FDA Update: Recent Enforcement Blockbusters

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Recent enforcement actions, court decisions, settlements, advisory opinions and government policies important to FDA-regulated companies have produced a series of blockbuster events, including:

- a food company quality assurance (QA) director pleading guilty to a criminal adulteration charge in the wake of the distribution of a breakfast cereal linked to a salmonella outbreak;
- a manufacturer entering into a three-year deferred prosecution agreement and paying a $10 million penalty for allegedly marketing an implantable medical device that had no function;
- a SEC enforcement action against a diagnostic test manufacturer arising from allegedly misleading press releases about a COVID-19 test;
- court decisions blocking FDA enforcement actions involving a stem cell treatment and an undeclared active pharmaceutical ingredient (API) supplier;
- kickback case settlements and judgments costing companies hundreds of millions of dollars;
- the Supreme Court's elimination of a frequently invoked False Claims Act defense;
- patient assistance programs cleared by health care fraud enforcement authorities; and
- new Department of Justice (DOJ) enforcement policies targeting repeat offenders and encouraging self-disclosure of wrongdoing.

In this white paper, Thompson FDA focuses on six areas of recent enforcement activity that have revealed the government's priories as it identifies companies and corporate officials for investigation, brings civil and criminal actions against those companies and individuals, and seeks civil and criminal penalties.

As always, compliance officials and corporate management at all levels in FDA-regulated companies must stay up to date with the government's enforcement activity, assess their companies' risk in light of that activity, and adjust their operations and corporate compliance programs as needed to prevent noncompliant activities within their organizations.

I. Violations of the Federal Food, Drug, and Cosmetic Act

Cereal Maker Pleads Guilty, Agrees to Largest Penalty Ever Assessed in Food Safety Criminal Case

A food manufacturer that operated a Gridley, Illinois, facility that produced breakfast cereal linked to a salmonellosis outbreak pleaded guilty in February 2023 to a strict liability misdemeanor charge of distributing adulterated food, was ordered to pay a $10.488 million criminal fine, and agreed to pay a forfeiture in the amount of $8.740 million (*United States v. Kerry Inc.*, No. 1:22-cr-10051-JES-JEH (C.D. Ill.)).

The DOJ said that the fine and forfeiture to which Kerry Inc. agreed constituted the largest-ever criminal penalty stemming from a conviction in a food safety case.

The company, a subsidiary of Ireland-based Kerry Group, was a contract manufacturer of cereal products. In June 2018, the FDA and the Centers for Disease Control and Prevention (CDC) determined that an ongoing outbreak of salmonellosis could be traced to Kellogg's Honey Smacks produced at Kerry's Gridley facility. More than 130 cases of the disease were linked to the outbreak, which resulted in a Kellogg's recall of all Honey Smacks cereal manufactured at the plant beginning in June 2017.

The company was charged in a criminal information filed Dec. 28, 2022, in the U.S. District Court for the Central District of Illinois with one count of introducing adulterated food into interstate commerce in violation of 21 U.S.C. §331(a) and 21 U.S.C. §333(a)(1).

Repeated findings of salmonella. According to the DOJ, a sealed plea agreement stated that between June 2016 and June 2018 routine environment tests at the Gridley facility revealed the presence of salmonella approximately 81 times, with at least one sample testing positive for salmonella being taken each month during the two-year period.

The plea agreement also stated that the facility's employees "routinely failed to implement corrective and preventive actions (CAPAs) to address positive salmonella tests," the DOJ said.

Warning Letter. A July 26, 2018, Warning Letter issued by the FDA Office of Regulatory Affairs Office of Human and Animal Food Operations alleged that an inspection conducted at the Gridley plant the previous month revealed serious violations of the current good manufacturing practice (cGMP), hazard analysis, and risk-based preventive controls regulation for human foods, 21 C.F.R. Part 117.

The cereal manufactured at the facility was prepared, packed or held under insanitary conditions, the FDA alleged. Moreover, a February 2018 hazard analysis performed for the company's cereal allegedly did not identify contamination with salmonella as a food safety hazard requiring a preventive control.

Scores of samples that tested positive for salmonella were taken throughout the facility, including in cereal production rooms and in the cereal coating room, according to the Warning Letter. "These repeated findings of salmonella in your environment should have resulted in a reanalysis of your food safety plan as required by 21 C.F.R. §117.170(b)(4)," the agency stated.

In the Warning Letter, the FDA also alleged that the company had not identified and implemented sanitation controls that were adequate to ensure that the Gridley facility was maintained in a sanitary condition to minimize or prevent the salmonella hazard.

Moreover, the company allegedly had not conducted a root cause analysis for the persistent findings of salmonella in the facility, and it had not implemented its sanitation correction action procedure.

"Your facility completed an 'environmental investigation report' for each positive pathogen sample that you found," the agency said in the Warning Letter. "However, there is no documentation that you formed a response team to determine the root cause and corrective actions necessary to prevent the routine reoccurrence of salmonella throughout your facility."

The company also had not fully implemented two environmental monitoring procedures because it had not swabbed some areas of the facility for environmental pathogens, even though ready-to-eat cereal was exposed to the environment in those areas, the FDA reported in the Warning Letter.

Company "regrets the unacceptable practices." In a statement, the company said that it "regrets the unacceptable practices and failures that occurred at Gridley." It added that "the issues, conduct and practices that occurred there" had led the company to close the facility permanently.

Kerry also said that in the wake of the salmonellosis outbreak it had undertaken "a comprehensive review of its food safety practices, policies and oversight, with a particular focus on ensuring adherence to group standards and governance."

"Though the issues at Gridley were plant-specific in nature," the company said, "Kerry has invested and continues to invest significantly in all aspects of food safety and quality processes and to further embed safety as a central pillar in everything that it does."

Former Kerry QA Director Pleads Guilty to Adulteration Charges Linked to Salmonella Outbreak

In October 2022, Kerry's former director of QA pleaded guilty to charges of introducing adulterated food into interstate commerce in connection with the production of the breakfast cereal linked to the 2018 outbreak of salmonellosis (*United States v. Chermala*, No. 1:22-cr-10032-JES-JEH (C.D. Ill.)).

In a criminal information filed in August 2022 in the U.S. District Court for the Central District of Illinois, Ravi Kumar Chermala was charged with three misdemeanor counts of introducing adulterated food into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §331(a), 21 U.S.C. §333(a)(1)).

Details of the alleged violations. According to the DOJ, Chermala was the QA director for Kerry Inc. until September 2018. In his position, Chermala was in charge of sanitation programs at Kerry manufacturing facilities, including the Gridley, Illinois, facility that manufactured the cereal for the Kellogg Co.

Chermala admitted that between June 2016 and June 2018 he directed employees not to report information about conditions at the Gridley facility to Kellogg's, and that he directed employees to alter the facility's program for detecting the presence of pathogens in the plant, federal prosecutors said. The government alleged that his actions limited the facility's ability to detect insanitary conditions accurately.

Chermala pleaded guilty to the three misdemeanor counts during a court appearance before a federal magistrate judge in Peoria, Illinois. In June 2023, he was sentenced to a one-year term of probation following the court's acceptance of his plea agreement.

The case against Chermala was investigated by the FDA's Office of Criminal Investigations.

Final FDA Guidance Identifies Types of Homeopathic Drugs Targeted for Prioritized Enforcement Action

Closing out a five-year guidance development, in December 2022 the FDA finalized its guidance on how the agency intends to prioritize enforcement and regulatory action for drugs and biological products labeled as homeopathic and marketed in the United States without the required FDA approvals.

The guidance identifies categories of unapproved homeopathic drug products that the agency has determined potentially pose higher risks to public health. The categories remained unchanged from those identified in an October 2019 revised draft version of the document.

However, the agency stresses in the guidance, the FDA "is not required, and generally does not expect, to give special notice that a drug product may be subject to enforcement action," and "any homeopathic drug product that is being marketed illegal is subject to FDA enforcement action at any time."

Development of the final guidance. The final guidance document, "Homeopathic Drug Products" (https://www.fda.gov/media/163755/download), was first released in draft form in December 2017.

The agency revised the draft guidance in October 2019 in light of what it called the "significant risk" posed by the products.

When the revised draft guidance was issued, the FDA withdrew a May 1988 Compliance Policy Guide (CPG) that described the agency's enforcement priorities for homeopathic drugs. CPG 400.400 had outlined conditions under which homeopathic drugs might be legally marketed.

In withdrawing the CPG, the FDA said that since the document was first issued there had been "multiple situations in which homeopathic drug products posed a significant risk to patients, even though the products, as labeled, appeared to meet the conditions described in [the CPG]."

CARES Act. In a Dec. 7, 2022, *Federal Register* notice announcing the availability of the final guidance (87 Fed. Reg. 75054), the FDA said that the document included "minor revisions" to the revised draft guidance made "for clarity and transparency."

New to the final version of the guidance is a discussion of the effect of revisions to the over-the-counter (OTC) drug review process under FD&C Act Section 505G (21 U.S.C. §355h), which was added to the statute by the CARES Act, enacted in March 2020 (Pub. L. No. 116-136).

Under the CARES Act, the FDA now issues administrative orders to make determinations that certain nonprescription drugs marketed without an approved application are generally recognized as safe and effective (GRAS/E).

"Prior to enactment of CARES, FDA had not reviewed any homeopathic drug products under the OTC drug review because the agency had placed homeopathic drug products in a separate category and deferred consideration of them," the final guidance states. "Subsequent to enactment of CARES, no GRAS/E determinations will be made for homeopathic drug products under Section 505G, because Section 505G does not apply to homeopathic drugs products."

"Because at this time no homeopathic drug products have been determined by FDA to be GRAS/E," the guidance continues, "all homeopathic drug products remain subject to the premarket approval requirements."

Citizen petition. In addition to considering comments submitted regarding the original draft guidance and the revised draft guidance, the FDA said that it took into consideration a citizen petition filed with the agency in June 2020 on behalf of the Americans for Homeopathy Choice Foundation and the agency's response to the citizen petition.

The citizen petition had sought to enact a regulation that would "recognize as safe and effective homeopathic drugs that are properly manufactured and labeled and listed in, or formally pending approval for listing in, the Homeopathic Pharmacopoeia of the United States and its supplements and addendums (HPUS)."

The regulation proposed by the foundation also would have prohibited drugs not listed in the HPUS from being labeled as homeopathic and would have made the FDA's cGMP standards applicable to HPUS-listed drugs.

In its 19-page response to the citizen petition, dated Dec. 6, 2022, the agency said that:

- it could not promulgate a regulation codifying a determination that all homeopathic drug products included or pending approval for inclusion in the HPUS are GRAS/E, absent an FDA determination otherwise; and

- it would not promulgate a regulation that codified a determination that all homeopathic drug products entitled to "grandfathered status" are GRAS/E and therefore do not require an approved application to be legally marketed.

On this basis, the FDA denied the foundation's citizen petition.

The agency also turned down the foundation's request to hold a public hearing to consider the contents of the petition, citing a two-day public hearing conducted in April 2015 to obtain comments from stakeholders about the current use of homeopathic drug products — as well as the more than 9,000 comments received through the public docket for the hearing and the approximately 54,500 comments received during the comment periods for the two draft guidance documents.

The Americans for Homeopathy Choice Foundation citizen petition and the FDA's response are available online at https://www.regulations.gov/ (Docket No. FDA-2020-P-1510).

Device Manufacturer Agrees To Pay $10 Million, CEO Indicted in Connection With Marketing of 'Dummy' Device

In March 2023, the DOJ announced the unsealing of a three-year non-prosecution agreement with a medical device company related to what the department called "a scheme to create and sell a nonfunctioning dummy medical device for implantation into patients suffering from chronic pain, resulting in millions of dollars in losses to federal health care programs."

Florida-based Stimwave L.L.C. also agreed to pay a $10 million monetary penalty.

The government also announced that a two-count indictment had been filed against the company's former CEO, Laura Perryman (*United States v. Perryman*, No. 1:23-cr-00117-UA (S.D.N.Y.)).

Components of the device. Stimwave marketed the StimQ PNS System, a neurostimulator device for treating chronic pain that used electrical currents to target peripheral nerves outside the spinal cord. The device included:

- an implantable electrode array or lead that stimulated the nerve;

- a 23-centimeter-long implantable receiver — the so-called Pink Stylet — that contained copper that functioned as an antenna and was connected surgically to the lead; and

- an externally worn transmitter with an antenna and a battery that powered the device.

The Pink Stylet transmitted energy from the battery of the external transmitter to the electrode array under circumstances where, because of the location of the implant, an external battery/transmitter could not be placed directly on or next to the electrode array.

The company marketed the PNS System to physicians at a price of more than $16,000 with the understanding that insurance providers, including Medicare, would reimburse practitioners for implanting the device into patients through two separate reimbursement codes (Current Procedural Terminology (CPT) codes):

- CPT code 64555 for implanting the electrode array, with reimbursement set at between $4,000 and $6,000; and

- CPT code 64590 for implanting the Pink Stylet, with reimbursement set at between $16,000 and $18,000.

Complications with the Pink Stylet. In 2017, Stimwave became aware that physicians who implanted the PNS System were complaining that the Pink Stylet could not be implanted to fit comfortably within a patient's smaller anatomical spaces, such as near the elbows. If that location was used, the device could function without the Pink Stylet, but only if an external battery was placed at or near the neurostimulator.

Use of the PNS System without the Pink Stylet was not included or referenced in the company's August 2017 premarket notification (510(k)) clearance for the device or in the product's instructions for use. The company did not notify the FDA of the device's modification.

If physicians implanted the device without the Pink Stylet, the $16,000-$18,000 reimbursement under CPT code 64590 would not be available to them. This meant that the procedure would not be economically viable for medical providers, and the company's management was concerned that providers would stop buying the device.

White Stylet introduced. As a result, allegedly at Perryman's direction, Stimwave designed and manufactured a component that was disguised as a receiver. The component was falsely represented as containing copper and as functioning as a receiver to transmit energy from the external battery.

The component — called the White Stylet — "was actually without function," according to a statement of facts stipulated by the company. "It provided no receiver functionality and had no medical purpose."

The company created the White Stylet so that practitioners could implant a second component in situations where the longer Pink Stylet would not fit or would be uncomfortable. By implanting the White Stylet, the practitioner could claim CPT code 64590 reimbursement from health insurers. Moreover, unlike the Pink Stylet, the White Stylet could be cut to fit in smaller anatomical spaces.

Perryman allegedly told physicians that the White Stylet contained copper and therefore was functional as a receiver "when in fact it was made of plastic and was not functional." Also, the company's sales representatives were instructed to tell medical providers that they could use CPT code 64590 for health insurance reimbursement after implanting the White Stylet and that they could cut the White Stylet to fit smaller anatomical spaces if necessary.

Although the company maintained standard operating procedures (SOPs) relating to quality system document and design controls during the period when the White Stylet was included as a component part of the PNS System, the company's management had circumvented those SOPs when producing the White Stylet.

New management. After a change in the company's leadership, the new management learned of the alleged misconduct and took what the statement of facts called "quick and significant steps" to address the matter — including issuing a recall of all PNS System kits and conducting an analysis of the possible harm caused by the marketing of the White Stylet. The analysis was provided to the government, including the FDA.

In October 2019, the DOJ sent Stimwave a civil investigative demand dealing with the PNS System. The following month, the company placed Perryman on leave and took steps to terminate her employment. The new management "has fully cooperated with the government in its civil and criminal investigation," the statement of facts reported.

In June 2022, Stimwave filed for Chapter 11 bankruptcy after operating at a net loss totaling more than $18 million in 2020 and $14 million in 2021 (*In re Stimwave Tech. Inc.*, No. 22-10541 (KBO) (Del. Bankr.)).

Charges against CEO. In an indictment filed on March 6, 2023, and unsealed three days later, Perryman was charged with one count of conspiracy to commit wire fraud and health care fraud and one count of health care fraud.

She faces the possibility of a sentence of 20 years in prison on the conspiracy count and a sentence of 10 years in prison on the health care fraud count.

In September 2023, Perry filed a motion to dismiss the indictment against her, arguing that the charges in the indictment lacked specificity and were unconstitutionally vague. In the alternative, she asked the court to compel the government to provide a bill of particulars under Federal Rule of Criminal Procedure 7(f).

False claims suit. In addition, the DOJ unsealed a civil suit brought under the False Claims Act originally brought by a limited liability corporation whose members included current and former Stimwave employees. The government also unsealed the parties' settlement of the suit (*United States ex rel. SWFC L.L.C. v. Stimwave Technologies, Inc.*, No. 1:18-cv-04599-GBD (S.D.N.Y.)).

