AMERICAN HEALTH LAW ASSOCIATION

HEALTH LAW Weekly
January 15, 2021

Compliance Issues with Overcoming "Friction" in the Sale of Expensive Pharmaceutical Products

By Gregg Shapiro

The pharmaceutical distribution and reimbursement system in the United States has many inherent "friction points" that discourage unnecessary use of expensive pharmaceutical products. Because having a robust compliance program makes good business sense,[1] compliance professionals in the pharmaceutical industry should understand the dynamics of these friction points and be aware of the compliance issues that can arise at each of them. In order to sell a pharmaceutical product, its manufacturer not only must convince physicians to prescribe the product—the friction point that has generated perhaps the most frequent enforcement activity involving pharmaceutical sales practices over the past two decades—but also may have to convince patients to purchase the drug, pharmacy and therapeutics committees to put the drug on formulary, nursing home pharmacies and electronic health record software vendors to recommend the drug, and insurers, both public and private, to pay for the drug. The pressure to overcome these challenges can be immense, and pharmaceutical executives and sales and marketing professionals may seek to smooth over these friction points through unlawful kickback schemes and false representations. This article discusses some of the potential compliance issues that may occur at each of these points in the pharmaceutical distribution and reimbursement system.

Remuneration to Prescribing Physicians

Law enforcement and whistleblower actions continue to target pharmaceutical manufacturers that violate the anti-kickback statute by providing remuneration to physicians in an attempt to influence their prescribing behavior, but the nature of the cases has broadened as manufacturers have developed new ways to compensate physicians. While speaker programs, advisory boards, and similar vehicles for providing remuneration to physicians still create compliance risks, pharmaceutical manufacturers also have found themselves facing compliance issues associated with providing physicians with free drug samples or free services, or by covering Medicare Part B patient cost-sharing obligations that physicians otherwise would have to collect themselves.

Speaker Programs and Advisory Boards. Traditional kickback cases involving pharmaceutical manufacturers often focused on payments that masqueraded as compensation for time physicians spent giving speeches or participating on "advisory boards," but where a purpose, if not the principal purpose, of the payments was to induce

the physicians to write prescriptions for the manufacturers' drugs.[2] In the wake of these cases, some pharmaceutical companies undoubtedly curtailed their use of advisory boards and strengthened their compliance oversight of physician speaker programs, yet compliance issues with these types of activities have continued.[3] Indeed, the Office of Inspector General of the Department of Health and Human Services (OIG) not only cautioned pharmaceutical manufacturers about risks of speaker programs in guidance issued in 2003,[4] it recently reinforced that guidance in strong terms, warning that physician speaker programs involve "inherent fraud and abuse risks" and that numerous past enforcement actions involving such programs "strongly suggest that one purpose of the remuneration to the . . . speaker and attendees is to induce or reward referrals."[5]

Drug samples. Providing physicians with free drug samples may constitute a non-monetary form of illegal remuneration. This is especially the case with physician-administered drugs that physicians purchase themselves and for which they may then obtain reimbursement from Medicare Part B. In 2001, pharmaceutical manufacturer TAP Pharmaceutical Products pleaded guilty to charges that it "provided to certain physicians thousands of free samples of the drug Lupron, knowing and expecting that those physicians would prescribe and administer those drug samples to their patients and thereafter seek and receive reimbursement for those free samples."[6] For the physicians who received Lupron samples, there would have been little difference if they had received cash from TAP, because the samples were easily, albeit illegally, convertible to cash through Medicare Part B reimbursement.

