charity awards assistance without regard to the drug manufacturer's interests and without regard to a patient's choice of product, provider, practitioner, supplier, or Medicare Part D drug plan.
- The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.
- The drug manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.[8]

On May 30, 2014, the OIG issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (2014 Special Advisory Bulletin),[9] which updated the 2005 Special Advisory Bulletin. There, the OIG indicated that PAPs generally have two "remunerative aspects" that require scrutiny under the AKS: (i) donor contributions to PAPs, which can be analyzed as indirect remuneration to patients; and (ii) financial assistance remuneration provided directly to patients by the PAPs. The OIG stated that the AKS could be violated "if a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federally reimbursable items," as well as if a PAP's grant of financial assistance to a patient is made "to influence the patient to purchase (or induce the patient's physician to prescribe) certain items."[10]

In the 2014 Special Advisory Bulletin, the OIG also stated that, although PAPs provide important safety net assistance to financially needy patients, these programs also present a risk of fraud, waste, and abuse with respect to federal health care programs. The 2014 Special Advisory Bulletin described potentially problematic features of PAPs and specifically addressed three additional areas of concern related to disease funds, eligible recipients, and the conduct of donors. Specifically, the OIG expressed concern that disease-specific PAPs were narrowly defining disease states such that PAPs were limiting assistance to a small subset of drugs (particularly expensive and specialty drugs), which in turn would steer patients in a manner that is costly to federal health care programs and even facilitate increases in drug prices.[11] Where PAPs subsidize the copays for patients covered by federal programs, patients lose "skin in the game," which can lead pharmaceutical manufacturers to raise prices charged to federal programs without the risk that patients would be dissuaded from the drug due to the high price tag.

In conjunction with its publication of the 2014 Special Advisory Bulletin, the OIG also sent letters to recipients of previous favorable Advisory Opinions, requesting the independent charities to certify to the OIG that: (i) the charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states; (ii) the charity will not maintain any disease fund that provides copay assistance for only one drug or only the drugs made or marketed by one manufacturer or its affiliates (with certain exceptions); and (iii) the charity will not limit its assistance to high-cost or specialty drugs.[12]

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Beginning in December 2015, the OIG modified six Advisory Opinions in order to update the analyses pursuant to certifications received.[13] However, on November 28, 2017, the OIG took an unprecedented action of issuing a letter rescinding Advisory Opinion 06-04—one of the modified Advisory Opinions—based on the charity's "failure to fully, completely, and accurately disclose all relevant and material facts to OIG" and the charity's alleged failure to comply with certain factual certifications made to the OIG. Specifically, the OIG determined that the charity "provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and allowed donors to directly or indirectly influence the identification or delineation of Requestor's disease categories."[14] The OIG noted that the charity's failure to comply with the certifications "materially increased the risk" that the PAP served as a conduit for financial assistance from a drug manufacturer donor to a patient and, thus, inappropriate steerage to the donor's drugs.[15]