Under the terms of the civil settlement, Stimwave admitted and accepted responsibility for conduct alleged in the DOJ's complaint in intervention, which was filed in the False Claims Act suit on March 13, 2023. The company agreed to pay $8.6 million in restitution to the government. This payment was to be credited towards the $10 million civil penalty. The relator share of the settlement amount was not specified in the settlement document.

The settlement with the company was approved by the district court. As of September 2023, claims under the federal False Claims Act brought in the suit against Perryman remained pending.

Three Executives Face Criminal Charges for Alleged Blood Lead Level Test Malfunction Cover-Up

Three former executives of a Massachusetts-based medical device company were arrested and charged with conspiracy to defraud the FDA and with other felonies for allegedly concealing malfunctions in three tests for the levels of lead in blood that allegedly produced inaccurately low lead level results for tens of thousands of children and other patients (*United States v. Winslow*, No. 1:23-cr-10094-PBS (D. Mass.)).

Named in a 46-page indictment filed in April 2023 in the U.S. District Court for the District of Massachusetts were three former Magellan Diagnostics Inc. officials: Amy Winslow, the company's former CEO; Hossein Maleknia, the company's former chief operating officer; and Reba Daoust, the company's former director of QA and regulatory affairs.

In addition to allegedly defrauding the FDA, the three were charged with conspiracy to commit wire fraud, wire fraud, and the introduction of misbranded devices into interstate commerce with the intent to defraud and mislead.

The three diagnostic products included Magellan's LeadCare II, which was used primarily to test fingerstick samples and which accounted for more than half of all blood level tests conducted in the United States between 2013 and 2017, and the company's LeadCare Ultra and LeadCare Plus devices, which were predominantly used to test venous samples (samples of blood drawn through the arm).

The DOJ alleged that the three company officials "repeatedly misled Magellan customers and the FDA about a serious malfunction that affected Magellan's LeadCare devices when they were used to test venous blood samples."

According to federal prosecutors, by concealing the malfunction and then deceiving the FDA and customers about when they discovered the malfunction, the nature, extent and frequency of the malfunction, and the risks associated with the malfunction, the three executives "caused an estimated tens of thousands of children and other patients to receive inaccurately low lead test results."

LeadCare Ultra defect. The government alleged that the three officials first learned in June 2013, during the 510(k) process for the LeadCare Ultra product, that the device could produce lead test results that were incorrectly low. "The defendants, however, allegedly released LeadCare Ultra to the market in December 2013 without informing customers or the FDA of the malfunction," the DOJ said.

Several months later, the department alleged, after the product's customers discovered the malfunction and complained about inaccurate test results, the three officials drafted and released false and misleading statements indicating that they had "recently identified cases" of the malfunction and that they had not detected the malfunction in the company's clinical trials before the product was released.

"According to court documents," the DOJ said, "the defendants, in fact, had known about the malfunction for over a year, including before the product release."

LeadCare II defect. The company's testing in 2013 revealed the same problem in Magellan's LeadCare II device, which was the company's highest-revenue product.

Federal prosecutors noted that at the time Winslow and Maleknia "were positioning Magellan for sale, which could have been put in jeopardy if there was a malfunction affecting LeadCare II."

Consequently, Winslow allegedly instructed a company employee to stop studying the LeadCare II malfunction "because Magellan needed to maintain 'plausible deniability.'"

The company allegedly notified customers and the FDA about the LeadCare II problem only after Magellan was acquired by Meridian Bioscience Inc. for $66 million in March 2016. The acquisition resulted in a bonus of approximately $2 million for Winslow and a bonus of approximately $448,000 for Maleknia, according to the government.

In its report to the FDA about the LeadCare II problem, Magellan "allegedly made materially false and misleading statements and concealed material facts" about the company's discovery of the product's malfunction, the DOJ said.

Consultant allegedly forces reporting. Moreover, the three officials allegedly reported the parallel problem with Magellan's LeadCare Ultra device only after an outside statistician consultant told Daoust in March 2015 that the consultant would notify the FDA about the malfunction if Magellan did not. The company submitted a medical device report about the problem to the FDA the following month, according to the indictment.

In 2017, the FDA asked Magellan when it had first detected the malfunction. According to federal prosecutors, Maleknia and Daoust instructed a Magellan representative to falsely tell the agency that the company had first discovered the problem after receiving customer complaints in late 2014 and shortly before Magellan notified the FDA in 2015.

The government asserted that Magellan "actually discovered the malfunction almost four years earlier, in 2013."

In addition, Winslow allegedly caused the company to submit a false time line to the FDA that omitted Magellan's internal 2013 studies concerning the malfunction.

Following the FDA's determination that Magellan's LeadCare devices could not accurately test venous samples for lead levels, all models of LeadCare devices using venous samples were recalled, and the public was warned not to use the three models of tests for venous blood samples.

On the charges brought against them, the defendants faced maximum possible sentences of:

- 20 years in prison, three years of supervised release and a fine of $250,000 on the charges of wire fraud and wire fraud conspiracy;

- five years in prison, three years of supervised release and a fine of $250,000 on the charge of conspiracy to defraud a federal agency; and

- three years in prison, one year of supervised release and a fine of $250,000 on the misbranding charge.

II. SEC Enforcement Actions

Philips Pays Over $62 Million To Resolve Alleged Foreign Corrupt Practices Violations in China

In May 2023, Philips N.V. agreed to pay the Securities and Exchange Commission (SEC) more than $62 million to resolve allegations that the Netherlands-based device manufacturer violated the Foreign Corrupt Practices Act (FCPA) by providing illicit price discounts and engaging in other illegal activity related to its sales of medical diagnostic equipment in China (*In re Koninklijke Philips N.V.*, No. 3-21411 (Sec. & Exch. Comm'n May 11, 2023)).

In a cease-and-desist order, the commission alleged that Philips violated the books and records and internal accounting controls provisions of the FCPA between 2014 and 2019 through improper conduct by Philips employees, distributors and sub-dealers in China that was undertaken "to influence foreign officials in connection with tender specifications in certain public tenders to increase the likelihood that Philips' products were selected."

In some cases, the commission alleged, the Philips China personnel "engaged in improper bidding practices to create the appearance of legitimate public tenders by preparing additional bids with other manufacturers' products to meet the minimum bids requirement under Chinese public tender rules."

The violative conduct caused Philips to be "unjustly enriched by approximately $41 million," the SEC said.

Details of the alleged FCPA violations. According to the SEC order, two Philips China subsidiaries sold diagnostic imaging equipment through distributors and sub-dealers who contracted with government-owned hospitals, which purchased most of the equipment through public tenders.

By 2016, about 91% of Philips China's sales were made indirectly through authorized distributors or through sub-dealers authorized by those distributors. To secure sales in an increasingly competitive market, the China subsidiaries provided special pricing discounts on the devices that it sold to its distributors.

"However," the commission stated, "Philips China's approval processes and its recording of the special pricing discounts were not subject to sufficient internal accounting controls to ensure appropriate management authorization of the discounts."

Public hospital tenders. The SEC order detailed alleged conduct used by Philips China employees, distributors and sub-dealers "to increase the likelihood that Philips China's distributors or their sub-dealers were awarded public tenders to sell medical equipment to government-owned hospitals."

In some cases, the commission alleged, a hospital employee responsible for writing the technical specifications for the desired equipment worked with a Philips employee, distributor or sub-dealer to determine the hospital's technical preferences and to draft technical specifications in a way that gave Philips a competitive advantage in the public tender before the bidding period opened.

The hospital employee would draft the specifications to boost the chances that Philips would qualify for the winning bid, and he or she would direct the winning bidder or its distributor or sub-dealer to prepare the manufacturer's bids as well as two additional accompanying bids to meet the three-bid requirement of the public tenders and "give the appearance of legitimacy."

Philips employees who engaged in this practice included district sales managers, sales employees, and employees in the technical group that supported sales.

For example, the SEC alleged, to win a procurement award in 2017 for two Philips devices valued at $4.6 million, a Philips China district sales manager delivered about $14,500 to the home of the director of a hospital's radiology department in return for the director's help in the procurement process. "The sales team discussed the specifications to be included in the bid with the relevant hospital director," the commission said, "and its distributor prepared an accompanying bid with another manufacturer's products."

The China subsidiaries' use of special price discounts "created the risk that excessive distributor margins could be used to fund improper payments to employees of government-owned hospitals," the SEC asserted, and the discounts were not adequately documented by Philips to ensure that the practice was justifiable and that the discounts would need to be approved by the company's management.

Inadequate internal accounting controls along with the pressure to boost sales "created an environment in which there was a risk that excessive distributor margins could be used to fund improper payments to employees of government-owned hospitals," the commission said.

Moreover, the SEC order alleged, Philips China "did not enforce certain of its due diligence and training procedures for the engagement of distributors or conduct adequate testing in high-risk areas of sales to identify control failures."

Philips' cooperation and remedial efforts. The commission noted in the case-and-desist order that Philips had undertaken an internal investigation of the alleged conduct by its China subsidiaries and provided regular updates on its findings. The company provided facts that were previously unknown to SEC investigators, and it provided translations of important nonprivileged documents to the commission.

Among Philips' ongoing remedial actions, the order reported, were the following:

- terminating or disciplining Philips China employees involved in the alleged illegal conduct;
- terminating business relationships with distributors involved in the conduct;
- improving internal accounting controls relating to distributors, bidding practices and the use of discounts and special pricing;
- making "structural improvements" to its policies and procedures;
- "improving its tone at the top and the middle, with a focus on Philips China";
- increasing enforcement of the company's compliance policies, thereby boosting personal accountability; and
- "highlighting compliance as a key component of ethical business practices."

To resolve the SEC proceeding, Philips agreed to report periodically to the commission over the next two years about its continuing remediation and compliance enhancements. "The reports will focus particularly on due diligence on prospective and existing third-party consultants and vendors, FCPA training, and the testing of relevant controls, including the collection and analysis of compliance data," the commission said.

Philips also pledged to report to the SEC any new credible evidence that the company or any entity or person acting on the company's behalf had made, offered or promised any corrupt payments or corrupt transfers of value to foreign officials.

In addition, Philips pledged that during the two-year period it would conduct internal compliance reviews, submit initial reports to the commission concerning the reviews, and submit follow-up reports based on SEC comments on the initial reports.

Philips' payment of $62,173,803 to the SEC was to include disgorgement of $41,126,170, prejudgment interest of $6,047,633, and a civil monetary penalty of $15 million.

April 2013 FCPA settlement. The commission noted that in April 2013 it had charged Philips in connection with similar misconduct in Poland between 1999 and 2007. The company had paid more than $4.5 million, including disgorgement and prejudgment interest, to resolve those allegations.

Commenting on the Philips China settlement, Charles Cain, the chief of the SEC Enforcement Division's FCPA Unit, said, "This matter highlights the need for companies to design and implement internal accounting controls sufficient for the scale of their business. Despite remediation done in connection with its prior violations, Philips nevertheless failed over the course of several years to implement internal accounting controls with respect to its sales of medical technology products in China."

The SEC noted that Philips did not admit or deny the findings reported in the commission's cease-and-desist order.

Diagnostics Firm Penalized by SEC for Allegedly Misleading Press Releases About a COVID-19 Test

In July 2023, Utah-based Co-Diagnostics Inc., a developer of molecular tools for the detection of infectious diseases, was ordered to pay the SEC $250,000 to resolve allegations that the company violated commission requirements by issuing misleading press releases in February 2020 concerning a test for detecting the virus that causes COVID-19 and by not reporting financial transactions involving family members of company officials.

According to the agency, the press releases "misleadingly suggested that the test could be used by consumers to detect COVID-19, when in fact, at the time, the test was intended for research use only (RUO), which meant it could not be sold for clinical diagnostic purposes."

The SEC also said that the company failed to disclose related party transactions involving family members of Co-Diagnostics' CEO, Dwight H. Egan, and the firm's then chief financial officer, secretary and general counsel, Reed L. Benson, in its annual reports for fiscal years (FYs) 2018 through 2020 and in its definitive proxy statements filed in 2019, 2020 and 2021.

Moreover, the agency alleged, the company failed to keep accurate books and records and failed to have disclosure controls and procedures designed to ensure that the firm disclosed related party transactions.

Decision to boost public relations. According to the statement of facts in a July 5, 2023, SEC cease-and-desist order, in July 2019 Nasdaq informed Co-Diagnostics that it was in danger of being delisted from the exchange because the company's stock had closed below $1 for the previous 30 consecutive business days.

To meet Nasdaq's requirement that the firm's stock close at or above $1 for 10 consecutive business days within the next 180 calendar days, the company decided to increase its public relations efforts to inform the public and its customers about its development of testing products.

The strategy included issuing frequent press releases and using third-party consultants — including a consulting firm co-owned by Andrew B. Benson, Co-Diagnostics' head of corporate communications and investor relations and the son of Reed L. Benson — to disseminate the press releases and other information about the firm.

In January 2020, Co-Diagnostics announced that it had finished the principal design work for a polymerase chain reaction (PCR) screening test for the novel coronavirus that was later named SARS-CoV-2, the virus that causes COVID-19. The test, named the Logix Smart Test, "was intended for research use only, which meant it could not be sold for clinical diagnostic purposes (i.e., to actually diagnose a patient as having COVID-19) without receiving further authorization," the SEC said.

February 2020 press releases. In a press release drafted by Egan and Andrew Benson and released on Feb. 6, 2020, Co-Diagnostics stated that its "research use only (RUO) CoPrimer Test for the 2019 n-Cov coronavirus" was "ready for sale to appropriate laboratories, hospitals and institutions in need of a solution to the current coronavirus epidemic."

The press release also stated that the company "believe[d] that the test's unique design [would] provide enhanced accuracy when detecting the presence of the coronavirus, including improved specificity over tests designed on a different platform."

According to the SEC, “specificity” referred to whether the company’s technology could differentiate the SARS-CoV-2 virus from other viruses with similar genetic sequences in patients so that those who did not have the COVID-19 virus could correctly be identified as negative.

On the date the press release was released, the company’s stock closed at $3.08 — an 18.92% increase over the previous day’s price — on a volume of more than 10.9 million shares, a 48% increase over the average volume for the previous 30 calendar days.

A second press release, released on Feb. 10, 2020, announced the company’s “sales of its screen test designed to identify the presence of the novel coronavirus” and quoted Egan as saying that the firm was “pleased to be able to offer a product to this market that excels in being both sensitive and specific, the two benchmarks for accuracy in molecular diagnostics.”

Egan also was quoted as saying that the company thought it could be “most helpful in this ongoing situation … by providing diagnostic solutions that are affordable and accessible in any market in the world.”

He also stated in the press release that the speed with which the company had designed and commercialized its test was a “compelling proof-of-concept that the company’s unique process and patented technology could quickly and efficiently be applied to address the diagnostic needs associated with other emergencies, including potential mutations of the virus.”

On that day, the firm’s stock closed at $3.96 — a 32% increase over the previous day — on a volume of more than 28.9 million shares.

At the times when the press releases were issued, the SEC stated, the company had not received authorization from the FDA or from any other regulatory authority to sell or use the test for diagnostic purposes.

Co-Diagnostics received such an authorization for the test from the European Union on Feb. 24, 2020, and an emergency use authorization (EUA) from the FDA on April 3, 2020, for diagnostic use of the test.

FDA concerns. On Feb. 11, 2020, an FDA official contacted Co-Diagnostics’ head of regulatory affairs to inform the company that the FDA “had concerns with, among other things, the … language in the Feb. 6 and 10 releases,” the SEC reported.

The FDA official said that the Feb. 6 press release implied that the firm’s test could be used for diagnostic purposes when it could not, and that the release impermissibly made claims about the test’s performance, given that the test had not been authorized for diagnostic use.

The agency official also said that the Feb. 10 press release implied that the test could be used for screening or diagnostic purposes when it could not.

The FDA official called for Co-Diagnostics to take immediate action to resolve these issues and to provide a list of proposed corrective actions by Feb. 14, 2020.

Corrective actions. On Feb. 14, 2020, Benson and the company’s head of regulatory affairs sent the FDA a CAPA plan that called for the head of regulatory affairs to review future press releases about the Logix Smart Test to ensure better accuracy.

Twelve days later, the FDA again contacted Co-Diagnostics with “remaining concerns” about the two press releases, which were still posted on the company’s website.

In response, the company added statements to the press releases saying (1) that the test was for research use only and (2) that the test was not available for sale in the United States.

Before those statements were added, the SEC alleged, the press releases "were materially misleading because they implied that the Logix Smart Test was able to be sold and used to diagnose COVID-19 with accuracy when it had not yet received the appropriate regulatory approval to be utilized in this manner either in the United States or abroad."