Just over a decade later, another pharmaceutical manufacturer, Sanofi, found itself facing similar enforcement scrutiny when the government alleged that its sales representatives offered physicians "samples" of an injectable Part B drug, Hyalgan, on the condition that the physicians purchase the drug. In settling those allegations with the company, the government alleged that Sanofi sales representatives "us[ed] the free drug as kickbacks and promis[ed physicians] to provide negotiated numbers of the syringes in order to lower Hyalgan's effective price," thereby increasing the "spread" the physicians earned when they obtained reimbursement from Medicare Part B for the drug.[7]

More recently, in 2017, a court declined to dismiss a relator's allegations that pharmaceutical manufacturer Allergan violated the anti-kickback statute by providing physicians with samples of drugs that were not covered by Medicare Part B and thus had more tenuous potential value for the physicians.[8] The court reasoned that "Allergan's provision of free drug samples (specifically, eye drop drugs that are administered prior to surgery and thus not reimbursable under Medicare) could plausibly have subsidized surgical costs, increasing ophthalmologists' profit per surgery."[9]

Together, these cases caution that a pharmaceutical manufacturer's provision of drug samples, regardless of whether the drug is reimbursed under Part B, may violate the anti-kickback statute if physicians potentially may use the samples to save or to make money.

Consulting and Reimbursement Support Services. In a recent decision, a court denied a motion to dismiss a relator's allegations that Janssen Biotech, a Johnson & Johnson subsidiary, violated the anti-kickback statute by providing "a variety of free business advisory services to rheumatology and gastroenterology practices that prescribed and infused" two Janssen rheumatology drugs.[10] In reaching this decision, the court cited the 2003 OIG Compliance Program Guidance and focused on whether the services had value that was "independent" of the Janssen products purchased by physician practices.[11] The court further noted a 2013 statement by OIG that it had "'long distinguished between free items and services that are integrally related to the offering provider's or supplier's services and those that are not.'"[12] Finding that the relator's complaint adequately alleged that the services Janssen provided were "entirely separate from [its] infusible medications," the court allowed the relator to proceed to discovery.[13]

Similarly, another court recently found that Sanofi's "reimbursement-assistance program" for physicians potentially violated the anti-kickback statute because the relator had presented evidence that the program "worked as a functional reimbursement guarantee" for physicians who purchased Sanofi's cancer drug, and thus provided value that was "independent" of the value the drug itself provided.[14]

By contrast, other courts have found that services provided by pharmaceutical manufacturers did not have independent value to physicians and thus did not violate the anti-kickback statute. In 2019, for example, a court dismissed a relator's claims that Abbvie provided illegal remuneration to physicians in the form of "product support services for Abbvie's prescription drug Humira" where the services involved registered nurses "train[ing] patients on obtaining insurance payment for the drug, self-injecting the drug, and disposing of injection equipment."[15] The court found that, although Abbvie "served doctors by providing these services to patients," all of these were "Humira-related services."[16] In a subsequent decision in the same case, however, the court declined to dismiss the relator's amended allegations concerning Abbvie's conduct in Florida because the relator had alleged Abbvie's program "extend[s] well beyond basic product support."[17] Not only did Abbvie nurses allegedly provide information on how to use Humira and how to obtain reimbursement for it, but the nurses also allegedly addressed general patient health concerns, thereby enabling "physicians [to] rely on the nurses' experience as medical professionals to give advice [they] would otherwise have to give."[18] The court concluded that, "[a]lthough these additional services may not be wholly unrelated to Humira, they can reasonably be characterized as exceeding basic product support services," and thus could be construed as illegal remuneration under the anti-kickback statute.[19]

Notably, the United States has moved to dismiss a series of qui tam cases where the relators, all affiliated with one another, alleged that various pharmaceutical companies violated the anti-kickback statute by providing drug product support services to physicians.[20] In those cases, as one court observed, the government asserted that "'federal healthcare programs have a strong interest in ensuring that . . . patients have access to basic product support relating to their medication.'"[21]