Recent DOJ Enforcement and Investigations

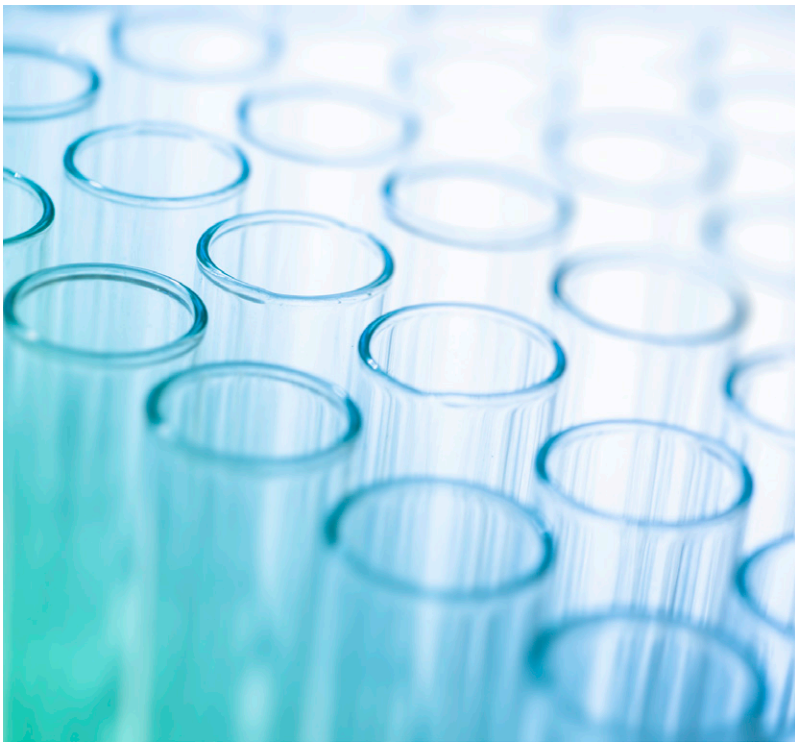
Going into 2019, pharmaceutical companies may have expected less DOJ scrutiny over PAPs after the DOJ sought dismissal of ten PAP-related FCA cases brought by relators the DOJ alleged were affiliated with the National Health-care Analysis Group, a company formed for the purpose of filing FCA cases.[16] However, the DOJ has only increased its enforcement in this area in 2019. In April alone, the DOJ entered into substantial settlements with six pharmaceutical manufacturers to resolve allegations under the FCA related to PAPs, although none of the defendants admitted any wrongdoing:

US World Meds LLC (USWM)

USWM agreed to pay $17.5 million to resolve allegations that it violated the FCA related to its drug, Apokyn, which treats loss of control of body movements in individuals suffering from advanced Parkinson's disease (PD).[17] The government alleged that USWM illegally paid Medicare patients' Apokyn copays through a third-party foundation related to a PAP for PD to which USWM was the only donor and for which virtually all of the donations were spent on Medicare Apokyn patients. The government alleged that donations to this foundation's PAP coincided with a substantial price increase of Apokyn that resulted in a corresponding increase to Medicare patients' copays, which exceeded $5,000 per year for many Medicare beneficiaries. The settlement also resolved allegations related to alleged kickbacks to physicians to induce prescriptions for Apokyn and another USWM drug.

Amgen Inc. (Amgen)

Amgen agreed to pay $24.75 million to settle allegations of FCA violations related to PAPs in connection with its hyperparathyroidism drug Sensipar and the multiple myeloma drug Kyprolis (which Amgen acquired as part of its acquisition of Onyx Pharmaceuticals Inc. (Onyx) in 2013).[18] 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. Until June 2014, the PAP covered only Sensipar, and 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. With respect to Kyprolis, the government alleged that Onyx was the sole donor of funds to a foundation's PAP that almost exclusively covered travel expenses to infusion centers for patients taking Kyprolis and that Amgen continued to donate to the PAP after the acquisition. The government also alleged that, for 2013, Onyx received data from the foundation for a second PAP that covered copays for multiple myeloma drugs, including Kyprolis, and tailored its donations to the amount needed to cover the copays of Kyprolis patients.



Astellas Pharma US, Inc. (Astellas)

Astellas agreed to pay $100 million to resolve allegations of AKS and FCA violations related to its androgen receptor inhibitor (ARI), Xtandi, which is used to treat certain prostate cancers.[19] The government alleged that, beginning in May 2013, Astellas began donating to foundations that operated PAPs for the purpose of providing copay assistance only for Medicare patients taking ARIs, but not for other types of prostate cancer drugs that are not ARIs. Astellas was the sole donor to both PAPs. The government alleged that Astellas knew that Xtandi would likely account for the vast majority of utilization from each PAP, and Medicare patients taking Xtandi received nearly all of the copay assistance from the two ARI PAPs.