The commission said that a reasonable investor would have found the assertion that the test could be shipped to "laboratories, hospitals and institutions in need of a solution to the current coronavirus epidemic" to be material, "especially because these statements were made in the early stages of the pandemic when COVID-19 testing was scarce."

As of Feb. 13, 2020, the SEC alleged, the company had offered and sold more than 3.32 million shares of its common stock at $3.08 per share in a registered direct public offering, earning gross proceeds of approximately $10.2 million.

"At the time of the offer and sale," the commission said, "Co-Diagnostics had neither retracted nor modified the materially misleading statements contained in the Feb. 6 or 10 releases."

Alleged related person transactions. The SEC also alleged that Co-Diagnostics violated its regulations by failing to disclose "any transaction … in which any related person had or will have a direct or indirect material interest" (SEC Regulation S-K, Item 404(a)).

"Related person" is defined to include any immediate family member of a director or executive officer of the company.

During the relevant time period, the firm was required to report any such transaction with a value exceeding "the lesser of $120,000 or 1% of the average of the … company's total assets at year end for the last two completed fiscal years." The related person reporting thresholds for Co-Diagnostics were $29,791 for FY 2018, $31,077 for FY 2019, and $18,842 for FY 2020.

During that time, the company employed Egan's son as the director of sales and marketing, paying the son compensation totaling $91,352 in FY 2018, $224,900 in FY 2019, and more than $1.1 million in FY 2020.

Also during that time, the SEC said, Co-Diagnostics paid Andrew Benson compensation of more than $327,000 in FY 2018, nearly $219,000 in FY 2019, and more than $1.1 million in FY 2020. Moreover, the company retained the services of a consulting firm that Andrew Benson co-owned, paying the consulting firm $60,000 in FY 2018, $78,500 in FY 2019, and $20,000 in FY 2020.

According to the SEC, the payments to Egan's son and to Andrew Benson constituted reportable transactions under Item 404. The payments were not recorded in the company's books and records as related party transactions, the commission alleged, and the firm failed to disclose them in its annual Form 10-K reports for the three fiscal years. Nor did the company have any related party transaction policies or procedures, the SEC said.

In separate July 5 cease-and-desist orders issued by the SEC:

- Egan was ordered to pay $75,000 to the commission in connection with the alleged press release and related person transaction violations;

- Reed Benson was ordered to pay $40,000 to the SEC in connection with the alleged related person transaction violations; and

- Andrew Benson was ordered to pay $40,000 to the commission in connection with the alleged press release violations.

III. Reach of FDA's Enforcement Authorities

Court Rejects FDA's Attempt To Regulate Procedures Performed by California Stem Cell Clinic

In August 2022, a federal district court in California rejected the FDA's attempt to enjoin a stem cell clinic from performing procedures involving what the agency alleged to be unapproved drugs and biological products. The court held that the clinic's current procedures did not involve products that were subject to FDA regulation (*United States v. California Stem Cell Treatment Center*, 624 F. Supp. 3d 1177 (C.D. Cal. 2022)).

Acting on behalf of the FDA, the DOJ filed an injunction action in May 2018 seeking to permanently enjoin California Stem Cell Treatment Center, based in Rancho Mirage and Beverly Hills, and two physicians who co-owned the clinic from performing various stem cell treatments on patients.

The government alleged that the treatments violated the FD&C Act by causing the adulteration and misbranding of drugs and the receipt of misbranded drugs.

Three procedures. The center offered patients a procedure in which a physician targeted stromal vascular fraction (SVF) cells for extraction and then implanted the same cells back into the same patient. SVF cells are comprised of multiple types of stem cells and are the naturally occurring part of adipose tissue that does not contain adipocytes (fat cells). The procedure is intended to treat chronic and systemic conditions by increasing the number of available SVF cells in circulation or around an injured area.

The clinic also offered a procedure in which a patient's adipose tissue was removed and sent to a tissue bank to isolate mesenchymal stem cells (MSC cells). Those cells were then replicated and stored until the same patient requested that they be returned for implantation into his or her body. The procedure was intended for patients who had medical conditions that would require multiple treatments but who were unable or unwilling to undergo multiple liposuctions.

The clinic's two physicians also had studied the safety of an experimental procedure through which SVF cells were used to deliver ACAM2000, an oncolytic virus, to cancer patients. The federal government maintains exclusive control over ACAM2000 as part of the Strategic National Stockpile, and the virus may be distributed only by certain government agencies. Although the virus is not publicly available, researchers may request vials of the virus for clinical studies.

The two physicians at the clinic had obtained the ACAM2000 they used from the CDC, and they had performed the treatment under institutional review board-approved clinical study protocols. They had not performed the experimental treatment since August 2017, when U.S. marshals acting on behalf of the FDA entered a laboratory and seized five vials of the virus that had been earmarked for injection into cancer patients at the clinic.

'Muddy' line between drugs and procedures. The district court noted that surgical procedures — like drugs as defined in the FD&C Act (21 U.S.C. §321(g)(1)) — are intended for the diagnosis, cure, mitigation, treatment or prevention of disease. However, "when passing the [FD&C Act]," the court said, "Congress explicitly rejected any attempt to 'limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship'" (21 U.S.C. §396).

"Indeed," the court continued, "Congress recognized the limitations of the FDA and rejected any intent to directly regulate the practice of medicine."

However, it noted, "the line between 'drug' and 'procedure' is muddy when licensed medical doctors enter a patient's body, extract that patient's cells, and reintroduce those cells to that patient after some amount of cellular processing."

The FDA contended that this scenario constitutes the production of drugs under the FD&C Act, the court said, while the clinic and the physicians argued that "this is mere surgery, the exclusive province of the medical practitioners, and not something which the [FD&C Act] may regulate."

The court concluded that neither the SVF surgical procedure nor the expanded MSC procedure were "drugs" within the meaning of the FD&C Act and therefore were not subject to the statute's adulteration and misbranding provisions. By contrast, the court said, the SVF/ACAM2000 treatment "involves the creation of a drug under the [FD&C Act]."

SSP exception. According to the court, neither the SVF procedure nor the MSC procedure involved creating "new drugs" or "prescription drugs" as defined in the FD&C Act.

Moreover, the court said, the SVF procedure (but not the MSC procedure) qualified for the "same surgical procedure" (SSP) exception, which exempts from FDA oversight any "establishment that removes [human cells, tissues, or cellular or tissue-based products (HCT/Ps)] from an individual and implants such HCT/Ps into the same individual during the same surgical procedure" (21 C.F.R. §1271.15).

"Because the entire SVP surgical procedure involves introducing the same HCT/Ps back into patients during a single outpatient procedure at the surgical clinic," the court said, "defendants' SVF surgical procedure involved introducing HCT/Ps back into patients during the 'same surgical procedure' as they were extracted, triggering the SSP exception."

"The same is not true of the expanded MSC procedure," the court continued. "Though the cells extracted for the SVF surgical procedure and the expanded MSC procedure are HCT/Ps, only the SVF surgical procedure qualifies for the SSP exception."

SVF procedure. The court concluded that because of the SSP exception, the SVF procedure did not involve an adulterated drug or prescription drug. Moreover, it concluded, the SVF procedure did not involve a "drug" as defined in the FD&C Act. Consequently, it said, the clinic and the physicians did not fall under the jurisdiction of the FDA and were not governed by the FD&C Act or FDA regulations.

The SVF surgical procedure was autologous, the court noted, "because it involves collecting a patient's cell population naturally occurring in the patient's adipose tissue and relocating that cell population back into the same patient."

Although the SSP exception does not have any requirement that an HCT/P be unaltered before reinsertion into the patient, the court noted, the SVP did not alter the biological characteristics of the SVF, and there was no evidence that the cells were "anything other than autologous cells removed from, belonging to, and returned back to the patient."

Rejecting an FDA argument, the court said that the SSP exception unambiguously did not require that the surgeon implant everything that had been removed for the exception to apply.

The physicians "may lawfully use FDA-cleared medical devices and FDA-approved pharmaceuticals in any manner that they determine is best to care for and treat their patients," the court added.

MSC procedure. With respect to the MSC procedure, the district court held that the cells involved in the procedure are not drugs but rather are "human cells removed from patients and then reintroduced into those same patients. They are not fungible goods that can be sold, mass produced, or patented."

"Defendants are engaged in the practice of medicine," the court said, "not the manufacture of pharmaceuticals."

SVF/ACAM2000 treatment. By contrast, the court said, "unlike the SVF surgical procedure, the SVF/ACAM2000 treatment constitutes the manufacture of a drug." The ACAM2000 had been shipped in interstate commerce from Georgia, the court noted (21 U.S.C. §331(k)).

However, it continued, the government had not met its burden of establishing standing to pursue injunctive relief regarding the procedure because the two physicians had stopped performing the treatment by June 2017, before the FDA's suit was filed and before ACAM2000 intended for use in the clinic had been seized on the agency's behalf.

"Defendants cannot perform the SVF/ACAM2000 treatment without the ACAM2000, which is in the exclusive control of the government and otherwise inaccessible to defendants," the court noted. "[The two physicians] have no desire or intention of performing the SVF/ACAM2000 treatment absent formal regulatory approval."

Accordingly, the court entered judgment in favor of the clinic and the two physicians on all the claims brought by the government.

In October 2022, the DOJ filed an appeal of the district court's decision with the U.S. Court of Appeals for the Ninth Circuit (*United States v. California Stem Cell Treatment Center, Inc.*, No. 22-56014 (9th Cir.)).

Proposed New FDA Enforcement Authorities for FY 2024 Include Expansions of Remote Regulatory Assessments

In connection with the release of its FY 2024 budget request in March 2023, the FDA proposed that Congress grant it a variety of new enforcement authorities, including additional tools to allow the agency to continue remote oversight activities when on-site inspections are not feasible, mandatory recall authority for all drug products, and additional authorities for the destruction of imported products that present a significant public health concern.

In announcing its proposed FY 2024 budget, the FDA said that the package of legislative proposals is "designed to bolster the FDA's authorities to further its mission to protect and promote public health."

Mandatory remote regulatory assessment participation. Under its current authority under FD&C Act Section 704(a)(4) (21 U.S.C. §374(a)(4)), the FDA may conduct remote regulatory assessments only to the extent of requesting records and other information in advance of or in lieu of drug, device and biomedical research monitoring (BIMO) inspections. The agency cannot require any establishment to participate otherwise in remote regulatory assessments.

The FDA relies on voluntary participation in remote regulatory assessments, the agency said, "but reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as firms can refuse to provide records or other information in advance of or in lieu of an inspection or to participate in remote regulatory assessments."

The agency sought to expand its Section 704(a)(4) authority to include food, tobacco product, and cosmetics establishments.

The FDA also sought express authority to conduct regulatory assessments that may include remote interactive evaluations such as livestreaming video or operations, teleconferences and screen-sharing so that agency investigators may interact with establishments virtually.

The expanded authority would promote regulatory compliance "particularly during a public health emergency like the COVID-19 pandemic," when in-person inspections and investigations were limited, the FDA said. Moreover, it said, the change would improve the agency's efficiency, reduce on-site inspection time, and "allow the FDA to assess conditions at a facility without going on-site when an in-person visit is not feasible or deemed necessary."

The agency noted that during the recent recall of infant formula products, it found that "the inability to remotely request records delayed FDA's response to complaints about adulterated products."

Mandatory drug recall authority. Under current law, with respect to drug products, the FDA has authority to order mandatory recalls of:

- biological products (under Section 351(d) of the Public Health Service Act (PHS Act) (42 U.S.C. §262(d)));
- controlled substances (under the SUPPORT Act, enacted in 2018); and
- cosmetics (under the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted in December 2022).

The agency currently does not have mandatory recall authority for other human and animal drugs.

"Under current law, the great majority of companies agree to recall their human or animal drug products when asked to voluntarily do so by FDA," the agency said. "However, there are cases where a company extensively delays initiating a recall or refuses to recall a violative drug product when asked to voluntarily do so."

The FDA said that expanding its mandatory recall authority "would help remove violative human and animal drugs more quickly, thereby reducing harm to consumers due to exposure to dangerous products."

Mandatory destruction of imported products. The agency is also asking Congress to amend FD&C Act Section 801 (21 U.S.C. §381) to give the FDA authority to

require an owner or consignee to destroy any FDA-regulated product offered for import that has been refused entry at the U.S. border and presents a significant public health concern.

The proposed authority would eliminate the option for an owner or consignee to export such a product under FD&C Act Section 801(a) (21 U.S.C. §381(a)).

The change in authority "would prevent the potential reimportation of such products and would deter owners and consignees from offering products they know to pose a significant public health risk for import into the United States," the agency said.

Also, the FDA asserted, the change would boost the efficiency of U.S. Customs and Border Protection (CBP) seizures of FDA-regulated products.

"Under current practice," the FDA said, "when CBP seizes an FDA-regulated product, an FDA violation is used to support the seizure. CBP then consults with FDA to confirm that the product seized violated the FD&C or PHS Acts and/or FDA regulations. Additionally, if the seizure is successful, the government will likely end up paying for the destruction."

If the legislative proposal is enacted, the FDA would order the destruction of an imported product based on the agency's admissibility review and its evaluation of the significant public health concern presented by the product, "thereby reducing the need for CBP consultations with FDA."

In addition, the agency said, the importer or record "would be required to pay the destruction costs up front so FDA and CBP do not have to file legal action to recoup the destruction costs."

Third Circuit Says Undisclosed API Source Does Not Make Drug 'Unapproved,' Nixes Conspiracy Charge

In July 2023, a federal appeals court affirmed the dismissal of a conspiracy charge brought by the DOJ against a drug manufacturer and two company officials for purportedly marketing an unapproved new drug after the company sourced the drug's API from a supplier that was not disclosed in the drug's FDA approvals (*United States v. Vepuri*, 74 F.4th 141 (3d Cir. 2023)).

Murty Vepuri headed Newtown, Pennsylvania-based KVK-Tech Inc., which manufactured the prescription generic drug Hydroxyzine, indicated for the treatment of anxiety and tension. Ashvin Panchal was the company's director of QA.

In April 2021, the DOJ, acting on behalf of the FDA, filed a criminal information against Vepuri in the U.S. District Court for the Eastern District of Pennsylvania. A superseding indictment filed two months later added Panchal and the company as defendants.

The government alleged that the three defendants sourced the API in Hydroxyzine from a facility that was not included in the approvals that they had obtained from the FDA for the drug. The DOJ also alleged that the defendants misled the FDA about the sourcing of the API.

The three were charged with conspiracy to defraud and to commit offenses against the United States under 18 U.S.C. §371. In addition, KYK-Tech was charged with mail fraud under 18 U.S.C. §1341.

At issue on appeal before the U.S. Court of Appeals for the Third Circuit was a portion of the conspiracy charge alleging that the three defendants conspired to

violate the FD&C Act provision prohibiting the introduction into interstate commerce of a "new drug" unless FDA approval "is effective with respect to such drug" (21 U.S.C. §355(a)).

Background. KYK-Tech obtained abbreviated new drug application (ANDA) approvals for three dose sizes of Hydroxyzine in 2006. The ANDAs stated that the drug's API would be sourced from a UCB Pharma S.A. facility in Belgium. Two years later, the company filed a supplement with the FDA and obtained the agency's approval to source the API from a Cosma S.p.A. facility in Italy.

In October 2010, Vepuri authorized the company's purchase of the API from a Dr. Reddy's Laboratories (DRL) facility in Mexico, which was not listed in the approved ANDAs or other otherwise approved by the FDA. When it received the shipments, KYK-Tech logged the incoming API as having been manufactured in Belgium.

Vepuri authorized another purchase of the API from DRL in May 2013. The following month, 19 drums of the API shipped from DRL were refused entry when they arrived in Philadelphia. The FDA detained the API based on the company's lack of approval to import the ingredient from DRL.

About two weeks later, Panchal filed a Change Being Effected in 30 Days Notice with the FDA stating that UCB Pharma had changed its manufacturing site to Mexico. The notice may be used only to inform the agency of prospective changes, and Panchal did not disclose that KVK-Tech had distributed drugs manufactured with the API sourced from DRL since 2011.

During a subsequent FDA inspection, Panchal told agency investigators that the company had not received previous shipments of API from DRL. When the investigators confronted him with photographs of drums stamped "Made in Mexico," Panchal told them that he was unaware that UCB Pharma had shipped API from Mexico.

Panchal then told the investigators that KVK-Tech had disclosed in its annual report that it was sourcing API from a new site in Mexico — contradicting his previous statement that he was unaware of API shipments from Mexico. In fact, however, KVK-Tech had not mentioned a change in API sourcing in its annual report.

After the inspection, Vepuri and Panchal blamed the company's use of API from DRL on "an inappropriate regulatory evaluation" by a former employee. They reiterated the claim during a meeting with FDA officials in June 2014.