Covering co-pays for Part B drugs. A number of ostensibly independent foundations cover patient out-of-pocket costs (co-pays) for drugs covered by Medicare Part B, but provide the remuneration directly to the physicians who purchase and administer the drugs, rather than to the patients who otherwise would be obligated to pay the co-pays.[22] These foundation payments, which derive almost entirely from financial support provided to the foundations by pharmaceutical manufacturers, allow physicians to prescribe expensive Part B drugs without having to worry about whether they will be able to collect co-pays from their patients. OIG has issued opinions advising that it would not consider such co-pay coverage to constitute illegal remuneration under the anti-kickback statute so long as the foundations complied with certain conditions.[23] Meanwhile, OIG repeatedly has cautioned that pharmaceutical manufacturers should not use such foundations as "conduits" and thus should not correlate their payments to the foundations with the foundations' expenditures on their drugs.[24] In a 2019 settlement, the United States alleged that Onyx (now owned by Amgen), the manufacturer of Kyprolis, a multiple myeloma drug that is reimbursed under Medicare Part B, violated the anti-kickback statute when it "us[ed] data [a foundation] provided to Onyx on [the foundation]'s anticipated and actual expenses for coverage of Kyprolis copays," and then paid the foundation's "multiple myeloma copay fund in an amount Onyx expected to be sufficient only to cover the copays of Kyprolis patients."[25] In other words, the government alleged that Onyx used the foundation as a conduit for money to physicians who purchased Onyx's drug for their patients.

Remuneration to Patients

Covering co-pays for Part D drugs, directly or indirectly. Manufacturers of expensive drugs have an incentive to make the costs of those drugs irrelevant to patients, thus skewing the demand curve for the drugs. The anti-kickback statute does not apply to products and services reimbursed by private insurers, and so pharmaceutical manufacturers can operate programs that cover private insurance co-pays on drugs without implicating that law.[26] OIG has cautioned, however, that pharmaceutical manufacturers risk violating the anti-kickback statute if they cover private insurance co-pays and "fail to take appropriate steps to ensure that such" coverage is not used to cover Medicare co-pays.[27] OIG explained that, as a policy matter, pharmaceutical manufacturers should not cover the Medicare co-pays for their own drugs, because the Medicare "cost-sharing requirements promote: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market."[28] To the extent a manufacturer allows its private co-pay coverage program also to cover Medicare co-pays, that would result in the manufacturer effectively providing remuneration directly to patients to induce them to purchase the manufacturer's drug at Medicare's expense, and thus would violate the anti-kickback statute.

The anti-kickback statute also proscribes providing remuneration "indirectly" to induce the purchase of a drug reimbursed by a federal health care program, and thus, as noted above, OIG has issued extensive guidance on the circumstances under which a

manufacturer's support of a co-pay foundation would, or would not, potentially implicate the anti-kickback statute. In recent years, the United States has reached settlements with numerous pharmaceutical manufacturers to resolve allegations that the manufacturers used foundations as conduits and thus provided unlawful remuneration indirectly to patients taking their drugs.[29] In these settlements, the United States alleged that pharmaceutical manufacturers, among other things: obtained drug-specific data from the foundations to correlate their payments to the foundations with the foundations' spending on co-pays for the manufacturers' drugs; coordinated with the foundations to exclude the drugs of competing manufacturers from eligibility for co-pay coverage; claimed that the payments to the foundations were "donations" even as they were calculating return on investment on those payments; and used the availability of foundation co-pay coverage to mask the effect of price increases on their drugs.[30]

Other remuneration to patients. In recent years, pharmaceutical manufacturers have begun paying patients directly, ostensibly to engage in marketing activities on behalf of the manufacturers through so-called "patient ambassador" programs. These programs carry the usual risks of improper promotion under the Food Drug and Cosmetic Act, but also may implicate the anti-kickback statute. This is especially the case when patients have few resources of their own and the remuneration from a pharmaceutical manufacturer may have the effect of inducing them to continue purchasing that manufacturer's drug when other less expensive therapies might exist.

Convincing Gatekeepers to Recommend Specific Drugs

In the process of marketing a drug, the manufacturer may find it helpful, or even necessary, to convince various gatekeepers—including pharmacy and therapeutics committees, electronic health record software vendors, and nursing home pharmacies—to recommend or arrange for the ordering of the drug. A pharmaceutical manufacturer's interactions with these gatekeepers can raise a variety of potential compliance concerns.