Jazz Pharmaceuticals plc. (Jazz)

Jazz agreed to pay $57 million to resolve the government's allegations of AKS and FCA violations in connection with a PAP that provided copay assistance to Medicare patients prescribed Xylem, a narcolepsy medication, and Prialt, an injectable severe chronic pain medication.[20] Regarding Xylem, the government alleged that in 2011, Jazz became the sole donor to a foundation's PAP created to provide Medicare beneficiaries copay assistance for narcolepsy medications. 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 Jazz made Medicare patients ineligible for Jazz's free drug program and referred Xyrem Medicare patients to the foundation's PAP, enabling Jazz to generate revenue from Medicare and induce purchases of the drug, rather than continuing to provide these patients with free drugs. Jazz also allegedly raised the price of Xyrem by over 150 percent from January 2011 through May 2014. Regarding Prialt, the government alleged that Jazz asked the same foundation to create a fund ostensibly to assist patients with the copays for any severe chronic pain drugs, but which, in practice, almost exclusively paid Prialt Medicare copays. The government alleged that Jazz was aware the foundation referred severe chronic pain patients seeking assistance with other drugs elsewhere and did not post information regarding this PAP on its website, thereby minimizing the number of non-Prialt patients seeking assistance from the PAP.

Lundbeck LLC. (Lundbeck)

In April 2019, Lundbeck agreed to pay $52.6 million to resolve allegations of AKS and FCA violations related to Xenazine, the only FDA-approved drug to treat chorea associated with Huntington's disease until a generic became available in 2015.[21] The government alleged that Lundbeck was the sole donor and made millions in payments to the foundation's PAP that ostensibly provided financial support only for patients with Huntington's disease. However, the government alleged that the foundation referred Xenazine patients with many other conditions to this foundation, which then paid the Xenazine copays for these unapproved uses. 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 allegedly 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 alleged understanding that the foundation would use these payments to pay Xenazine copays for these same patients. The government also alleged that Lundbeck did not permit Medicare or ChampVA patients to participate in its free drug program for Xenazine, which was open to other financially needy patients, but rather referred financially needy Medicare and ChampVA non-Huntington's disease Xenazine patients to the foundation for cost-sharing assistance, which resulted in claims to Medicare and ChampVA to cover the cost of the drug.

Alexion Pharmaceuticals Inc. (Alexion)

In April 2019, Alexion agreed to pay $13 million to resolve the government's allegations of AKS and FCA violations related to its product Soliris, which was indicated for certain uses to treat patients with paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome and can cost each patient up to approximately $500,000 per year.[22] Specifically, the government alleged that Alexion was the sole donor to a foundation's PAP that provided financial assistance only to patients taking Soliris. Alexion was also allegedly 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 on Soliris therapy. Additionally, Alexion allegedly did not permit Medicare patients to participate in its free drug program, which was open to other financially needy patients, but rather referred Medicare patients prescribed Soliris to the foundation to receive copay or other financial assistance through the PAP, which resulted in claims to Medicare to cover the cost of Soliris.

Foundations and charities that receive donations from pharmaceutical companies to operate PAPs are also facing government scrutiny and enforcement under the FCA as the OIG continues to be concerned that these organizations are not operating independently from their manufacturer donors as required by government guidance. On October

25, 2019, the DOJ announced that two foundations, Chronic Disease Fund, Inc. d/b/a Good Days (CDF) and Patient Access Network Foundation (PANF), agreed to pay $2 million and $4 million, respectively, without admitting wrongdoing, to resolve allegations that they violated the FCA by enabling pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.[23] As part of the settlements, each foundation entered a three-year Integrity Agreement, which requires each foundation to implement measures designed to ensure that it operates independently and that its arrangements with pharmaceutical manufacturer donors are legally compliant, among other requirements.[24]

Key Insights

Government Intervention and Aggravating Factors

Government intervention following a relator's qui tam complaint is frequently a critical factor in the outcome of the case. For example, in 2018, recoveries from qui tam cases in which the government intervened constituted approximately 96 percent of total qui tam recoveries. Therefore, it is important to understand what could impact the government's decision whether or not to intervene in a PAP-related FCA qui tam case, as this decision can dramatically affect the case outcome.[25]

Taking a holistic view of the DOJ's recent complaints and settlements regarding PAPs, certain aggravating factors may increase the chance of the DOJ intervening in a qui tam case or the penalties imposed upon defendants. In addition to narrowly defining the PAP program so that it primarily applies to only the manufacturer's drug, these factors may include: (i) increasing the drug price dramatically during the relevant period of the copay assistance program, (ii) the exclusion of Medicare patients from free drug programs and direction of such patients to the copay PAP, and (iii) improper data sharing or communication between the copay foundation and the pharmaceutical manufacturer.