Following a second agency inspection, in December 2014 Panchal sent the FDA a report detailing a KVK-Tech internal investigation and concluding that it was "not clear" why UCB Pharma had shipped API from Mexico.

On the basis of an FDA investigation of KVK-Tech completed in March 2015, the government alleged that because of the company's misconduct more than 368,000 bottles of Hydroxyzine made with API sourced from DRL had been delivered to KVK-Tech customers.

Motion to dismiss. In the conspiracy charge against Vepuri, Panchal and KVK-Tech that was included in the June 2021 superseding indictment, the government alleged that the three defendants:

- defrauded the United States by impeding the lawful function of the FDA;
- with intent to defraud and mislead, introduced or delivered for introduction "unapproved new drugs" in violation of 21 U.S.C. §331(d) and 21 U.S.C. §355(a); and

• made false statements to the FDA in violation of 18 U.S.C. §1001.

The defendants moved to dismiss the indictment on various grounds. The district court granted the defendants' motions in part, dismissing the portion of the superseding indictment alleging that the defendants conspired to violate 21 U.S.C. §331(d) and 21 U.S.C. §355(a) (*United States v. Vepuri*, No. 2:21-cr-00132-HB, 2022 U.S. Dist. LEXIS 31408, 2022 WL 541772 (E.D. Pa. Feb. 23, 2022)). The government appealed.

FD&C Act provisions. Among other things, Section 331(d) prohibits the introduction or delivery for introduction into interstate commerce of any drug that does not comply with Section 355.

Section 355(a) states that "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to Subsection (b) or (j) is effective with respect to such drug."

Subsection (b) provides the procedure through which the FDA evaluates and approves new drug applications (NDAs) for nongeneric drugs. Subsection (j) provides the procedure through which the FDA evaluates and approves ANDAs for generic drugs.

For purposes of Section 355(a), the FD&C Act defines a "new drug" as one that is not "generally recognized, among experts … as safe and effective" or that is not grandfathered in (meaning that, as of the enactment of the FD&C Act in 1938, the drug was not subject to the Food and Drugs Act of 1906) (21 U.S.C. §321(p)).

The government and the defendants agreed that Hydroxyzine is a "new drug" under the FD&C Act.

Government's allegations. The appeals court noted that throughout the superseding indictment the government "repeatedly" stated that the defendants violated Section 335(a) by distributing the Hydroxyzine containing the DRL-supplied API because it was an "unapproved" new drug.

"But the relevant statutory provisions do not prohibit the introduction of 'unapproved' new drugs," the Third Circuit panel stated. "They instead prohibit the introduction of any 'new drug, unless an approval of an [NDA or ANDA] is effective with respect to such drug.'"

"We have held that the provision requires only that a new drug approval be in effect before a new drug is marketed" the court continued; "our jurisprudence does not recognize the government's premise that distributing 'unapproved' drugs violates Section 355(a). Thus, alleging that the drugs are 'unapproved' — without demonstrating how that violates Section 355(a) — is therefore not enough on its own to state the offense of conspiracy to violate Section 355(a)."

DOJ's two theories of liability. The appeals court reasoned that, by claiming the drug is "unapproved," the DOJ appeared to be relying on two phrases in the statute:

- Relying on the phrase "with respect to such drug" in Section 355(a), the government's theory of liability was that because the new drug's API was sourced from a facility not listed in the ANDAs, the Hydroxyzine that KVK-Tech distributed was not the same "new drug" as the one that had approvals in effect. Because the drug manufacturer had not received FDA approval for the Hydroxyzine manufactured with API sourced from DRL, introduction of that drug into commerce allegedly violated Section 355(a). In essence, the DOJ argued, the use of a manufacturing facility not listed in the ANDAs meant that the existing approval of the ANDAs was not effective "with respect to such drug."

- Relying on the phrase "is effective" in Section 355(a), the government theory of liability suggested that because the API in the Hydroxyzine was manufactured at a facility not included in the ANDAs, the approval of the ANDAs for KVK-Tech's Hydroxyzine stopped being "effective" with respect to that drug.

"With respect to such drug." Any liability on the part of the defendants under Section 355(a) based on the statutory language "effective with respect to such drug," the Third Circuit panel stated, "must mean that the drug introduced into interstate commerce is no longer the 'such drug' with an effective approval."

"The text of Section 321(p) … defines a 'new drug' in terms of its composition and labeling," the appeals court noted. "Put another way, for a 'new drug' to no longer be the 'such drug' with the effective approval of an NDA or ANDA, it must have a different composition or labeling than the 'new drug' with the effective approval."

"The superseding indictment in this case does not include any allegations that the KVK-Tech Hydroxyzine manufactured with active ingredient from DRL had a different composition or labeling than the KVK-Tech Hydroxyzine with the effective approval," the court continued, "In the language of the statute, the 'new drugs' at issue here are the 'such drugs' that have an effective approval. The government, therefore, cannot state an offense under this theory of liability."

The government argued that the "new drug" definition in Section 321(p), with its focus on composition and labeling, should not be imputed into Section 355(a), stating that "the two sections serve entirely different purposes," with Section 355(a) "intended to protect the public from the risks associated with unapproved drugs."

The appeals court disagreed. "When defining a statute's terms," it said, "we are required to look first to the definitions in the statute itself."

Moreover, the court said, the government discussed Section 355(a) "as if it exists in isolation and is the only means to avoid adverse public health outcomes. But the [FD&C Act] includes several civil enforcement provisions that could have been invoked to address the conduct alleged in the superseding indictment."

For example, the Third Circuit panel said, the FD&C Act "contains civil enforcement provisions that could have been invoked to address the conduct alleged in the superseding indictment" — including withdrawing or suspending the agency's approval of the ANDAs (21 U.S.C. §355(e)) or imposing civil penalties (21 U.S.C. §335b).

"Relying upon the composition and labeling of a 'new drug' — as the term is defined in 21 U.S.C. §321(p) — to interpret the meaning of 21 U.S.C. §355(a)," the court said, "is textually appropriate and does not threaten the government's ability to protect the public by enforcing the [FD&C Act]."

Because the Hydroxyzine at issue "has the same composition and labeling as the Hydroxyzine for which an approval of an ANDA is effective," the appeals court panel held, "the government cannot rely in this case upon the premise that the two drugs are different. The government's first theory of liability — that the Hydroxyzine that was introduced into interstate commerce is not the same Hydroxyzine with an effective approval — accordingly does not state the offense of conspiracy to violate Section 355(a)."

Whether the ANDAs are "effective." The court then turned to the DOJ's second theory of liability — the argument that the superseding indictment stated the offense of

conspiracy to violate Section 355(a) because the "new drug" was manufactured at a facility not included in the approved ANDAs (i.e., the DRL facility that produced the drug's API), meaning that the approved ANDAs stopped being "effective."

The Third Circuit panel dismissed this theory as well, saying that the theory had been rejected by the Supreme Court in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

In *Weinberger*, the Court stated that the FD&C Act "did not provide any mechanism other than [the FDA's] suspension authority under [21 U.S.C. §355(e)] whereby an NDA once effective could cease to be effective. Indeed, [Section 355(e)] leads to the conclusion that an NDA remains effective unless it is suspended."

"Under that holding," the Third Circuit concluded, "an NDA or ANDA only stops being effective when the procedures for suspension or withdrawal in Section 355(e) are followed."

Because the FDA had not suspended or withdrawn the ANDAs for KVK-Tech's Hydroxyzine, the appeals court stated, the ANDAs remained effective, "so this theory of liability fails, and the government has not stated the offense of conspiracy to violate Section 355(a)."

"The second theory of liability — that a deviation from the approved NDA or ANDA means that the approval is no longer effective — fails because the approval of an NDA or ANDA ceases being effective only when it has been withdrawn or suspended," the court concluded. "Because the existing ANDAs here are still effective, the government cannot rely upon this theory to state the offense of conspiracy to violate Section 355(a)."

On this basis, the appeals court affirmed the district court's order dismissing the conspiracy charge based on a purported violation of 21 U.S.C. §331(d) and 21 U.S.C. §355(a), and it remanded the case for proceedings on the remaining charges.

IV. False Claims Act/Anti-Kickback Act Litigation and OIG Advisory Opinions

Appeals Court Affirms Rejection of Pfizer's Challenge to HHS OIG Advisory Opinion on Drug Co-Pays

In July 2022, a federal appeals court has affirmed a district court ruling that rejected a drug manufacturer's request for a declaratory judgment holding that a proposed co-pay assistance program would not violate the Anti-Kickback Statute despite the conclusions of a Department of Health and Human Services (HHS) Office of Inspector General (OIG) advisory opinion (*Pfizer, Inc. v. U.S. Department of Health and Human Services*, 42 F.4th 67 (2d Cir. 2022), *cert. denied*, 143 S. Ct. 626 (2023)).

Pfizer Inc. marketed its drug tafamidis under the brand names Vyndaqel and Vyndamax for the treatment of a rare, progressive heart condition known as transthyretin amyloid cardiomyopathy (ATTR-CM). The disease, which can eventually cause heart failure, affects between 100,000 and 150,000 Americans. Because the disease disproportionately affects the elderly, most patients with the disease are covered by Medicare.

The drug, which is not a cure but can slow the decline in quality of life and help patients live longer, was approved by the FDA with an orphan drug designation. The medication can cost $225,000 per year, and a Medicare beneficiary's co-pay for the drug is about $13,000 per year. An HHS study in 2020 concluded that tafamidis is "the most expensive cardiovascular drug ever launched in the United States."

To address its concern that ATTR-CM patients might not be able to afford the medication, Pfizer proposed a direct co-pay assistance program through which the manufacturer would cover most of the cost of a patient's co-pay for the drug if the patient met specified eligibility criteria, including financial need criteria. Under the program, patients would be responsible for paying only $35 per month, with the manufacturer covering the remainder of the annual co-pay.

Seeking the OIG's opinion. In June 2019, Pfizer sought an HHS OIG advisory opinion to ensure that the program did not violate federal statutes targeting health care fraud. In its submission to the OIG, the company stressed that it would not use the co-pay program to solicit new patients and that the program would not provide a financial incentive to physicians to write prescriptions for tafamidis.

In September 2020, the OIG issued an unfavorable advisory opinion (OIG Advisory Opinion No. 20-05) stating that the co-pay program would violate the Anti-Kickback Statute if implemented with the intent specified in the statute. The program would "induce [a] beneficiary to purchase [tafamidis] by removing the financial impediment" of the cost-sharing obligation, and it would be "highly suspect" for fraud and abuse under the Anti-Kickback Statute," the OIG stated, "because one purpose of the [program] — perhaps the primary purpose — would be to induce Medicare beneficiaries to purchase [Pfizer's] federally reimbursable medications."

Declaratory judgment action. The company filed suit in the U.S. District Court for the Southern District of New York under the Administrative Procedure Act (APA), challenging the agency's interpretation of the Anti-Kickback Statute. Pfizer argued that the Anti-Kickback Statute requires an element of corrupt intent to impose liability and that its co-pay assistance program would have to be administered with a corrupt intent in order to violate the statute.

In September 2021, the district court granted summary judgment in favor of the government, holding that the mental state elements of the Anti-Kickback Statute do not include a corrupt intent. Rather, the court said, "the statute is implicated where a defendant (1) knowingly and willfully provides remuneration (2) to induce (inter alia) a purchase."

The court said that it found nothing in the text of the statute that is "amenable to a reading that there be corruption involved." It concluded that "because the stated intent of the payments Pfizer proposes here [is] to increase the number of Medicare beneficiaries who purchase the drug, the court is unable to … issue judgment in [Pfizer's] favor on the APA claim, since the [Anti-Kickback Statute] prohibits all remuneration that induces purchases of drugs like tafamidis" (*Pfizer Inc. v. U.S. Department of Health and Human Services*, No. 1:20-cv-04920-MKV, 2021 U.S. Dist. LEXIS 189381, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021)). Pfizer appealed.

Scrutinizing the text of the statute. Pfizer contended that a quid pro quo was required for there to be liability under the Anti-Kickback Statute. The district court disagreed, stating that the statutory language prohibiting "any remuneration … to induce" "implies a one-way transaction."

The appeals court noted that the OIG had found that the co-pay program would "operate as a quid pro quo," in that Pfizer "would offer remuneration … to the beneficiary in return for the beneficiary purchasing [tafamidis]."

"We have no doubt that at least some kind of quid pro quo, direct or indirect, exists here," the Second Circuit panel said. "However, we do not think it is the case, as Pfizer suggests, that every quid pro quo is inherently corrupt. There are, of course, many such transactions made without corrupt intent. A commercial contract, for example, is literally a quid pro quo — a 'this for that.'"

The appeals court also rejected Pfizer's contention that the word "induce" implies a corrupting influence or ill motive. "The word is … neutral with regard to intent — one can persuade another to take an action with good or bad motives," it said.

Pfizer also argued that the parenthetical following the term "remuneration" in the statute — "(including any kickback, bribe, or rebate)" — limits the statute to corrupt payments. The district court had rejected Pfizer's contention that the term "rebate" implied corrupt intent and referred to a particular kind of corrupt payment for Medicare and Medicaid services. The lower court reasoned that the plain meaning correct on that score," the appeals court said, "the Supreme Court has made clear that the word 'includes,' when used in a statute, 'is usually a term of enlargement, and not of limitation' (*Burgess v. United States*, 553 U.S. 124 (2008)). … Therefore, the listed examples of 'kickback, bribe, or rebate' in the [Anti-Kickback Statute] do not limit the meaning of 'any remuneration'; they are merely non-exhaustive examples."

In addition, Pfizer argued that the willfulness mens rea (state of mind) required by the Anti-Kickback Statute suggested "an element of corruption or improper influence," because a willful act is one taken with a "bad purpose." "But," the Second Circuit panel responded, "a 'bad purpose' is not synonymous with a corrupt intent — it is more accurately understood as a voluntary, intentional violation of a known legal duty. … The [statute] does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute. Contrary to Pfizer's assertion, the mens rea element goes no further."

Other arguments. The appeals court also rejected Pfizer's contention that the criminal Anti-Kickback Statute should be read more narrowly than the Beneficiary Inducement Statute, a civil statute that also seeks to combat fraud against government health care programs. According to the company, the civil statute's prohibition against improper "influence" is broader than the term "induce" in the Anti-Kickback Statute.

"We find no reason to interpret the [Anti-Kickback Statute] by reference to the text of the [Beneficiary Inducement Statute]," the appeals court said. "The [Anti-Kickback Statute] is not simply a narrower version or criminal counterpart of the [Beneficiary Inducement Statute]." Moreover, it said, the two statutes were not enacted through the same bill or even close in time.

Pfizer also urged that there is a corruption element in the relationship between the Anti-Kickback Statute and the False Claims Act. The appeals court rejected this argument as well. The fact that Congress in 2010 added a statutory provision specifying that a reimbursement claim including goods or services resulting from an Anti-Kickback Statute violation constitutes a false or fraudulent claim for purposes of the False Claims Act (42 U.S.C. §1320a-7b(g)) "does not, as Pfizer contends, mean that all [Anti-Kickback Statute] violations are inherently 'corrupt,'" the Second Circuit panel said.

The appeals court also rejected Pfizer's contention that the OIG's interpretation of the Anti-Kickback Statute "criminalizes a range of beneficial activities" and leads to an "absurd and unjust result." The court said that it was "unpersuaded that the agency's reading of the [Anti-Kickback Statute] would produce an absurd and unjust result which Congress could not have intended."

Finally, the Second Circuit panel rejected Pfizer's argument that the OIG's advisory opinion process would be superfluous in light of the lower court's "far-reaching interpretation of the [Anti-Kickback Statute] as prohibiting any conceivable influence on a prescribing decision, which essentially means that the offer of anything of value is inevitably within the statute's reach."

The district court "never suggested that the [Anti-Kickback Statute] prohibits any conceivable

influence on a prescribing decision," the appeals court said. "Rather, the court concluded based on the plain meaning of the text that the [Anti-Kickback Statute] 'prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of [certain] medical treatments or services.' The advisory opinion process is thus helpful for determining when a proposed program is designed to induce the purchase of a federally reimbursable medical treatment, just as the agency did here."

On this basis, the Second Circuit panel unanimously affirmed the judgment of the district court.

Court Dismisses False Claims Case in Which DOJ Suggested Liability Could Be Based on FD&C Violations

In July 2022, a federal district court in Florida granted a medical device manufacturer's motion to dismiss a False Claims Act suit in which a whistleblower had asserted that the company's liability under the statute stemmed from its alleged violations of the FD&C Act and FDA regulations (*United States ex rel. Crocano v. Trividia Health Inc.*, 615 F. Supp. 3d 1296 (S.D. Fla. 2022)).