Misrepresentations and remuneration to members of pharmacy and therapeutics committees. Many hospitals and health plans maintain formularies—lists of preferred or covered drugs—and they have so-called pharmacy and therapeutics, or "P&T", committees that decide which drugs will go on those formularies. P&T committee members are often pharmacists and physicians who work for the health system that the P&T committee serves. Because inclusion on a formulary can have a substantial effect on sales, there can be a temptation to seek improper influence over members of a P&T committee. Pharmaceutical manufacturers have faced enforcement actions as a result of their allegedly improper interactions with health system P&T committees.

In 2014, for example, the state of Texas intervened in two qui tam lawsuits alleging that AstraZeneca made misleading claims to persuade the P&T committee of the Texas Medicaid program to add an AstraZeneca drug to the Texas Medicaid preferred drug list, and that the company paid cash remuneration to individuals in a position to influence the status of another AstraZeneca drug on the state hospital system

formulary.[31] Specifically, one of the lawsuits alleged that AstraZeneca falsely represented to the Texas Medicaid P&T committee that AstraZeneca's cholesterol drug, Crestor, was superior to a competing cholesterol drug, and that AstraZeneca further arranged for private physicians to make misleading presentations to the P&T committee without disclosing that the company had prepared the physicians for their presentations.[32] The other lawsuit alleged, among other things, that AstraZeneca paid two state mental health officials $465,000 to influence the state hospital system's formulary committee to add Seroquel, an AstraZeneca antipsychotic drug, to the state hospital formulary, and to recommend that Texas Medicaid health care providers prescribe Seroquel.[33]

In July 2020, Indivior, the manufacturer of the anti-overdose drug Suboxone, pleaded guilty to a criminal information charging the company with making false statements to the Massachusetts Medicaid program, MassHealth, to convince MassHealth to include the latest form of Suboxone as a preferred drug on its formulary.[34] As part of this effort, the information alleged Indivior falsely claimed to a MassHealth official that the latest form of Suboxone was less prone to unintended pediatric exposure than an earlier form of the drug.[35] Shortly thereafter, in a statement that cited the false data provided by Indivior, MassHealth announced that it would provide access to the latest form of Suboxone for individuals who lived in households with children under six years old.[36] Indivior did not correct its representations to MassHealth until three years later, after the government executed a search warrant at the offices of its corporate parent.[37] In conjunction with Indivior's guilty plea, its chief executive officer also pleaded guilty to charges related to the false statements to MassHealth, and he was subsequently sentenced to a six-month prison term.[38]

Remuneration to electronic health records software vendors. Since the passage of the Health Information Technology for Economic and Clinical Health Act in 2009, health care providers in the United States increasingly rely on electronic health record (EHR) software, which not only stores medical records but also may have the capacity to influence clinical decision-making. The government's recent criminal case against Purdue Pharma, the maker of OxyContin and other opioid drugs, illustrates the potential perils that a pharmaceutical manufacturer may face if it tries to influence an EHR software vendor to arrange for the ordering of, or to recommend, its drugs. In a criminal information to which Purdue pleaded guilty, the government alleged that Purdue conspired to violate the anti-kickback statute by paying Practice Fusion, an EHR software vendor, nearly $1 million to implement in its software "clinical decision support" alerts that would appear when providers were treating patients with pain and that arranged for and recommended use of extended-release opioid drugs, such as those made by Purdue.[39] According to the information, Purdue projected that its payment to Practice Fusion would generate a positive return on investment from increased prescriptions for Purdue drugs, and Purdue went forward with the arrangement even though a company physician raised concerns about Purdue being involved in therapy recommendations and even though a company attorney also expressed reservations about it.[40]

Remuneration to nursing home pharmacies. By law, all nursing homes must have a pharmacist conduct a monthly review of the medications prescribed to each patient.[41] These pharmacists, who are often employees of the pharmacies that supply drugs to the nursing homes, make recommendations regarding patients' drug regimens. Through these pharmacists, nursing home pharmacies can influence the drug regimens of patients in nursing homes. Recognizing this influence, many pharmaceutical manufacturers have sought to induce nursing home pharmacies to recommend their drugs, and have found themselves the subjects of enforcement actions for allegedly doing so improperly.