Echoing earlier legislative concerns regarding PAP programs for high-cost drugs, the government appears especially motivated by pharmaceutical companies whose donations it views as "kickbacks that undermine[] the structure of the Medicare program and illegally subsidize[] the high costs of the companies' drugs at the expense of American taxpayers."[26] In announcing settlements with several drug manufacturers, the DOJ has focused on how pharmaceutical manufacturers allegedly raised drug prices several times over to the detriment of Medicare and other federal health care programs.[27] The concerns about Medicare expenditures are also evidenced by government attention on pharmaceutical manufacturers who allegedly denied Medicare patients from the manufacturer's own free drug program and instead directed them to a PAP, resulting in the manufacturers receiving Medicare funds for Medicare patients who were not paying their own copays.[28] The government also appears especially sensitive to alleged data sharing between foundations and pharmaceutical manufacturers, which may allow a pharmaceutical manufacturer to specifically calculate how much to donate, such that its contributions are sufficient to cover the copays of only the patients taking their specific drugs.[29]

Ongoing Enforcement Cases

Government attorneys in FCA cases have submitted several alleged theories of liability, but they have primarily maintained that pharmaceutical manufacturers improperly use PAPs as a conduit to pay copays of Medicare patients for their drugs, with an intent to induce patients to purchase Medicare-reimbursed products or services, in violation of the AKS and FCA.[30] Although the PAPs prevent pharmaceutical manufacturers from directly paying for Medicare patients' copays, the government has emphasized that liability may still attach for indirect or covert payments made with the requisite intent.[31]

New DOJ policy prohibits prosecutors from bringing cases solely on the basis of a violation of a guidance document, requiring prosecutors to establish violations by reference to statutes and regulations. With the issuance of the new Justice Manual, the DOJ instructed its prosecutors that "[c]riminal and civil enforcement actions brought by the [DOJ] must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies," noting that "guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation."[32] Therefore, in order to establish an FCA or AKS violation, the government "must establish a violation by reference to statutes and regulations" and "may not bring actions solely on allegations of noncompliance with guidance documents."[33]

In addition, President Donald J. Trump recently signed an executive order echoing the updated Justice Manual, requiring administrative enforcement agencies to "establish a violation of law by applying statutes or regulations," not "impose new standards of conduct" through guidance documents, except as expressly authorized by law or as expressly incorporated into a contract.[34]

However, as evidenced below in the discussion of a pending PAP-related FCA and AKS case, advisory opinions may still be useful for an entity seeking to establish that it did not have the requisite intent to violate the FCA or AKS.[35]

United States ex rel. Strunck v. Mallinckrodt ARD LLC

Recently, the DOJ intervened in a FCA lawsuit filed against Mallinckrodt ARD LLC (Mallinckrodt) (previously known as Questcor Pharmaceuticals Inc. (Questcor)) in connection with its drug H.P. Achthar Gel (Achthar), which is an adrenocorticotropic hormone utilized to treat relapsing multiple sclerosis, infantile spasms, and nephrotic syndrome.[36] According to the DOJ's complaint, Mallinckrodt and Questcor allegedly used a PAP operated by a foundation to fund copay subsidies to facilitate increased drug prices in violation of the AKS, raising the price of Achthar from approximately $50 to over $32,200 per 5 mL vial since acquiring the drug in 2001 through 2014.