The DOJ had filed a statement of interest in the case presenting the government's view that FD&C Act violations could trigger False Claims Act liability.

"Here," the court continued, "relator alleges a pattern of illicit behavior concerning defendant's response to a serious defect in its products. But she alleges no conduct expressly contemplated by the False Claims Act, and the court must rein in relator's expansive view of the statute."

Background. The device company manufactured glucose test strips. Between 2013 and 2016, thousands of the company's test strips were rendered defective, presumably due to a change in packaging equipment at the company's manufacturing facility that left the test strips insufficiently sealed in their vials and subject to adulteration by ambient air.

As a consequence, the test strips reported inaccurate readings of patient glucose levels, and some patients who relied on the test strip readings took too much or too little insulin. The resulting adverse patient outcomes included a lost pregnancy.

The company recalled more than 5.5 million units of the test strips between April 16, 2015, and July 30, 2015, and it issued a press release about the product recall. The FDA issued a series of public notices about the recall in September 2016.

The whistleblower, a licensed nurse and compliance specialist, was a former employee of the manufacturer's customer care department and postmarket compliance department.

According to the relator, the company knew of the defect in the test strip vials years before the product recall but engaged in various fraudulent practices to continue placing the products into the stream of commerce covered by government health care programs — practices including failing to investigate a high volume of customer complaints about the test strips; manipulating customer complaint and laboratory testing data to conceal the defect; hiding, falsifying and failing to submit medical device reports to the FDA; excluding many defective units from the eventual product recall; and otherwise violating the FD&C Act.

The suit was brought in February 2017 in the U.S. District Court for the District of South Carolina. The following September, the DOJ filed a notice on behalf of itself and the 27 plaintiff states

declining to intervene in the suit. The relator filed an amended complaint in November 2021, and the case was transferred to the U.S. District Court for the Southern District of Florida on Jan. 20, 2022. The manufacturer filed a motion to dismiss on March 25, and the DOJ filed its statement of interest on June 3.

DOJ statement of interest. In its June 3 Statement of Interest as to Defendant's Motion To Dismiss, the DOJ asserted that, despite the fact that it declined to intervene in the case, the United States "remains the real party of interest in this matter" because "the relator has asserted claims on behalf of the United States for harms purportedly suffered by the government."

Noting the company's assertion that alleged FD&C Act violations cannot serve as a basis for False Claims Act liability, the DOJ argued that "deficiencies in the affected product resulting from [FD&C Act] violations may, in certain circumstances, be material to the government's decision whether to pay for the affected product, and thus relevant in [a False Claims Act] case."

Specifically, the department stated, FD&C Act violations may be relevant in False Claims Act cases "where the violations are significant, substantial, and give rise to actual discrepancies in the composition, functioning, safety, or efficacy of the affected product" — for example, "where, as a result of the regulatory violations, the affected product's quality, safety and efficacy fell below what was specified to and cleared by the [FDA] through its approval processes."

"In some cases," the DOJ said, "manufacturing deficiencies could affect the quality, safety and efficacy of the affected products such that the FDA never would have approved or cleared the affect products — or allowed them to remain on the market — if it had known the truth, and claims involving those devices never would have been eligible for federal health care program reimbursement."

"For example," the department continued, "when a medical device manufacturer obtains FDA approval or clearance for a device and then palms off a defective version of that device both directly on the government itself and on the unsuspecting government payors, the manufacturer may be liable under the [False Claims Act] if the elements of the [False Claims Act] are sufficiently met."

Consequences of "an original fraud." Notably, the DOJ said that a claim can be false or fraudulent for purposes of the False Claims Act "if it is submitted under a contract or extension of government benefit that was originally obtained through false statements or fraudulent conduct." Under this theory, the department said, "subsequent claims are false because of an original fraud, even if the subsequent claim for payment is not false on its face and makes no false certification."

Consequently, the DOJ continued, "it is possible to articulate a viable [False Claims Act] claim based on materially false or fraudulent statements made to the FDA regarding drugs or medical devices for which the government provides payment or reimbursement."

The department noted that when deciding whether to cover a drug or device, federal health care programs "often rely on the FDA's decision as to whether the drug or device is sufficiently safe and effective to be sold in the United States" — a decision based on information provided by the manufacturer "and therefore the manufacturer's compliance with its reporting obligations, including reporting of adverse events."

Moreover, the government noted, "FDA approval or clearance of a drug or medical device is required for Medicare coverage."

Fraud on the FDA. Importantly, the DOJ asserted, "when a manufacturer perpetrates a fraud on the FDA by hiding material information concerning the safety or efficacy of a device — either during or after the approval process or to avoid a recall — and federal health care programs then pay for that device, that fraud may be integral to a causal chain leading to payment and can be actionable under the [False Claims Act]."

"In circumstances in which the defendant's false statements or material omissions masked problems that, for example, would have prompted the FDA to institute or require a product recall," the department stated, "subsequent claims relating to the affected devices could be rendered false or fraudulent because the government would not have paid the claims for those affected devices but for the defendant's conduct."

Effect of regulatory violations. "Further," the DOJ said, "in some situations, manufacturing deficiencies violating the [FD&C Act] or FDA regulations could materially affect the safety, efficacy, or performance of a device such that the product is essentially worthless and not eligible for payment by the government. Submitting claims (or causing claims to be submitted) to federal health care programs for products or services that are so deficient as to be essentially worthless may give rise to [False Claims Act] liability. That these manufacturing deficiencies might separately violate FDA regulations does not preclude [False Claims Act] liability arising from the claims for payment submitted for the affected products."

"However the court rules on the present motion," the department concluded, "the United States requests that the ruling not foreclose the possibility that, under certain circumstances, conduct giving rise to violations of the [FD&C Act] or FDA regulations could be material to the government's payment decisions and provide a basis for [False Claims Act] liability assuming all necessary [False Claims Act] elements are demonstrated."

Arguments for dismissal. The manufacturer argued in its motion to dismiss that the relator's amended complaint was barred by the False Claims Act's public disclosure bar, that it did not meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), and that it failed to state a claim under the statute.

(1) Public disclosure bar. A qui tam action brought under the False Claims Act must be dismissed if substantially the same allegations were publicly disclosed before the qui tam suit was initiated, unless the relator is an original source of the information (31 U.S.C. §3730(e)(4)(A)).

The facts underlying the relator's allegations were publicly disclosed through the manufacturer's press release, FDA notices, and media reports about the product recall. However, the relator argued, the facts contained in those disclosures were not substantially the same as her allegations because they did not directly allege fraud against the government.

"Upon the release of the information disclosed in the [manufacturer's] product recall and the subsequent FDA notices and media coverage," the court noted, "the government was in full possession of each element from which fraud might be inferred." However, the court stressed, those disclosures contained no information about a false or fraudulent claim being submitted to the government.

"Where only one element of the fraudulent transaction is in the public domain …, the qui tam plaintiff may mount a case by coming forward with either the additional elements necessary to state a cause of fraud … or allegations of fraud itself," the court said. On that basis, the court rejected the manufacturer's public disclosure bar argument.

(2) Rule 9(b) particularity: Presentment claim. Rule 9(b) requires allegations of fraud to be pleaded with particularity. On this basis, the court held that the relator's so-called presentment claim — her claim that the manufacturer knowingly presented, or caused to be presented, a false or fraudulent claim for payment in violation of 21 U.S.C. §3729(a)(1)(A) — must be dismissed.

"A False Claims Act complaint satisfies Rule 9(b) if it sets forth facts as to the time, place, and substance of the defendant's alleged fraud, specifically the details of the defendant's allegedly fraudulent acts, when they occurred, and who engaged in them," the district court said.

However, it continued, the relator's allegations lacked "any of the details required to satisfy particularity. They do not provide the dates any claims were submitted, the name of any individual or individuals who submitted the claims, or copies of a single bill or payment."

Moreover, it said, despite the relator's argument that her allegations had "sufficient indicia of reliability," including "extensive personal knowledge of the fraudulent content," the court said that Rule 9(b) "requires more than inferences, consistencies and suppositions. It is not enough for a relator to simply allege that fraudulent claims must have been submitted, were likely submitted, or should have been submitted."

The amended complaint "does not merely leave out some particularities of the submissions of a false claim," the court continued. "It lacks any particularities at all. And although relator alleges personal knowledge of various improper practices by defendant, … she does not allege personal knowledge of any fraudulent submissions themselves."

(3) Rule 9(b) particularity: False statement or document claim. The relator had also brought a claim under 21 U.S.C. §3729(a)(1)(B), under which the False Claim Act is violated if a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

Rule 9(b) requires that such a claim "must be pled with particularly regarding the document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result," the court said. "In short, the false statement must be material to a claim for payment. 'Material' in this context means 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.' Thus, the false statement or document must play a meaningful role in causing payment of a specific claim."

Applying this standard, the court found that the relator failed to specify any false document or statement that had the "natural tendency to influence" the payment of a claim or link such a statement to an actual claim.

Although medical device reports, customer support call scripts, and customer complaint tracking records referred to by the relator allegedly contained false statements, the court said, "the amended complaint does not allege how they had a natural tendency to influence the payment of any claim or are material to a false or fraudulent claim. Consequently, the court held, the relator's false statement or document claim must be dismissed."

"Ordinarily," the court said, "a plaintiff whose complaint falls short of the heightened pleading requirements of Rule 9(b) would be afforded leave to amend. [However,] the court finds that relator's failure to state a claim for falsity under the False Claims Act is ultimately fatal to her case."

Statute not for "targeting weaselly behavior." Agreeing with the manufacturer that the relator had failed to state a claim, the court said that the False Claims Act "is not a catch-all statute for targeting weaselly behavior. Rather, it has the singular purpose of placing the federal government on notice of potential fraudulent claims in relation to its assistance and other spending programs."

"There is no question that relator alleges a cornucopia of weaselly practices on the part of defendant," the court continued. "But, at bottom, these allegations amount to a series of regulatory violations whose connection to claims for payment by the government is tenuous at best."

"To be clear," the court cautioned, "a regulatory violation can rise to the level of creating liability under the False Claims Act. Indeed, if a statute governing certain claims expressly conditions reimbursement on compliance with specific regulatory obligations, violation of said obligations is material to the claims and therefore relevant to a defendant's liability. But allowing a theory of liability based merely on a regulatory violation would sanction use of the False Claims Act as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct."

The relator claimed that the manufacturer's test strips were statutorily ineligible for reimbursement and accordingly false because they were misbranded and adulterated, the court noted. "This argument fails," it responded, "because none of the alleged regulatory violations resulting in 'misbranded and adulterated' test strips were material to any claim for payment."

The relator did not allege that the statutes governing health care programs prohibited reimbursement for adulterated or misbranded medical products, the court also noted. "Rather," it said, "her central argument hangs on alleged violations of the [FD&C Act] and of FDA regulations":

- introducing adulterated or misbranded devices into interstate commerce; and

- failing to investigate adverse events, evaluate their causes, and furnish to the agency within 30 days information suggesting that a death or serious injury was linked to the devices, rendering the devices misbranded and therefore ineligible for reimbursement by government health insurance companies — meaning that "any claims for any test strip manufactured during this period were necessarily false."

However, the court said, even if the test strips were misbranded, the relator had cited no portion of the FD&C Act "closing the circuit" between misbranding and claims for reimbursement from the government. Instead, the relator offered merely the "conclusory assertion" that misbranding would be material to a decision to pay for the defective product because a defect rendering the product worthless and unmarketable "necessarily is … important to any decision to pay for the product."

The relator identified "no statutory condition tying adverse event reporting to eligibility for reimbursement," the court said, and she floated "a 'false certification' argument, but because compliance with FDA regulations is not required for payment by Medicare and Medicaid, defendant has not falsely stated such compliance to the government."

Finally, the court said, the relator had not identified any false statement or other fraudulent misrepresentation that the manufacturer made to the government. "What she alleges," it said, "is a long pattern of shady behavior designed to conceal a serious product defect from the relevant governing body."

"But unless such violations are material to the alleged fraudulent claims," the court stressed, "they do not create liability under the False Claims Act. They are proscribed by other statutes subject to their own enforcement regimes. The court will not expand the scope of the False Claims Act into the realm of regulatory enforcement."

Rejecting two more of the relator's contentions, the court said that:

- the faulty test strip units could not be ineligible for reimbursement due to being not "reasonable and necessary," because the "reasonable and necessary" standard "is applied at the product level, not the unit level"; and

- while "worthless services" have been found by some courts to be ineligible for reimbursement, "relator attempts to expand case law concerning 'worthless services' theory under the False Claims Act into the realm of 'worthless products.' The 11th Circuit has not endorsed this view, and the court declines to do so here."

For these reasons, the court found that the relator had failed to state a claim upon which relief may be granted.

The court declined to give the relator an opportunity to amend her complaint because "any amendment would be futile in light of the holding that adulterated devices are not barred from reimbursement by Medicare and Medicaid and, therefore, claims for reimbursement for these devices cannot be false under the False Claims Act."

Having dismissed the relator's federal False Claims Act claims, the court declined to exercise jurisdiction over the relator's state law claims, dismissing them without prejudice.

"To be clear," the district court said, "the court does not condone defendant's alleged violations of the FDA's reporting requirements and other practices designed to illicitly protect itself from the consequences of placing potentially dangerous medical products into the stream of commerce. But the court is convinced that the False Claims Act is not the proper avenue for holding defendant accountable for this behavior and is confident that the FDA's use of its regulatory enforcement powers may be exercised fully to ensure further compliance."

In its opinion, the district court acknowledged the filing of the DOJ's statement of interest, but it did not otherwise directly address the statement.

Respironics Settles Allegations That It Gave Prescribing Data to DME Suppliers To Induce Purchases

In August 2022, a manufacturer of durable medical equipment (DME) agreed to pay more than $24 million to resolve allegations that between November 2014 and April 2020 it provided illegal kickbacks to DME suppliers in the form of free physician prescribing data (*United States ex rel. Respiratory Care, L.L.C. v. Respironics, Inc.*, No. 2:10-cv-029130BHH (D.S.C.)).

The allegations stem from a False Claims Act suit filed by a whistleblower in the U.S. District Court for the District of South Carolina in October 2019 against Pittsburgh-based Philips RS North America L.L.C., formerly Respironics Inc., and dozens of DME suppliers. Respironics' products include ventilators, oxygen concentrators, continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines, and other respiratory-related medical equipment.

Relator's allegations. A third amended complaint filed in the case in June 2021 alleged that Respironics was engaged in the illegal kickback scheme even while it was subject to a Corporate Integrity Agreement (CIA) with the HHS OIG.

The CIA was related to a 2016 settlement agreement in which the company had agreed to pay over $34 million to the federal government to resolved allegations that Respironics had paid illegal kickbacks to DME suppliers in the form of free call center services. The remuneration allegedly was offered in exchange for DME suppliers' purchases of the company's CPAP masks.

In the CIA, the company "solemnly promised to stop its kickbacks to DME suppliers," the qui tam complaint alleged. "Moreover, senior Respironics management pledged to sign annual certifications attesting that they and their employees were complying with [the] Anti-Kickback Statute."

"In direct contradiction of those obligations," the relator said, "Respironics was engaging in the kickback scheme alleged [in the complaint] in 2016, at the time of the [CIA]. At least two senior Respironics managers, who are required to sign annual certifications under the [CIA], are directly responsible for orchestrating and perpetuating the kickback scheme."

Physician data. The illicit kickbacks allegedly provided to the suppliers were hospital management systems (HMS) data that Respironics had purchased from third parties.

The complaint alleged that the HMS data indicated "in incredible detail" the prescribing decisions of doctors across the country, including recent prescriptions for CPAP, BiPAP and ventilator machines by identified physicians and the DME suppliers that filled the prescriptions.

The data "allows each supplier to more effectively market itself and its services to the physicians in their region who are most likely to send them business," the relator said. Such data allegedly would have cost a DME supplier up to $160,000 per year.

"Respironics knew that the data was of incredible value to DME suppliers, who could use the data to identify physicians in their area to target for sales," the whistleblower said.

"Respironics' purpose, when giving the data to DME suppliers," he said, "was to induce the DME suppliers to recommend Respironics' … products to patients and physicians — and the DME suppliers knew that this was Respironics' purpose."

Relator identified. The DOJ identified the qui tam relator as Jeremy Orling, a Respironics employee who was the sole member of Relator Respiratory Care L.L.C. Orling named his company as the relator in the suit.

After joining Respironics in 2016, Orling reported in his complaint, he was told about the HMS data. "Once the whistleblower learned how valuable the HMS data was," the complaint stated, "he realized that giving the data away was an inducement to the DME suppliers and therefore a violation of the [Anti-Kickback Statute]."