In 2010, the United States filed suit against Johnson & Johnson (J&J), alleging that the pharmaceutical manufacturer paid a variety of kickbacks to Omnicare, then the nation's largest nursing home pharmacy, to induce Omnicare and its pharmacists to recommend J&J drugs. The alleged kickbacks included (1) rebates contingent on Omnicare implementing specific "Active Intervention Programs" to drive prescribing of J&J drugs, (2) payments for data that Omnicare did not provide, and (3) "grants" and "educational funding" whose true purpose was to induce Omnicare to recommend J&J drugs.[42]

Two years later, in 2012, Abbott, the manufacturer of Depakote, an anti-seizure drug, agreed to a settlement resolving allegations by the United States that Abbott paid "illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Depakote."[43] The next year, Amgen reached a settlement with the United States to resolve allegations that it had paid kickbacks to three nursing home pharmacies to induce them to recommend an Amgen drug, Aranesp. Much like the government's complaint against J&J, the settlement agreement alleged that Amgen's kickbacks took multiple forms, including "purported market-share rebates, purported volume-based rebates, grants, honoraria, speaker fees, consulting services, dinners, travel, or the purchase of unnecessary data," all intended ultimately to result in increased utilization of Aranesp.[44]

Prior Authorization Fraud

To ensure that expensive drugs are dispensed only when necessary, many insurance plans, including Medicare Part D plans, require the patient and/or the patient's prescriber to contact the plan and obtain "prior authorization" or a non-formulary "exception" before the plan will reimburse a pharmacy for the drug.[45] The prior authorization process for a particular drug may require a showing that the patient has a particular clinical condition that justifies use of the drug, or that the patient has engaged in "step therapy," i.e., that the patient has previously tried and failed a less expensive drug that has been proven effective for other people with the same condition.[46]

In the past six years, several pharmaceutical companies, and many of their employees, have faced enforcement actions for engaging in fraud schemes to obtain prior authorizations for expensive drugs. In 2015, pharmaceutical manufacturer Warner Chilcott pleaded guilty to an information charging the company with directing sales representatives to fill out prior authorization requests with "clinical reasons [that] were false or of uncertain application to the particular patient and were used simply to gain approval of the [prior authorization]."[47] The information further alleged that Warner

Chilcott "sales representatives (a) completed [prior authorizations] in physicians' offices; (b) took patient files from physicians' offices and prepared [prior authorizations] at home; (c) called insurance companies, falsely claiming that they were an employee in the physician's office, to request that [the Warner Chilcott drug] be covered; and (d) forged physicians' signatures on [prior authorizations]."[48]

Two years later, in 2017, another pharmaceutical manufacturer, Aegerion, pleaded guilty to an information charging it with conspiring to violate the patient privacy provisions of the Health Insurance Portability and Accountability Act by, among other things, directing its employees "to gain access to protected health information without patient authorization to complete or to assist with the completion of statements of medical necessity or prior authorizations to support insurance coverage of prescriptions for" Aegerion's expensive cholesterol drug.[49]

Meanwhile, in late 2016, the government charged multiple executives of Insys Therapeutics with a wide-ranging conspiracy that included allegations concerning the company's "Reimbursement Unit."[50] According to the indictment, the defendants directed "Reimbursement Unit employees to tell agents of insurers and pharmacy benefit managers that they were calling 'from' the doctor's office," and they "set up the Reimbursement Unit phone system to block access to the unit's number, so that agents of insurers and pharmacy benefit managers would not notice that the Reimbursement Unit employees were calling from an area code different than the area code of the prescribing practitioner."[51] Employees in Insys's Reimbursement Unit then allegedly made various false and misleading statements to insurers and pharmacy benefit managers, including that patients had "tried and failed" certain medications on the plans' step therapy protocols.[52]

With increased enforcement activity against pharmaceutical companies that engage in prior authorization fraud, some pharmacies have stepped into the same role, sometimes with similar consequences.[53] Pharmaceutical companies risk vicarious liability for such misconduct if they take steps to steer prescriptions to pharmacies that have success in obtaining prior authorizations as a result of fraudulent practices.