On August 19, 2019, Mallinckrodt filed a Motion to Dismiss DOJ's complaint against Mallinckrodt and Questcor; the motion is still pending. In its Motion to Dismiss, Mallinckrodt noted that a plaintiff must allege facts demonstrating that the defendant's conduct was knowing and willful in order to plausibly allege a violation of the AKS.[37] Mallinckrodt further noted that, to allege knowing conduct within the meaning of the FCA, a plaintiff must plausibly allege that the defendant had "actual knowledge that the alleged false claims were fraudulent, deliberate ignorance as to the claims' fraudulent nature, or reckless disregard of the claims' truth or falsity."[38] Therefore, Mallinckrodt argued that, because its alleged conduct was consistent with OIG guidance during the relevant time frame, the facts alleged did not plausibly state an AKS violation or plausibly allege that Mallinckrodt acted knowingly within the meaning of either the AKS or the FCA.[39] Specifically, Mallinckrodt argued that (i) the government did not allege that the foundation was not a bona fide, independent charity; (ii) the complaint was "replete with allegations demonstrating that [the foundation] operated independently from [Mallinckrodt], including that [the foundation] made the ultimate decision whether and how to create a fund"; (iii) the complaint did not allege facts plausibly suggesting that Mallinckrodt controlled the foundation; and (iv) Mallinckrodt received information that the foundation informed the OIG it would provide to donors.[40] Although Mallinckrodt acknowledged that OIG had since changed its position, and provided revised guidance and modified advisory opinions reflecting that change, Mallinckrodt argued that its activities were lawful under the prior guidance and advisory opinions.[41]

In response, the government argued that its complaint adequately pled that Mallinckrodt knowingly and willfully provided remuneration, in the form of financial subsidies to pay Medicare copays, with an intent to induce Medicare-reimbursed purchases of its drug Acthar.[42] To demonstrate that it adequately pled knowing and willful conduct on behalf of Mallinckrodt, the government pointed to portions of its complaint that alleged that "Mallinckrodt created an arrangement that did not avoid the risks that HHS-OIG had warned against, including by directly or indirectly influencing [the PAP foundation], to create Acthar-specific symptom funds at the exclusion of other drugs, and funding Acthar subsidies through them based on detailed financial data, to keep Mallinckrodt's copay conduit functioning smoothly so it could reliably market Acthar as 'free' despite its sky-high cost."[43] The government also pointed to alleged efforts by Mallinckrodt "to conceal the true nature of its conduct with [the PAP foundation]," including "contracts with [the PAP foundation] that concealed Mallinckrodt's role in creating the funds" and an alleged "deliberate scheme" by Mallinckrodt to "'exclude' other drugs through 'exacerbation' funds while using the funds to subsidize long-term 'pulse maintenance' Acthar prescriptions anyway."[44] Finally, the government pointed to allegations in its complaint that Mallinckrodt ignored red flags, such as the PAP foundation "needing to consult with its own attorneys about the arrangement" and the PAP foundation "finally closing the funds altogether."[45]

Additionally, the government pointed out that none of the advisory opinions relied upon by Mallinckrodt were issued directly to Mallinckrodt and argued that the test for whether Mallinckrodt violated the AKS is the AKS itself.[46] The government also argued that Mallinckrodt failed to comply with the safeguards in the advisory opinions and regulatory guidance it claimed to rely on, citing HHS OIG concerns about any "direct or indirect influence or control" by the drug company over the foundation, influencing a foundation to create an artificially narrow fund defined in reference to a disease's symptoms to cover just the donor's product, seeking data to correlate manufacturer donations to subsidies of their own products, and foundations functioning as conduits for payments by the pharmaceutical manufacturer to patients.[47]

Mallinckrodt has since filed a reply memorandum in support of its Motion to Dismiss.[48] The Eastern District of Pennsylvania has not yet ruled on Mallinckrodt's Motion to Dismiss, but its decision could shape defendant pharmaceutical manufacturers' defenses to PAP-related AKS and FCA charges. However, the government's response to Mallinckrodt's Motion to Dismiss demonstrates how difficult and fact-intensive the analysis of a claim of conformance to HHS OIG guidance can be.[49]

Conclusion

With the changing role of guidance documents in enforcement actions, PAPs and the pharmaceutical companies that donate to them face uncertainty in an area dominated by OIG guidance documents and advisory opinions. K&L Gates' health care and investigations, enforcement, and white collar practice groups routinely advise clients on best practices for PAP compliance and, if necessary, defend clients in connection with FCA and ACA cases brought by a qui tam relator or the U.S. government.