The relator brought his suit under the federal False Claims Act and the false claims statutes of 28 states and the District of Columbia.

On Aug. 25, 2022, the federal government partially intervened in the case and filed with the court a settlement agreement in which the DOJ alleged that through the kickback scheme Respironics had caused DME suppliers to submit false claims to the Medicare, Medicaid and TRICARE programs.

Under the terms of the settlement agreement, Respironics was to pay $22.625 million to the federal government. Of that amount, $10.273 million was designated as restitution. In addition, the company was to pay $2.125 million to state Medicaid programs that participated in the settlement.

Orling was to receive nearly $4.298 million as the relator's share of the federal settlement amount.

Corporate Integrity Agreement. As part of the settlement, Respironics also entered into a new five-year CIA with the HHS OIG.

The Aug. 25 CIA required the company to maintain a robust compliance program that included reviews of arrangements with referral sources and compliance monitoring of the Respironics sales force.

In addition, the CIA required the appointment of an independent monitor by the OIG at Respironics' expense to conduct compliance assessments of the company's business relationships. The monitor was required to report its findings to the OIG within six months, and the company was then to implement the monitor's compliance recommendations within time frames specified in the agreement.

Biogen Settles False Claims Allegations for $900 Million; Relator To Receive Nearly $250 Million

In September 2022, the Cambridge, Mass.-based pharmaceutical manufacturer Biogen Inc. agreed to pay $900 million to resolve allegations that by paying illegal kickbacks to physicians to induce them to prescribe its multiple sclerosis (MS) drugs, the company caused the submission of false reimbursement claims to Medicare and Medicaid (*United States ex rel. Bawduniak v. Biogen Idec Inc.*, No. 1:12-cv-10601-IT (D. Mass.)).

According to the DOJ, the qui tam relator in the False Claims Act litigation in the U.S. District Court for the District of Massachusetts that led to the settlement, Michael Bawduniak, was to receive more than $249.7 million as the whistleblower's share of the federal recovery.

In the litigation, Bawduniak, who worked as a Biogen sales manager from 2004 to 2012, alleged that between January 2009 and March 2014 Biogen offered and paid the illicit kickbacks in the form of speaker honoraria, speaker training fees, consulting fees and meals to health care professionals who spoke at or attended the company's speaker programs, speaker training meetings and consultant programs.

The kickbacks allegedly were intended to induce the providers to prescribe the Biogen medications Avonex, Tysabri and Tecfidera, and violated the federal Anti-Kickback Statute.

Under the settlement, Biogen was to pay more than $843.8 million to the federal government and nearly $56.2 million to 15 states participating in the settlement.

In the DOJ announcement of the settlement Sept. 26, Principal Deputy Assistant Attorney General Brian M. Boynton, the head of the department's Civil Division, noted that Bawduniak "diligently pursued this matter on behalf of the United States for over seven years."

Alleged targeting of kickbacks. In a third amended complaint filed in the case in June 2016, Bawduniak and a second relator, Fernando Villegas, a former senior product manager for Tecfidera, alleged that the goal of the kickback scheme was "to preserve the eroding market share

of Biogen's oldest biological product Avonex, increase the market share of its biological product Tysabri, and to ensure that its new oral MS drug Tecfidera, once approved, would be prescribed at a high rate." (The court dismissed Villegas from the case in February 2018.)

The complaint alleged that Biogen "knowingly identified the top prescribers and paid them millions of dollars to keep their prescriptions at profitable levels. The return on Biogen's investment in this kickback scheme was significant and came largely at the expense of federal and state coffers."

In 2009 and 2010, for example, Biogen paid a total of $18 million to 1,500 doctors and nurses, "who collectively write prescriptions totaling approximately 60% of the MS market," according to the complaint. "Rather than waste its time and money marketing to the other 16,000 neurologists who only account for 40% of the market, Biogen found it more cost effective and profitable to simply buy commercial loyalty from the minority that writes a majority of the prescriptions."

The complaint also alleged that, because of the high annual cost of MS treatment with the drugs (between $35,000 and $70,000), and because "there are a relatively small number of neurologists who treat MS, each prescriber has the ability to direct millions of dollars in revenue to one company's benefit or another" — resulting in "the obvious temptation … to influence these decisions through kickbacks."

The impact on federal health care programs was large, according to the complaint. "Nearly a quarter of all noncancer enrollees in Medicare were MS patients," the complaint asserted, "and approximately 30% of all MS drug payments are paid for by Medicare." The health care program allegedly spent over $500 million on MS treatments in 2006 and 2007, with Avonex accounting for approximately $170 million of that amount.

"The economics and demographics of [MS] make it a fertile ground for a kickback scheme," the complaint said. "Pharmaceutical companies, over the years, have recognized that occasional payments of a few thousand dollars … have strongly motivated the recipients to prescribe the payor's drug for their patients."

Because kickbacks are illegal, the complaint alleged, "Biogen exploited two mechanisms for making payments to physicians — retaining them as consultants and hiring them as speakers — that were permissible if performed in a reasonable and limited fashion." The company allegedly "exploited these exceptions well beyond permissible boundaries so that its sham consulting and speaking schemes were mere conduits for the channeling of illegal payments to the maximum number of high prescribers."

According to the complaint, "the kickback program was a success. Avonex was able to stop its loss of market share and hold constant, despite FDA approval of the oral MS drug Gilenya. With price increases, Biogen pushed its U.S. sales of Avonex to $1.5 million annually. And Tysabri sales continued to grow, despite a black box warning of deadly side effects."

The program of illegal kickbacks "was so successful that Biogen continues to use sham consulting meetings and unnecessary speaking engagements to pay favored physicians," the complaint alleged.

Biogen statement. Biogen issued a statement in which it insisted that it "believes its intent and conduct was at all times lawful and appropriate." The company denied all the allegations raised in the litigation and stressed that the settlement does not include any admission of liability by Biogen.

The company also noted that the United States and the 29 states named in the suit as coplaintiffs chose not to intervene in the case.

Device Firm To Pay Over $12 Million To Resolve Claims Related to Alleged Misrepresentations to FDA

In December 2022, a manufacturer of cochlear implant system devices agreed to pay more than $12 million to resolve allegations originally brought by a whistleblower under the False Claims Act that the company caused the submission of false reimbursement claims to federal health care programs by misrepresenting to the FDA information about the radio frequency (RF) emissions generated by its products (*United States ex rel. Nyberg v. Advanced Bionics Corp.*, No. 2:19-cv-03439-JHS (E.D. Pa.)).

The DOJ said that, in submitting premarket approval (PMA) applications to the FDA for its Neptune and Naída cochlear implant processors, Advanced Bionics L.L.C. (AB) represented that the devices satisfied an internationally recognized RF emissions standard "when, in fact, [the company] did not comply with that standard."

According to DOJ allegations included in a 19-page settlement agreement, "AB did not adequately disclose to the FDA that it failed to test the Neptune and Naída sound processors using 'worst case' configurations and that it shielded certain emissions-generating system components during emissions testing, methods that the United States alleges were improper."

The testing was intended to measure the extent to which the cochlear implant systems generate RF emissions that potentially can interfere with other devices that use the RF spectrum, such as telephones, alarm and security systems, televisions and radios.

The company subsequently sought reimbursement for the devices from Medicare, Medicaid, TRICARE, the Federal Employees Health Benefits Program, and Department of Veterans Affairs health care programs, the government alleged.

"The United States alleges that claims to the federal health care programs for AB's Neptune and Naída cochlear implant systems were false, regardless of whether or not there were safety issues with the Neptune and Naída systems due to the RF emissions testing methods," the settlement agreement stated.

Qui tam suit. The settlement followed the filing of a lawsuit in July 2019 in the U.S. District Court for the Eastern District of Pennsylvania under the qui tam provisions of the False Claims Act by David Nyberg, a former AB engineer. Nyberg filed an amended complaint in the case in November 2022. The DOJ intervened in the case for purposes of settlement on Dec. 19, 2022.

Under the terms of the settlement agreement, AB was to pay $11,361,420 plus interest to the United States, of which $5,680,710 was designated as restitution. AB was also to enter into separate settlement agreements with participating Medicaid programs, to which the company was to pay a total of $1,238,580.

The DOJ said that Nyberg was to receive approximately $1.87 million of the federal settlement amount.

Corporate Integrity Agreement. As part of the settlement, AB agreed to enter into a five-year CIA with the Department of Health and Human Services Office of Inspector General.

The CIA requires AB to undertake an independent review of activities and processes related to the preparation and submission of PMA applications to the FDA and to set performance standards for preparing and submitting PMAs.

The CIA also calls for AB to develop a corporate compliance program that includes a risk assessment program and to submit compliance certifications from the company's board of directors and from key managers.

DOJ warns device companies. In the DOJ's announcement of the settlement, Principal Deputy Assistant Attorney General Brian M. Boynton, the head of the department's Civil Division, said, "The United States expects device manufacturers to provide accurate information when they claim that their devices meet certain tests or standards. The integrity of our health care system depends on the government being able to rely on the information provided by manufacturers when they apply for permission to market their devices."

"The FDA's approval process requires companies to demonstrate the efficacy of their products," Jacqueline C. Romero, the U.S. attorney for the Eastern District of Pennsylvania, said. "The settlement in this case demonstrates our commitment to hold responsible any medical device manufacturer that skirts these rules and seeks FDA approval of a device it knows is not as effective as represented."

Company statement. The company denied the DOJ's allegations. In an emailed statement, a spokesperson for AB said, "Advanced Bionics places the highest priority on the safety and efficacy of our devices, and we take compliance with all laws and regulations governing our industry very seriously."

"It is important to emphasize that this settlement agreement with the government does not allege that the devices at issue — older versions of our Neptune and Naída processors that we no longer market — were unsafe or ineffective for our patients," the AB spokesperson continued. "The settlement relates exclusively to the adequacy of our disclosures to the FDA about our procedures for [RF] emissions testing for these legacy devices. The RF testing at issue does not analyze the efficacy of AB's sound processors in performing their FDA-approved use of enabling hearing."

"While we deny the government's allegations," the spokesperson said, "we believe it is in the best interests of our company to resolve this matter so it will not distract from our focus on developing technology and devices that help restore hearing for so many people."

OIG: 'Coalition Model' of Beneficiary Subsidies May Violate Anti-Kickback Statute, Lead to Sanctions

A proposed arrangement under which manufacturers of oncology drugs covered by Medicare Part D would provide cost-sharing subsidies to program beneficiaries through a charity could generate remuneration prohibited by the Anti-Kickback Statute and result in the imposition of sanctions, according to the HHS OIG (OIG Advisory Opinion No. 22-19).

A Sept. 30, 2022, OIG advisory opinion was the first to scrutinize a so-called "coalition model" of beneficiary cost subsidizing — an arrangement in which a coalition of manufacturers subsidizes cost sharing for their own drugs — in the context of the Part D program.

According to the company that submitted the request for an advisory opinion, the proposal was based on a suggestion in a 2005 OIG bulletin that such an arrangement could present a lower risk of inducements that would be illegal under the statute.

The goal: Increased access to oncology drugs. The company requesting the advisory opinion had applied for 510(c)(3) status under the Internal Revenue Code. Under the proposed arrangement, the charity's operations would be funded entirely by drug manufacturers that produce oncology drugs reimbursed by Medicare Part D.

The charity wanted to address the significant financial burdens associated with the care of cancer patients. Citing evidence that high out-of-pocket costs for prescription drugs result in high rates of delaying treatment after a new cancer diagnosis, delays in obtaining refills, and early discontinuation of drug use, the charity said that "patient access to prescription drug treatment is often hindered by prescription drug benefit designs and, specifically, the out-of-pocket costs incurred by patients under these benefit designs."

The charity also said that "existing patient assistance models involving cost-sharing subsidies and OIG guidance regarding these models" were "inadequate to facilitate access to prescription drugs."

To address these problems, the charity proposed a new model based, in part, on the OIG's guidance in its Nov. 22, 2005, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623). The bulletin referred to "nascent efforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing obligations for the manufacturers' products."

Details of the arrangement. The proposed arrangement would subsidize three categories of costs:

- cost sharing incurred by Part D enrollees when filling prescriptions for the funding manufacturers' Part D oncology drugs;
- "specified programs," such as programs designed to increase health equity in clinical trial participation; and
- the charity's operating costs.

The funding drug manufacturers would subsidize cost-sharing amounts for their own products through the charity — i.e., the arrangement would establish a pathway for each funding manufacturer to subsidize the cost-sharing amounts owed only for its own drugs, not for the drugs of any other funding manufacturer.

Participation would be open to all manufacturers of branded and generic oncology products reimbursed by Medicare Part D. The charity estimated that drug manufacturers whose products constitute about 90 percent of existing Medicare Part D oncology utilization would participate in the arrangement — meaning that the charity would make cost-sharing subsidies available for about 50 oncology products reimbursed by Part D.

A Part D enrollee would be eligible for the subsidies if he or she:

- had a cancer diagnosis;
- had a household income of between 150 percent and 350 percent of the Federal Poverty Level;
- had been prescribed a Part D oncology drug manufactured by a drug maker that funded the arrangement; and
- was enrolled in a Part D plan that had made an initial decision to cover that product for the enrollee.

An enrollee receiving cost-sharing benefits from the charity would pay $35 per month for branded drugs and $10 per month for generic drugs, as well as either 10 percent or 25 percent of the total

coinsurance that otherwise would be owed for branded drugs during the catastrophic phase of coverage. All remaining cost-sharing obligations would be paid by the funding manufacturers of the enrollee's drugs.

Without the proposed arrangement, a Part D enrollee with the current standard prescription drug benefit who takes a branded drug with a retail cost of $10,000 per month would be responsible for a $480 deductible, 25 percent of the coinsurance during the initial coverage phase, and 25 percent of the coinsurance during the coverage gap — totaling approximately $2,800 in the first month.

The arrangement would also require the funding manufacturers to contribute to financing health insurance premiums, including some Part D premiums, and select programs to promote oncology screening and health equity. Part D enrollees with a cancer diagnosis and a household income of between 150 percent and 350 percent of the Federal Poverty Level would be eligible for health insurance premium subsidies. The premium subsidies would be available to qualifying Part D enrollees regardless of whether they used oncology drugs manufactured by the funding manufacturers.

The charity certified that it would impose certain compliance safeguards, including implementing a compliance program that aligned with the May 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731), conducting regular compliance audits, and discouraging "unauthorized conversations," including the marketing or advertising of the arrangement to prescribers, beneficiaries or other third parties as a reason to prescribe or use any product.

Legal analysis. While stressing that "beneficiary access to potentially life-saving medications, including [the] funding manufacturers' Part D oncology products, is of paramount concern to OIG," the office said that to produce an advisory opinion it was called upon to evaluate the proposed arrangement in terms of:

- what constitutes prohibited remuneration within the Anti-Kickback Statute (i.e., whether the remuneration would violate the statute if the requisite intent were present); and

- whether the arrangement would constitute grounds for the imposition of sanctions by the OIG (i.e., whether the arrangement would pose a sufficiently low risk of fraud and abuse under the statute that the OIG would not seek to impose sanctions).

"High drug list prices often translate into prohibitively high out-of-pocket costs for Medicare Part D enrollees and other patients that render them unwilling or unable to fill their prescription," the OIG acknowledged. For example, it noted, in 2019 the mean annual out-of-pocket cost for 78 Part D oncology drugs was $5,285.

Streams of remuneration. The OIG examined the three categories of costs that would create "several distinct streams of remuneration" that could implicate the Anti-Kickback Statute.

According to the OIG, the cost-sharing subsidy payments would create:

- indirect remuneration from the funding manufacturers to the qualifying Part D enrollees;

- remuneration from the charity to the enrollees purchasing the funding manufacturers' drugs; and

- direct remuneration from the funding manufacturers to the charity to cover the subsidies.

The cost-sharing subsidies, the OIG concluded, "would fit squarely within the federal Anti-Kickback Statute's plain language prohibiting the offer of remuneration to induce the purchase … of an item for which payment may be made under a federal health care program, if the requisite intent were present." Moreover, the office noted, the subsidies would be substantial — close to $8,000 annually under the current standard Part D benefit.

All three streams of remuneration created by the cost-sharing subsidies appear to be designed to remove the financial barrier that prevents some Part D enrollees from purchasing the funding manufacturers' drugs, the OIG noted. Moreover, it said, "while [the charity] would be agnostic as to which funding manufacturer's Part D oncology drug a qualified enrollee would purchase, that does not change the fact that the … arrangement would involve paying remuneration … to Medicare Part D enrollees so that such enrollees would 'purchase … any item for which payment may be made … under a federal health care program,' so long as the item is a Part D oncology drug manufactured by a funding manufacturer."