Conclusion

The foregoing examples show just a few of the many potential ways in which a pharmaceutical manufacturer can create significant compliance issues as it attempts to overcome friction points in the pharmaceutical distribution and reimbursement system. Compliance professionals can serve their employers well by understanding why these various rules and safeguards exist. They do not exist to prevent or to discourage the use of expensive drugs; instead, they serve to prevent *unnecessary* use of expensive drugs and to impede behavior that distorts prescribing or purchasing decisions. While the pharmaceutical distribution and reimbursement system in the United States is undoubtedly complex, it is not irrational. Compliance professionals who understand not only how the system works, but also the purpose behind the rules and the government

enforcement decisions that apply them, can serve a critical strategic function in pharmaceutical firms. In particular, as market structure and firm practices evolve, these professionals can be in a position to advise their employers on how to comply with existing rules and to assess the risks associated with new strategic behavior, so that the company can continue to focus on its core mission of helping patients.

About the Author

Gregg Shapiro is an Assistant United States Attorney and Chief of the Affirmative Civil Enforcement Unit in the United States Attorney's Office for the District of Massachusetts, but the views expressed herein are his own.

[1] An effective compliance program not only can prevent misconduct, but can detect and cabin it promptly when it occurs. Thus, a company's investment in compliance can reduce the likelihood of costly and disruptive government investigations. Further, in the event such an investigation commences, the existence of an effective compliance program can be used to show the company's general good faith. *See* DOJ Manual § 9-28.300.A (directing prosecutors to make corporate charging decisions considering, among other factors, "the adequacy and effectiveness of the corporation's compliance program at the time of the offense," and "the corporation's remedial actions, including, but not limited to, any efforts to implement an adequate and effective corporate compliance program or to improve an existing one").

[2] *See, e.g.*, *United States ex rel. Gobble v. Forest Pharmaceuticals, Inc.*, No. 03-10395, United States' Complaint in Intervention (D. Mass. Feb. 13, 2009) (alleging, *inter alia*, that Forest Pharmaceuticals paid over 19,000 physician "consultants"—including perhaps a majority of the psychiatrists in the United States—to attend advisory boards where the real purpose was to "induce the attendees to prescribe more" of Forest's anti-depressant drugs); Department of Justice, Press Release, *Pharmaceutical Manufacturer Daiichi-Sankyo to Pay $39 Million to Resolve Allegations that It Paid Kickbacks to Physicians* (Jan. 9, 2015) (describing allegations that Daiichi Sankyo "paid physicians who participated in the speaker programs even if, among other things: (1) the honoraria recipient spoke only to members of his or her own staff in his or her own office; (2) the physician participants in ['Physician Opinion & Discussion programs'] took turns accepting a 'speaker' honoraria for duplicative discussions; (3) the audience included the honoraria recipient's spouse; (4) the honoraria recipient did not speak at all because the event was cancelled beforehand; and/or (5) the associated dinners were lavish").

[3] *See, e.g.*, *United States v. Novartis Pharmaceuticals Corp.*, Stipulation and Order of Settlement and Dismissal, No. 11 Civ. 0071 (S.D.N.Y. July 1, 2020) (describing United States' allegations that "Novartis paid remuneration in the form of cash, meals, alcohol,

hotels, travel, entertainment, and honoraria payments to [health care practitioners] who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or lunch-n-learns to induce them to prescribe [Novartis drugs] in violation of the [anti-kickback statute]"); *United States ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc.*, No. 13 Civ. 3702, 2019 WL 1245656, at *13 (S.D.N.Y. Feb. 27, 2019) (denying summary judgment to Teva on relator's kickback allegations where relator presented evidence that Teva "[s]ales representatives linked prescriber habits with their retention as paid speakers for Teva").

[4] *See* OIG, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23738 (May 5, 2003) (advising that "the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute").

[5] OIG, Special Fraud Alert: Speaker Programs, at 2, 3 (Nov. 16, 2020).

[6] *United States v. TAP Pharmaceutical Products Inc.*, Information, No. 1:01cr10354 (D. Mass. Oct. 3, 2001); Department of Justice, Press Release, *TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges* (Oct. 3, 2001).