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[1] The information provided in this article does not, and is not intended to, constitute legal advice; instead, this article is for general informational purposes only.

[2] *See* 42 U.S.C. § 1320a-7b(b); 42 C.F.R. §§ 1001.952 *et seq.*

[3] 42 U.S.C. § 1320a-7b(b).

[4] Pub. L. No. 111-148, § 6402(f)(2) (Mar. 23, 2010).

[5] *See United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Gerber*, 760 F.2d 68 (3d. Cir. 1985).

[6] 42 U.S.C. § 1320a-7b(g).

[7] OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

[8] *See id.* at 70625.

[9] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).

[10] *Id.* at 31121.

[11] *Id.* at 31122.

[12] *Id.* at 31121—22.

[13] *See* OIG, Modification of Adv. Op. 07-11 (Dec. 7, 2015); OIG, Modification of Adv. Op. 06-13 (Dec. 16, 2015); OIG, Modification of Adv. Op. 11-05 (Dec. 29, 2015); OIG, Modification of Adv. Op. 07-06 (Dec. 29, 2015); OIG, Modification of Adv. Op. 06-04 (Dec. 30, 2015); Modification of Adv. Op. 04-15 (Jan. 6, 2016).

[14] OIG, Rescission Letter re: Adv. Op. 06-04 (Nov. 28, 2017).

[15] See OIG, Adv. Op. 06-04 (Apr. 20, 2006), *as subsequently modified* Dec. 23, 2015, and rescinded Nov. 28, 2017.

[16] *See* Motion to Dismiss Relator's Second Amended Complaint, United States *ex rel.* Health Choice Grp. LLC v. Bayer Corp., No. 5:17-00126 (E.D. Tex. Dec. 17, 2018); Motion to Dismiss, *United States ex rel. SAPF, LLC, v. Amgen, Inc.*, No. 16-cv-5203 (E.D. Pa. Dec. 17, 2018); Motion to Dismiss, *United States ex rel. SMSPF, LLC v. EMD Serono, Inc.*, No. 16-cv-5594 (E.D. Pa. Dec. 17, 2018); Motion to Dismiss, *United States ex rel. SMSF, LLC v. Biogen, Inc.*, No 1:16-cv-11379-IT (D. Mass. Dec. 17, 2018); Motion to Dismiss Relators' First Amended Complaint, *United States ex rel. NHCA-TEV, LLC v. Teva Pharms.*, No. 17-cv-2040 (E.D. Pa. Dec. 17, 2018); Motion to Dismiss, *United States ex rel. SCEF, LLC v. Astra Zeneca PLC*, No. 17-cv-1328 (W.D. Wash. Dec. 17, 2018); Motion to Dismiss Relators' First Amended Complaint, *United States ex rel. Miller, v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex. Dec. 17, 2018); Motion by Plaintiff United States of America to Dismiss Relators' Complaint, *United States ex rel. Carle v. Otsuka Holdings Co.*, No. 17-cv-966 (N.D. Ill. Dec. 17, 2018); Motion to Dismiss, *United States ex rel. CIMZNHCA v. UCB, Inc.*, No. 3:17-cv-00765 (S.D. Ill. Dec. 17, 2018); Motion to Dismiss Relator's Second Amended Complaint, *United States ex rel. Health Choice All., LLC v. Eli Lilly & Co.*, No. 5:17-cv-123 (E.D. Tex. Dec. 17, 2018).

[17] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Company Agrees to Pay $17.5 Million to Resolve Allegations of Kickbacks to Patients and Physicians (Apr. 30, 2019), https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients; Settlement Agreement, United States v. US WorldMeds, LLC, No. 3:13-cv-00363 (D. Conn. Apr. 30, 2019); HHS OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and US WorldMeds, LLC and Solstice Neurosciences, *LLC*, https://oig.hhs.gov/fraud/cia/agreements/US_WorldMeds_LLC_and_Solstice_Neurosciences_LLC_04032019.pdf.