Possible grounds for sanctions. Because the cost-sharing subsidies would not come within any statutory exception or regulatory safe harbor to the Anti-Kickback Statute, the OIG said, the analysis then turned to identify whether the subsidies would constitute grounds for the imposition of sanctions.

"We recognize that [the charity] based the structure of the proposed arrangement on our brief discussion in the 2005 bulletin about a potential 'coalition model' program," the OIG said, "and the proposed arrangement would include many of the provisional safeguards that, in 2005, we posited

might reduce the risk of fraud and abuse. … This advisory opinion reflects our first opportunity to evaluate an arrangement involving a coalition of manufacturers subsidizing cost sharing for their own drugs and to do so in the context of an implemented Part D program."

"While OIG previously acknowledged the possibility of a 'coalition model,'" the office continued, "OIG also had consistently expressed concerns about manufacturers subsidizing beneficiaries' cost sharing for the manufacturers' own drugs. [The charity's] design of the proposed arrangement would ensure that each funding manufacturer can funnel its financial contributions for cost sharing through [the charity] to only those eligible Part D enrollees who are taking that funding manufacturer's drugs — thereby creating a fact pattern that collides with OIG's prior warnings."

The 2005 bulletin warned against cost-sharing subsidies that can be "very profitable for manufacturers," the OIG noted, and it specified that "these profits can be considerable, especially for expensive drugs for chronic conditions." Moreover, the May 2014 OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (79 Fed. Reg. 31120) warned that "the ability to subsidize copayments for their own products may encourage manufacturers to increase prices."

An individual funding manufacturer's cost-sharing subsidies "would be contingent on the purchase of that particular funding manufacturer's oncology products," the OIG stressed. "This remuneration presents many of the hallmark risks of fraud and abuse that the federal Anti-Kickback Statute is designed to prevent."

Those risks included the potential for inappropriately increased costs to federal health care programs (through manufacturers increasing their prices or setting high launch prices because of the reduced sensitivity of beneficiaries toward prices), the potential for beneficiary steering and anticompetitive effects, and possible interference with or skewing of clinical decision-making.

"We conclude that the cost-sharing subsidies under the proposed arrangement would present more than a minimal risk of fraud and abuse under the federal Anti-Kickback Statute," the OIG said.

"Redesign" of Part D cost sharing. Moreover, the OIG said, the proposal "effectively would permit [the charity] and funding manufacturers to redesign the current Part D cost-sharing structure for qualifying Medicare Part D enrollees for approximately 90 percent of Part D oncology products by implementing a self-designed cost-sharing structure."

Because formularies for Part D plans must include all oncology drugs, with limited exceptions, the OIG said, "the proposed arrangement would target a class of drugs over which Part D plan sponsors already have more limited ability to negotiate favorable pricing terms and for which the majority have seen price increases … that exceed inflation." Moreover, the office reasoned, the arrangement would hinder Part D plan sponsors' ability to control costs for these drugs "because, for example, it would largely insulate beneficiaries from price increases or high launch prices."

The arrangement, the OIG said, "would circumvent one of the key pricing controls (exposing beneficiaries to the economic effects of drug prices set by manufacturers) that Congress instituted in the current standard Medicare Part D prescription drug benefit and would lay bare the dangers of allowing manufacturers to dictate the terms of this market safeguard."

"Simply put, the cost-sharing subsidies … would leave funding manufacturers' prices for their products largely unconstrained by a key market control inherent to the current Medicare Part D drug benefit design, while the Medicare program and taxpayers would bear the financial brunt of those unchecked drug prices."

Although it could not conclude that increased drug prices and improperly increased federal health care program costs would indeed result from the arrangement, the OIG said, the arrangement "presents significant risks of such outcomes, thus making it inappropriate for OIG to offer prospective immunity in connection with the proposed arrangement."

Other potential risks. The OIG also cited a number of potential risks posed by the proposed cost-sharing arrangement, including:

- the risk of penalizing a manufacturer that did not participate in the arrangement, "because a nonparticipating manufacturer could be at risk of having beneficiaries steered away from their products if they do not subsidize cost sharing for their products"; and

- the risk that prescribers would learn which products are or are not subsidized through the arrangement and choose the product covered by the arrangement rather than another clinically appropriate option.

Although the OIG did not specifically analyze the risks of fraud and abuse associated with the categories of costs related to "specified programs" and operating costs, the office said that these contributions "would be intrinsically tied to the funding manufacturers' contributions to subsidize cost-sharing amounts for their own drugs and [the charity's] use of those funds to subsidize Part D enrollees' cost sharing, and therefore the proposed arrangement, as a whole, would carry the unacceptable risks … with respect to cost-sharing subsidies."

Consequently, the OIG concluded, the proposed arrangement "would generate prohibited remuneration if the requisite intent were present, which would constitute grounds for the imposition of sanctions."

Charity Asks Court To Nullify HHS OIG Advisory Opinion on Kickback Implications of Cancer Drug Help

In January 2023, a charity seeking to help lower-income Medicare patients with cancer obtain Part D-covered drug treatments sued the HHS OIG, alleging that the agency's conclusion in its Advisory Opinion No. 22-19 that the charity's patient assistance program (PAP) might violate the Anti-Kickback Statute was arbitrary and capricious and violated the charity's First Amendment rights (*Pharmaceutical Coalition for Patient Access v. United States*, No. 3:22-cv-00714 (E.D. Va.)).

Proposed arrangement. The charity, the Glen Allen, Va.-based Pharmaceutical Coalition for Patient Access (PCPA), had proposed a patient assistance model based in part on the OIG's guidance in its Nov. 22, 2005, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623).

In its Jan. 5, 2023, amended complaint for declaratory judgment and injunctive relief, filed in the U.S. District Court for the Eastern District of Virginia, the charity said that it had requested a favorable advisory opinion from the OIG "based on regulatory guidance that OIG itself issued which permits a coalition of manufacturers to provide assistance to Medicare Part D patients in financial need — exactly what PCPA stands ready to do."

Nevertheless, PCPA said, the OIG concluded in Advisory Opinion No. 22-19 that the charity's proposal "constituted 'prohibited remuneration' that 'induces' the purchase of Medicare items and services under the federal [Anti-Kickback Statute]. The agency told the charity that there was "no pathway" forward for the plan, PCPA claimed.

Because the Anti-Kickback Statute is a felony criminal law, PCPA told the court, the charity and any prospective donors "cannot implement the program that would assist patients with cancer in immediate and dire need because OIG has refused to issue a favorable advisory opinion."

Alleged APA violations. The charity alleged that the OIG's conclusions in the advisory opinion were arbitrary and capricious, contrary to law, beyond statutory authority, and an abuse of discretion in violation of the Administrative Procedure Act (APA).

First, PCPA said, the advisory opinion was contrary to law because its proposed program does not violate the Anti-Kickback Statute. Under the statute, "any prohibited kickback [must] involve a quid pro quo 'in return for' or to 'induce' the purchase of a specific item or service," the charity told the court. "Under PCPA's program, a needy patient with cancer may receive assistance for any one of a broad range of drug and nondrug cancer services after a course of treatment independently has been approved by the patient's medical doctor. As such the proposed program cannot, as a matter of law, satisfy the parallel 'in return for' and 'to induce' requirements of the [Anti-Kickback Statute]."

"Where there are a wide range of options presented to a patient, as is the case here," the charity told the court, "OIG has itself conceded that the range of options would 'sever any nexus' between the offered remuneration and a subsequent purchase under the [statute]. In such circumstances, the remuneration is not 'in return for' and does not 'induce' a specific item or service."

"Contrary to the advisory opinion," the charity continued, "the PCPA program does not result in prohibited remuneration because it does not involve any element of corruption, which is an element of an illegal kickback as reflected in the language, structure and history of the [Anti-Kickback Statute]. … It is arbitrary and capricious to conclude that a charitable program offering a wide range of assistance to patients with documented financial need in an open and transparent fashion is corrupt, in any way."

Second, the charity asserted, the advisory opinion "treats PCPA fundamentally differently than other similarly situated parties in an arbitrary and capricious manner." The charity alleged that the OIG has allowed other charities to secure funding from manufacturers to support patients using those manufacturers' products, and that the office has allowed other providers to reduce or even completely waive copayments for their own patients."

Third, PCPA said, the advisory opinion was arbitrary and capricious "because it conflicts with OIG's own guidance" — the November 2005 special advisory bulletin. "OIG has specifically advised that, where certain safeguards are present in a 'coalition' of manufacturers working together, such a coalition may provide financial assistance without fear of [Anti-Kickback Statute] prosecution. That 2005 guidance has not been rescinded or modified in any way by OIG. … PCPA has, furthermore, complied in all respects with that 2005 guidance."

First Amendment argument. Finally, the charity asserted, in evaluating its proposal the OIG "failed to consider the First Amendment rights of PCPA, as a charitable entity, in seeking to engage in protected solicitation of funds and in the protected speech it would make in securing funds and then dispensing assistance."

Because the OIG's "sweeping advisory opinion conclusions … flatly prevent PCPA from proceeding with its charitable mission" and because the OIG "failed to consider or adopt any narrowly tailored alternative" to those conclusions, the charity argued, "OIG has violated PCPA's constitutional rights."

"OIG reads the [Anti-Kickback Statute] so broadly that it improperly criminalizes innocuous, or even beneficial conduct, that is itself protected by the First Amendment. The courts, including the Supreme Court, have not allowed the government to assert overly broad interpretations of criminal statutes [citing *Skilling v. United States*, 561 U.S. 358 (2010), and *Liparota v. United States*, 471 U.S. 419 (1985)]. This court should take the same step here."

PCPA asked the district court to enter declaratory judgments that the OIG's failure to issue a favorable advisory opinion to the charity was arbitrary and capricious in violation of the APA; that the proposed arrangement was not subject to enforcement under and did not violate the AKS; that the arrangement was entitled to a favorable advisory opinion with respect to enforcement under the AKS; and that the Sept. 30 advisory opinion was invalid in that it violated the First Amendment rights of the charity and its prospective donors to engage in protected free speech.

Jury Returns Kickback, False Claims Verdict for Over $43 Million Against Ophthalmic Device Distributor, Leading to Judgment of Nearly Half a Billion Dollars

In February 2023, a federal jury in Minnesota returned a verdict for more than $43 million against an ophthalmic device distributor that for nearly a decade operated an illegal kickback scheme in violation of the False Claims Act and the Anti-Kickback Statute. The federal district court subsequently entered a judgment of nearly $500 million against the company (*United States ex rel. Fesenmaier v. The Cameron-Ehlen Group, Inc., dba Precision Lens*, No. 0:13-cv-03003-WMW-DTS (D. Minn.)).

The DOJ had alleged that between 2006 and 2015 the Cameron-Ehlen Group Inc., which operated as Precision Lens, a Bloomington, Minnesota-based distributor of intraocular lenses, viscoelastics and other products related to ophthalmic surgeries, and Paul Ehlen, the owner of the business, paid kickbacks to ophthalmic surgeons to induce their use of the firm's products in cataract surgeries reimbursed by the Medicare program.

The jury found that the kickbacks had caused the submission of 64,575 false claims to Medicare, the DOJ said in announcing the verdict.

The kickbacks took the form of travel and entertainment, including "high-end" skiing, fishing, golfing, hunting, sporting and entertainment vacations. For many of the trips, the government had alleged, the company transported physicians to luxury vacation destinations on private jets. The trips included jaunts to New York to see a Broadway musical, to the January 2009 College Football National Championship Game in Miami, and to the April 2011 Masters golf tournament in Augusta, Georgia.

The company also sold frequent flyer miles to its customers "at a significant discount," the government said, allowing the physicians to take personal and business trips at well below fair market value.

In an effort to conceal their behavior, the government had alleged in a February 2018 complaint in intervention filed in the U.S. District Court for the District of Minnesota, the firm and Ehlen created what was referred to as a "slush fund" or "secret fund" that was used in part to fund "lavish hunting and fishing trips" for the physicians.

Motion to dismiss. The defendants had sought to have the government's charges against them dismissed in March 2018. They contended that the government had failed to plead an underlying violation of the Anti-Kickback Statute because it failed to plausibly allege that the defendants acted willfully and with the intent to induce purchases funded by Medicare. The allegations, according to the defendants, "do not demonstrate that [either defendant] intended to enter into a quid pro quo with physicians."

In an Oct. 22, 2018, ruling, the district court rejected the argument, noting that under the statute the inducement need not be the primary motivation behind the remuneration, and concluding that the DOJ's complaint permitted "a reasonable inference that [the] defendants provided benefits to physicians in exchange for their business and would have discontinued the benefits if they did not result in sales" (*United States ex rel. Fesenmaier v. The Cameron-Ehlen Group, Inc.*, No. 0:13-cv-03003-WMW-DTS, 2018 U.S. Dist. LEXIS 247522, 2018 WL 11451362 (D. Minn.)).

As to an alleged intent to have Medicare pay for the devices that they sold to physicians who received the trips and other benefits, the court said that an Anti-Kickback Statute violation exists "even if a defendant's remuneration generated legitimate transactions in addition to unlawful transactions." It was sufficient, the court determined, for the government to allege that the defendants "provided remuneration to physicians to obtain their business, a significant portion of which included Medicare-billed business."

Moreover, the court concluded, the DOJ had plausibly alleged that the defendants had acted "knowingly and willfully" — i.e., knowing that their conduct was wrongful. The government had alleged, the court noted, that the company kept an overview of the Anti-Kickback Statute in its files; that in 2004 Ehlen had acknowledged that the statute prohibited the firm from providing inducements to physicians; and that in 2007 company executives discussed another company's settlement of a lawsuit pertaining to kickbacks that arose from the company's entertainment practices and concluded that Precision Lens "should proceed with caution in this area."

The defendants also asserted in their motion to dismiss that as to 17 of the 29 physicians identified in its complaint, the government had not pleaded the existence of false claims and that consequently the complaint should be dismissed with respect to the 17 physicians.

Rejecting the argument, the court said, "The United States does not allege 29 distinct fraudulent schemes involving each physician; rather, it alleges one complex scheme that involved multiple

physicians. [The] defendants offer no legal authority requiring a court to dissect a claim into its component allegations and dismiss those allegations piecemeal when the claim as a whole is otherwise viable."

The court also rejected the defendants' assertion "that the complaint must allege that the physician who received the remuneration also made the purchasing decision, performed a surgery using the product purchased from Precision Lens, and billed the surgery to Medicare." The defendants had provided "no persuasive authority for requiring this degree of detail," the court said.

The court also found that the government had pleaded its False Claims Act claims with particularity as required by Federal Rule of Civil Procedure 9(b), saying that the DOJ's complaint described the defendant's alleged fraudulent scheme "in considerable detail."

Whistleblower suit. The civil lawsuit against the Cameron-Ehlen Group and Ehlen was originally brought in November 2013 by Kipp Fesenmaier, who worked for 15 years for Sightpath Medical Inc. and its corporate predecessor. Sightpath, also a supplier of ophthalmic devices, was for a time a corporate partner of Precision Lens. Fesenmaier served for many years as Sightpath's vice president.

In August 2017 Sightpath, an affiliated company, and their CEO agreed to pay more than $12 million to resolve kickback allegations brought under the False Claims Act in a separate qui tam suit that was initiated by Fesenmaier and in which the DOJ intervened.

In February 2018, the DOJ announced that Dr. Jitendra Swarup had agreed to pay more than $2.9 million to resolve allegations that he had received unlawful remuneration from Sightpath, Precision Lens and Ehlen in the form of various trips, including hunting and international fishing trips, and sham consulting agreements with Sightpath.

Motion for judgment. Following the verdict, in a March 17, 2023, memorandum in support of its motion for judgment, the DOJ had argued that the False Claims Act calls for a civil penalty of between $5,500 and $27,018 for each violation of the statute, depending on when the false claim was submitted, plus three times the amount of damages (31 U.S.C. §3729(a)). The defendants were jointly and severally liable for the damages assessed, the government asserted.

"Trebling the verdict of $43,694,641.71 for each defendant, with application of joint and several liability, results in damages in the amount of $131,083,925.13," the DOJ told the court.

In addition, the DOJ sought mandatory civil penalties totaling $358,445,780, which when added to the damages amount would result in a judgment of $489,529,705.13.

Defendants' response. In their response to the government's motion for judgment, the defendants disputed the DOJ's calculation.