[7] Department of Justice, Press Release, *Sanofi Agrees to Pay $109 Million to Resolve Allegations that It Gave Free Drug as Kickbacks to Physicians* (Dec. 19, 2012).

[8] *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*, 889 F.3d 163 (2d Cir. 2018).

[9] *Id.* at 807.

[10] *United States ex rel. Long v. Janssen Biotech, Inc.*, No. 16-12182, Slip Op. at 1 (D. Mass. Oct. 21, 2020).

[11] *Id.* at 14.

[12] *Id.* (quoting OIG, Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79202, 79210 (Dec. 27, 2013)).

[13] *Id.* at 19.

[14] *United States ex rel. Gohil v. Sanofi U.S. Services, Inc.*, No. 02-2964, 2020 WL 4260797, at *8 (E.D. Pa. July 24, 2020).

[15] *United States ex rel. Suarez v. Abbvie Inc.*, No. 15 C 8928, 2019 WL 4749967, at *1-2 (N.D. Ill. Sept. 30, 2019).

[16] *Id.* at *7.

[17] *United States ex rel. Suarez v. Abbvie Inc.*, No. 15 C 8928, 2020 WL 7027446, at *9 (N.D. Ill. Nov. 30, 2020).

[18] *Id.* (quotation omitted).

[19] *Id.*

[20] *See, e.g.*, *United States v. EMD Serono, Inc.*, 370 F. Supp. 3d 483 (E.D. Pa. 2019); *United States ex rel. SCEF, LLC v. AstraZeneca, Inc.*, No. 2:17-CV-1328, 2019 WL 5725182 (W.D. Wash. Nov. 5, 2019); *United States ex rel. NHCA-TEV, LLC v. Teva Pharmaceutical Products Ltd.*, No. 17-2040, 2019 WL 6327207 (E.D. Pa. Nov. 26, 2019).

[21] *NHCA-TEV*, 2019 WL 6327207, at *3.

[22] *See, e.g.,* PAN Foundation, Provider Billing Guide.

[23] *See, e.g.*, OIG, Advisory Opinion No. 15-17 (Dec. 28, 2015); OIG, Advisory Opinion No. 15-16 (Dec. 28, 2015).

[24] OIG, Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005); OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).

[25] Settlement Agreement between the United States and Amgen Inc. (Apr. 25, 2019).

[26] *See* 42 U.S.C. § 1320a-7b(b)(2)(A) (referring to "any item or service for which payment may be made in whole or in part *under a Federal health care program*) (emphasis added); 42 U.S.C. § 1320a-7b(f) (defining "Federal health care program" as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the [Federal Employees Health Benefits Program])").

[27] OIG, Special Advisory Bulletin, Pharmaceutical Manufacturer Copayment Coupons, at 3 (Sept. 2014).

[28] *Id.* at 2.

[29] *See, e.g.*, Department of Justice, Press Release, *Gilead Agrees to Pay $97 Million to Resolve Allegations that it Paid Kickbacks through a Co-Pay Foundation* (Sept. 23, 2020) (listing certain settlements).

[30] *See*, *e.g.*, Settlement Agreement between the United States and Pfizer, Inc. (May 24, 2018) (alleging that Pfizer raised the price of a drug by 44% and then arranged for a foundation to create a fund that would cover that drug almost exclusively); Settlement Agreement between the United States and Astellas Pharma U.S., Inc. (Apr. 25, 2019) (alleging that Astellas arranged with two foundations to create funds that would cover Astellas' drug almost exclusively and then "promoted the existence of the . . . funds as an advantage for [its drug] over competing . . . drugs in an effort to persuade medical providers to prescribe [Astellas' drug]"); Settlement Agreement between the United States and Actelion Pharmaceuticals, US, Inc. (Dec. 16, 2018) (alleging that "Actelion routinely obtained data from [a foundation] detailing how many patients on each [Actelion drug the foundation] had assisted, how much [the foundation] had spent on those patients, and how much [the foundation] expected to spend on those patients in the future," and that Actelion then "used this information to budget for future payments to [the foundation] on a drug-specific basis and to confirm that its contribution amounts . . . were sufficient to cover the copays of patients taking [its drugs], but not of patients taking other manufacturers' . . . drugs").