[18] See Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations (Apr. 25, 2019), https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid [hereinafter, "April 25, 2019 DOJ Press Release"]; U.S. Dep't of Justice, Settlement Agreement between the United States and Amgen Inc., https://www.justice.gov/usao-ma/press-release/file/1157171/download; HHS OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Amgen Inc., https://oig.hhs.gov/fraud/cia/agreements/Amgen_Inc_04242019.pdf.

[19] *See* April 25, 2019 DOJ Press Release; U.S. Dep't of Justice, Settlement Agreement between the United States and Astellas Pharma US, Inc., https://www.justice.gov/usao-ma/press-release/file/1157176/download; HHS OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Astellas Pharma US, Inc., https://oig.hhs.gov/fraud/cia/agreements/Astellas_Pharma_US_Inc_04242019.pdf.

[20] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations (Apr. 4, 2019), https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid [hereinafter, "April 4, 2019 DOJ Press Release"]; U.S. Dep't of Justice, Settlement Agreement between the United States and Jazz Pharmaceuticals plc, https://www.justice.gov/usao-ma/press-release/file/1150901/download; HHS OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals plc, https://oig.hhs.gov/fraud/cia/agreements/Jazz_Pharmaceuticals_PLC_04032019.pdf.

[21] *See* April 4, 2019 DOJ Press Release; U.S. Dep't of Justice, Settlement Agreement between the United States and Lundbeck, LLC, https://www.justice.gov/usao-ma/press-release/file/1150906/download; HHS OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Lundbeck, LLC, https://oig.hhs.gov/fraud/cia/agreements/Lundbeck_LLC_04032019.pdf.

[22] *See* April 4, 2019 DOJ Press Release; U.S. Dep't of Justice, Settlement Agreement between the United States and Alexion Pharmaceuticals Inc., https://www.justice.gov/usao-ma/press-release/file/1150896/download. Alexion was not required to enter into a Corporate Integrity Agreement.

[23] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Oct. 25, 2019), https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare. The United States alleged that, from 2010 through 2014, CDF conspired with five pharmaceutical manufacturers to enable them to pay kickbacks to Medicare beneficiaries taking those manufacturers' drugs, and from 2011 through 2014, PANF permitted four pharmaceutical manufacturers to use PANF as a conduit to pay kickbacks to Medicare patients taking their drugs.

[24] HHS OIG, Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Chronic Disease Fund d/b/a Good Days, https://oig.hhs.gov/fraud/cia/agreements/Chronic_Disease_Fund_Inc_dba_Good_Days_10242019.pdf; HHS OIG, Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Patient Access Network Foundation, https://oig.hhs.gov/fraud/cia/agreements/Patient_Access_Network_Foundation_10242019.pdf.

[25] *See* U.S. Dep't of Justice, Fraud Statistics 2018, https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery (last accessed Oct. 8, 2019).

[26] *See* April 25, 2019 DOJ Press Release.

[27] *See id.* ("Jazz raised the price of Xyrem by over 150 percent from 2011 through the end of the relevant time period."); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, United States Intervenes In False Claims Act Lawsuit Against Drug Maker Mallinckrodt Alleging Illegal Kickbacks (June 5, 2019), https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-drug-maker-mallinckrodt-alleging [hereinafter, "Mallinckrodt Press Release"] ("The government further alleges that since its acquisition of Acthar in 2001, Mallinckrodt had raised its price from approximately $50 to over $32,200 per 5 milliliter vial by the end of 2014."); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks (May 24, 2018), https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks ("Pfizer raised the wholesale acquisition cost of a package of forty .125 mg capsules of the drug by over 40 percent in the last three months of 2015.").

[28] *See* April 4, 2019 DOJ Press Release ("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."); *id.* ("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."); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 20, 2017), https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability ("The Government also alleged that UT had a policy of not permitting needy Medicare patients to participate in its free drug program, which was open to other financially needy patients, and instead referred Medicare patients to the foundation, which allowed claims to be submitted to Medicare.") [hereinafter, "United Therapeutics Press Release"].

[29] *See* April 25, 2019 DOJ Press Release ("While this latter fund had multiple donors, the government alleged that, for 2013, Onyx received data from the foundation on the fund's anticipated and actual expenses for coverage of Kyprolis copays, which it used to tailor its donations to the fund to just the amount needed to cover the copays of Kyprolis patients."); United Therapeutics Press Release ("The government alleged that UT routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug and that this data was used by UT to decide how much to donate to the foundation.").

[30] *See, e.g., United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498–99, 501 (D.S.C. 2016) (holding that the government's complaint alleging waivers of federal copays and deductibles adequately states a False Claims Act claim predicated upon AKS violations), *appeal pending at* No. 18-1811 (4th Cir.); *United States ex rel. Riedel v. Bos. Heart Diagnostics Corp.*, 332 F. Supp. 3d 48, 68 (D.D.C. 2018) ("[T]he Court finds that the relator sufficiently alleges that Boston Heart's waiver of patients' co-payments and deductibles constitutes a kickback[.]").

31 *See* United States' Statement of Interest at 2, 5–6, 9–10, *United States ex rel. Vitale v. MiMedx Grp., Inc.*, No. 3:17-cv-00166-RBH (Nov. 6, 2018) [hereinafter "Statement of Interest"].

32 U.S. Dep't of Justice, Justice Manual, Section 1-20.100, U.S. Dep't of Justice, https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation#1-20.100.

33 *Id.*

34 Exec. Order No. 13892, 84 Fed. Reg. 55239 (2019).

35 An advisory opinion recipient, or even a third party relying on an advisory opinion, may argue that it lacked the requisite scienter to make a material misrepresentation in connection with a claim due to its compliance with the advisory opinion. On the other side of the coin, under the right factual scenario, an advisory opinion recipient, or even a third party relying on an advisory opinion, may also have a strong argument of government knowledge of and acquiescence to its actions undertaken in compliance with the safeguards of the advisory opinion. As the U.S. Supreme Court noted in *Universal Health Services, Inc. v. United States*, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." 136 S. Ct. 1989, 2003–04 (2016).

[36] *See* Mallinckrodt Press Release.

[37] *See* Memorandum in Support of Motion to Dismiss the United States' Complaint in Intervention and to Strike Portions Thereof at 13, *United States ex rel. Strunck v. Mallinckrodt ARD LLC*, No. 2:12-cv-00175-BMS (E.D. Pa. Aug. 19, 2019) (quoting 42 U.S.C. § 1320a–7b(b)(2)).

[38] *Id.* at 13–14 (quoting *United States v. Medtronic, Inc.*, No. CV 15-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017)).

[39] *Id.* at 16–18.

[40] *Id.*

[41] *Id.* at 18.

[42] *See* United States' Opposition to Mallinckrodt's Motion to Dismiss the United States' Complaint in Intervention and to Strike Portions Thereof, *Mallinckrodt* 2:12-cv-00175-BMS (E.D. Pa. Sept. 24, 2019) at 5–6.

[43] *Id.* at 7–8 (internal citations omitted).

[44] *Id.* at 8.

[45] *Id.*

[46] *Id.* at 10–12.

[47] *Id.* at 13–14.

[48] *See* Reply Memorandum in Support of Motion to Dismiss the United States' Complaint in Intervention and to Strike Portions Thereof, *Mallinckrodt*, No. 2:12-cv-00175-BMS (E.D. Pa. Oct. 3, 2019).

[49] *See* also Statement of Interest (conceding that, if an entity that is not the recipient of an HHS OIG advisory opinion "nevertheless strictly adheres to the letter and spirit of the safeguards in an existing opinion, that might provide the entity with a basis to assert that it did not possess the requisite intent to violate the AKS" although such an inquiry would involve a fact-specific, case-by-case determination).

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