[31] *See State of Texas ex rel. Foote v. AstraZeneca L.P.*, No. D-1-GV-13-000812, State of Texas' Motion to Unseal (Tex. Dist. Ct. Travis Cty. Dec. 30, 2014) (referencing prior intervention); *State of Texas ex rel. Zayas v. AstraZeneca*, No. D-1-GN-13-003530, Notice of Intervention (Tex. Dist. Ct. Travis Cty. Oct. 1, 2014).

[32] *State of Texas ex rel. Foote v. AstraZeneca L.P.*, No. D-1-GV-13-000812, Plaintiffs' First Amended Petition, ¶¶ 55-58, 73-77, 82, 94-95 (Tex. Dist. Ct. Travis Cty. Dec. 22, 2014).

[33] *State of Texas ex rel. Zayas v. AstraZeneca*, No. D-1-GN-13-003530, Plaintiffs' Third Amended Petition, ¶¶ 116-121 (Tex. Dist. Ct. Travis Cty. July 1, 2016).

[34] *United States v. Indivior Solutions, Inc.*, No. 1:19-cr-00016, Information (July 27, 2020).

[35] *Id.* ¶ 24.

[36] *Id.* ¶ 26.

[37] *Id.* ¶ 27.

[38] Department of Justice, Press Release, *Suboxone Manufacturer Indivior's Former Chief Executive Officer Sentenced to Jail Time in Connection with Drug Safety Claims* (Oct. 22, 2000).

[39] *United States v. Purdue Pharma L.P.*, No. 2:20cr1028, Information (D.N.J. Nov. 24, 2020).

[40] *Id.* at pp. 73, 78-81, 85.

[41] *See* 42 C.F.R. § 483.45.

[42] Department of Justice, Press Release, *United States Files Suit Against Drug Manufacturer Johnson & Johnson for Paying Kickbacks to Nation's Largest Nursing Home Pharmacy* (Jan. 15, 2010).

[43] Settlement Agreement between the United States and Abbott Laboratories (May 7, 2012).

[44] Settlement Agreement between the United States and Amgen Inc. (Apr. 4, 2013).

[45] *See, e.g.*, 42 C.F.R. § 423.578 (describing Part D non-formulary exception process and providing that "[a] prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's condition - (i) [w]ould not be as effective for the enrollee as the requested drug; [or] (ii) [w]ould have adverse effects for the enrollee").

[46] *See* Medicare.gov, Drug Plan Coverage Rules.

[47] *United States v. Warner Chilcott Sales (U.S.) L.L.C.*, No. 1:15cr10327, Information, ¶ 40 (D. Mass. Oct. 29, 2015).

[48] *Id.*, ¶ 50.

[49] *United States v. Aegerion Pharmaceuticals, Inc.*, No. 17cr10289, Information, ¶ 13 (D. Mass. Sept. 22, 2017). Further, in 2018, the government charged a former Aegerion sales representative, Mark Moffett, with conspiracy to commit wire fraud by, among other things, "personally complet[ing] prior authorizations with false information," thereby "caus[ing] health insurance plans to pay for prescriptions for [Aegerion's drug] for patients who did not meet the health insurance plans' coverage criteria." *United States v. Moffett*, No. 1:18cr10249, Criminal Complaint Affidavit, ¶ 21 (D. Mass. May 11, 2018).

[50] *United States v. Babich, et al.*, No. 16cr10343, Indictment (Dec. 6, 2016).

[51] *Id.*, ¶¶ 176, 177,

[52] *Id.*, ¶ 190.

[53] *See, e.g., United States v. Shtindler*, Mag. No. 19-8271, Criminal Complaint (D.N.J. Aug. 29, 2019) (charging pharmacist with health care fraud for allegedly directing his employees to make false statements on prior authorization forms concerning patients' clinical conditions and prior step therapy).