The defendants asserted that the department had wrongly asserted that the False Claims Act "provides for the full recovery of all claims filed during a government-proclaimed 'taint period' in which every single claim is automatically and inherently false if the government proves a 'causation-free' Anti-Kickback Statute violation." The defendants argued that such an approach had been rejected by the U.S. Court of Appeals for the Eighth Circuit (*United States ex rel. Cairns v. D.S. Medical L.L.C.*, 42 F.4th 828 (8th Cir. 2022)).

Contrary to the DOJ's assertions, the defendants said, "the False Claims Act is not an all-purpose anti-fraud statute. Even defendants found to have violated the Anti-Kickback Statute cannot be held strictly liable for all claims submitted to Medicare thereafter; to the contrary, the law

requires proof that a defendant would not have included particular items or services but for the illegal kickbacks. There is no 'presumption of falsity' that attaches when an Anti-Kickback Statute violation is found — and certainly not one that extends a year or more (or forever) into the future."

Moreover, the defendants asserted, "the products used in those surgeries were used by the physicians for years before any purported kickback event and for years after the alleged kickback events; in other words, the evidence failed to show any meaningful changes in utilization before, during or after any kickback events, including during the so-called 'taint periods.' … Simply put, it was pure speculation that any claims submitted to Medicare were rendered false due to any kickback event."

The defendants also objected to having the calculation include Medicare fees paid for physician services "which include no items or services rendered by [Precision Lens]. … Plaintiffs should not have been allowed to seek recovery for every claim associated with these medically necessary surgeries, but at most only those claims that reimbursed for products supplied by the defendants."

In addition, the defendants argued that "the government had adduced no evidence reflecting any actual damages based on the record at trial," and that the court should offset any award by the full amounts that the government had received from settlement in related cases.

Finally, the defendants asserted that even the damages award "does not reflect any actual loss to the government and is itself entirely punitive," and that trebling the damages "reflects an amount that has no bearing on defendants' conduct as found by the jury, which reflects less than $4 million in sales."

"Both the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth Amendment prohibit punitive damages that are grossly disproportional and grossly excessive to a defendant's conduct," the defendants told the court, which they argued had discretion to apply statutory penalties in amounts less than the range set forth in the False Claims Act or to exercise discretion in how to apply those amounts so as to not violate the Constitution.

In the end, the defendants urged the court to enter a maximum award of "around $20 million ($4 million in compensatory damages plus $16 million in punitive damages and/or penalties) … properly reduced by the full amount of the government's settlements with other parties."

Court's order. In entering judgment in the amount of $487,048,705.13, the district court noted that the defendants had not disputed the accuracy of the government's calculation of damages under the False Claims Act.

The court also said that it was "highly unlikely" that it would revisit any of the legal conclusions it had reached before and during the trial — many of which the defendants had disputed again in their March 24 filing. "The parties remain free to raise any argument in support of its post-judgment motions and may be obligated to raise certain arguments in order to preserve those arguments on appeal," the court said.

However, the court noted that the government had modified its request for entry in judgment to account for $2,481,000 that it had received in related settlement proceeds. The court's final judgment reflected this modification.

On June 27, 2023, while post-judgment motions were pending in the court, Precision Lens founder Paul Ehlen died when a World War II era P-40 single-engine fighter plane that he was piloting crashed soon after takeoff at the Ravalli County Airport in Montana.

OIG: No Sanctions for Providing Treatment Assistance to Pediatric Patients With Rare Immune Disorder

In February 2023, the HHS OIG issued an advisory opinion saying that a medical product manufacturer's PAP — in this case, a program that would provide assistance for transportation, lodging and meal expenses to financially needy pediatric patients suffering from a rare immune disorder and to their caregivers — would not lead to the imposition of administrative sanctions under federal health care fraud statutes (OIG Advisory Opinion No. 23-01).

The advisory opinion's requestor developed a regenerative tissue-based therapy indicated for immune reconstitution in pediatric patients. The biologic is indicated for the treatment of an "ultra-rare" primary immunodeficiency disorder that affects approximately 17 to 24 of every 4 million children born each year in the United States.

The condition is caused by the absence of a thymus at birth. The organ is essential to the development of T-cells, one type of infection-fighting white blood cell. The condition is detected through newborn screening for severe combined immunodeficiency and through follow-up testing.

Medical care addressing the condition involves prolonged hospitalizations, frequent outpatient visits, home health care, diagnostic and monitoring testing, treatment and prophylactic medications, and diagnostic and surgical procedures.

Treatment provided. The manufacturer's biologic is "a one-time, potentially curative treatment and the only treatment option available to rebuild the immune system of a patient diagnosed with the condition," the OIG reported. The product is developed from thymus tissue provided by donors nine months of age or younger who are undergoing cardiac surgery. The thymus tissue is processed and cultured for 12 to 21 days and then surgically implanted in the thigh muscle of a pediatric patient.

Under the terms of the FDA biologics license application approval letter for the product, there is only one approved manufacturing facility, which is located on the campus of the treatment center where the product has been investigated since 1993. Because the product's shelf life is only three hours, the biologic must be administered near to where it is manufactured.

A patient's preparation for treatment with the biologic involves testing, clinical evaluations and immunosuppressive therapy as needed for five to 11 days before implantation. Patients remain at the treatment center for two to seven days to ensure that there is no infection and that proper healing occurs. Immune reconstruction sufficient to protect against infection usually begins no earlier than six to 12 months after treatment.

Details of the assistance. The proposed PAP would provide round-trip medical flights for patients and for up to two caregivers, ground ambulance travel, lodging assistance for up to $150 per night, and coverage for out-of-pocket expenses ($50 per day for one caregiver or $100 per day for two caregivers) to cover ground transportation and meals.

A "hub" of the manufacturer would administer the program, screening patients for eligibility, fulfilling requests for assistance, obtaining documentation of financial need, and providing recordkeeping services.

Anti-Kickback Statute. In its legal analysis of the proposed arrangement, the OIG said that the proposal implicated the Anti-Kickback Statute in two ways:

- Any combination of free or subsidized transportation, lodging and meal expenses constitutes remuneration from the manufacturer to patients — remuneration that may induce the patients to purchase the biologic and to receive other federally reimbursable items and services provided at the treatment center.

- Because patients receive assistance that facilitates their travel to and lodging near the treatment center, the assistance could constitute remuneration to the treatment center and the treating surgeon in the form of fees related to administering the biologic.

Even though the manufacturer had told the OIG that it would not shift the arrangement's costs to federal health care programs, the office noted, the company might increase the price of the biologic to help it recoup costs related to the arrangement. The OIG also said that it was concerned that such an arrangement could encourage manufacturers to compete for market share using the free items and services and could create a barrier to entry for potential competitors.

Nevertheless, the OIG concluded that the risk of fraud and abuse presented by the arrangement "is sufficiently low" under the Anti-Kickback Statute, for the following reasons:

- The arrangement facilitates safe access to the treatment for a patient population that cannot travel long distances safely by car or commercial airlines and that lacks the financial resources to travel in a safe manner. The costs associated with the treatment could either inhibit patients from receiving a treatment that has the potential to restore their immune systems or cause them to take a means of transportation to the treatment center that would be unsafe, given the patients' lack of functioning immune systems.

- The biologic is a one-time, potentially curative treatment, and it is the only treatment option available for patients affected by the condition. "Therefore," the OIG said, "the arrangement is distinguishable from problematic seeding programs where a manufacturer provides remuneration to patients in connection with an initial dose of a drug to induce patients to continue purchasing the drug."

- The nature of the condition and the biologic "reduces the risk that the arrangement would result in interference with clinical decision-making, overutilization or inappropriate utilization," the OIG said. "This is not a mass-produced drug and does not appear to be subject to risks of inappropriate utilization. It is unlikely that the health care professional diagnosing the patient with the condition and prescribing the [biologic] will receive any financial benefit related to the procedure to implant the drug." Also, the office said, "it would be exceedingly rare that a doctor who practices at the treatment center would be the physician who diagnoses the patient with the condition and prescribes the drug."

- The arrangement is unlikely to increase costs to federal health care programs inappropriately, the OIG added. "Because it is the only potentially curative treatment option," the office noted, "many (if not most) patients with the condition might attempt to access the drug even in the absence of the arrangement." Moreover, the OIG said, because patients with the condition have an associated total economic burden of more than $5.5 million or more during the first three years of life, helping a patient obtain a potentially curative treatment "has the potential to offset some of the costs that these patients might otherwise incur for their supportive care in the first three years of life and might continue to incur over time."

- Patients must meet several criteria to qualify for the assistance, and each element of the assistance is available under the arrangement only if there is no other coverage option.

- The remuneration that the manufacturer would provide to patients, thereby creating an opportunity for the treatment center to earn fees related to implanting the drug, "is sufficiently low risk under the federal Anti-Kickback Statute in the context of the arrangement," the OIG concluded, particularly given that all patients prescribed the biologic must obtain it from the treatment center, regardless of the arrangement.

Beneficiary Inducements CMP Statute. The OIG also noted that remuneration offered by a manufacturer to a beneficiary that the manufacturer knows or should know is likely to influence the beneficiary to select a particular provider or supplier would implicate the Beneficiary Inducements Civil Monetary Penalty (CMP) Statute.

"Because the treatment center is a provider," the office said, "the provision of remuneration under the arrangement potentially implicates the statute."

However, the OIG said, "it is the limitations relating to the manufacturing and distribution of the [biologic], rather than the remuneration offered under the arrangement, that would be likely to influence a patient to select the treatment center for items and services for which payment may be made, in whole or in part, by Medicare or a state health care program. As such, the remuneration offered under the arrangement is not likely to influence a beneficiary to order the [biologic] from a particular provider, i.e., the treatment center."

The OIG therefore concluded that it would not impose administrative sanctions on the manufacturer in connection with the arrangement with respect to the Anti-Kickback Statute's prohibitions, and that the arrangement would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

OIG: Providing Free Drugs During Coverage Determination Process Poses Low Risk of Health Care Fraud

A pharmaceutical manufacturer's proposal to provide a limited supply of a drug free of charge to patients suffering from a rare disease to cover the period during which an insurance coverage determination for the drug is pending would not trigger administrative sanctions under federal health care fraud statutes, the HHS OIG concluded in February 2023 (OIG Advisory Opinion No. 23-02).

The FDA approved the enzyme replacement therapy (ERT) drug in October 2018 for the treatment of an inherited genetic disorder that was not identified in the advisory opinion. Only about six to 15 new patients are diagnosed with the condition in the United States annually. The condition is fatal if left untreated.

The only FDA-approved treatments for the condition in the United States are ERT and bone marrow transplantation. According to the manufacturer, the enzyme replacement drug, which the company acquired in November 2020, is the only currently available ERT approved in the United States for treatment of the condition.

Administered by intramuscular injection, the drug does not cure the condition but rather treats it on an ongoing basis. In the absence of successful bone marrow transplant surgery or some yet-to-be-developed treatment, patients affected by the condition could continue taking the drug for the rest of their lives.

According to the manufacturer, 49 U.S. patients were receiving the drug to treat the condition as of July 2021. Six patients were Medicare beneficiaries, and 32 patients were Medicaid beneficiaries.

Proposed arrangement. The manufacturer proposed to provide a free 14-day supply of the drug to patients who:

- are diagnosed with the condition by a licensed health care professional;
- have received a prescription for the drug but have not previously been treated with the drug;
- are insured, "regardless of the source of insurance"; and
- experience a delay in the insurance coverage determination for the drug of at least 48 hours after the patient's insurer has received all required information.

The company also proposed to provide a second 14-day supply if the patient continues to await a coverage determination or if the patient has been denied coverage and "is diligently pursuing appeal rights."

The drug maker said that the 48-hour period included in the arrangement's criteria was established based on the severe nature of the condition, existing payor policies, and federal and state statutes and regulations, some of which require payors to make coverage determinations within 48 hours or less in such circumstances.

The manufacturer certified that participation in the arrangement would not be contingent on a requirement to purchase the drug. Moreover, neither providers nor patients could seek reimbursement for the drug or for its administration.

The company expected that only 0.0078% or fewer of all prescribed vials of the drug would be provided through the proposed arrangement.

In addition, the manufacturer certified that the one specialty pharmacy that manages the drug would implement certain safeguards, such as certifying that the free drugs could not be sold, traded or distributed for sale and could not be billed to a third-party payor.

The company also pledged not to advertise the arrangement and to notify physicians that they were barred from advertising their participation in the arrangement.

However, the manufacturer said that its website might provide information about the arrangement and its terms and conditions, and the company might include information about the arrangement in nonpromotional materials (such as educational materials about disease states) intended to inform the public of the programs and initiatives that the company has established "to help facilitate the well-being of patients with rare diseases."

Legal analysis. In its analysis of the proposed arrangement, the OIG concluded that the arrangement would implicate the Anti-Kickback Statute "because patients, some of whom are federal health care program beneficiaries, receive remuneration (the free 14-day supply of the drug, with one possible 14-day refill) that could induce future purchases of the drug."

Nevertheless, the OIG determined that the arrangement would be "sufficiently low risk" under the statute.

- First, the office said, it was not likely that the arrangement would lead to overutilization of the drug, given the arrangement's participation requirements. Moreover, if insurance coverage is eventually approved, a patient who received free drugs would be subject to any applicable cost-sharing amount for the drug after administration of the free doses. Also, regardless of the ultimate coverage determination, the patient would be eligible for no more than one 14-day free supply and possibly one 14-day refill.

- Second, the OIG distinguished the arrangement from "seeding" programs in which a drug maker might offer a drug for free or at reduced cost to induce a patient to use the product in the future, with subsequent supplies in some cases being billed to federal health care programs. "Because the arrangement is available only in the event of a delay in the insurance coverage determination process," the office said, "patients and prescribers likely assume at the time the drug is prescribed that the patient's insurance will cover the drug and that the patient will be subject to applicable cost-sharing amounts. Thus, having the arrangement in place for those cases in which insurance approval decisions extend beyond 48 hours is unlikely to influence patients or prescribers to choose the drug over alternative therapies, particularly where, as here, the only current treatment alternative is [a bone marrow transplant]."

- Third, the OIG said, the prescriber would receive no financial benefit under the arrangement, because the drug would be dispensed directly to the patient from the specialty pharmacy, and the prescriber would have no opportunity to bill for the drug.

- Fourth, there would be no cost to federal health care programs, the OIG noted. "No patient, pharmacy, payor or other third party is billed for the free supplies of the drug or for administration of the drug," the office said.

- Fifth, the OIG stated, although giving remuneration to a federal health care program beneficiary to purchase an item from a particular pharmacy could implicate the Anti-Kickback Statute, "we consider the circumstances present in the arrangement to be sufficiently low risk. … Accepting the free drug under the terms of the arrangement does not obligate a patient to continue obtaining the drug, or any other item or service, from the specialty pharmacy in the future."

The OIG noted that its Anti-Kickback Statute analysis might have reached a different conclusion "if the arrangement were used as a marketing tool, or if [the manufacturer] were providing free drug outside of the context of a legitimate delay in a coverage determination or appeal."

Beneficiary Inducements CMP analysis. The OIG also examined whether the proposed arrangement would be likely to influence a beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which Medicare or a state health care program could provide coverage.

Remuneration offered by a drug manufacturer to a beneficiary that the manufacturer knows or should know is likely to influence the beneficiary to select a particular pharmacy implicates the Beneficiary Inducements CMP Statute, the OIG stated.

Here, however, the office said, the specialty pharmacy would be the only source of the drug, so the remuneration offered under the arrangement would not be likely to influence a beneficiary to purchase the drug from the specialty pharmacy.

"In addition," the OIG said, "we believe it is unlikely that the possibility of receiving an initial free supply of the drug following an insurance delay (with one possible refill) is likely to influence a patient to purchase other federally reimbursable products from the specialty pharmacy in the future."

OIG Okays Offering $75 Gift Cards To Incentivize Patients To Return Samples for Cancer Screening

In March 2023, the HHS OIG concluded that offering gift cards worth up to $75 to patients as an incentive to return a noninvasive colorectal cancer screening test sample for laboratory analysis would not present grounds for the imposition of administrative sanctions under federal health care fraud statutes (OIG Advisory Opinion No. 23-03).

The company that requested an advisory opinion from the OIG manufactures the only FDA-approved noninvasive stool-based DNA colorectal cancer screening text available to patients who are at average risk for developing the cancer. A laboratory that is a wholly owned subsidiary of the manufacturer is the only laboratory that analyzes the test samples provided by patients.

Medicare Part B covers the test once every three years for program beneficiaries aged 45 or older who meet certain criteria. As of January 2023, the laboratory is reimbursed approximately $500 for each test it performs.

Advantages of the noninvasive test. In a November 2022 coverage determination that lowered the eligibility age from age 50, the Centers for Medicare and Medicaid Services (CMS) noted the advantages of choosing a noninvasive test as opposed to a screening colonoscopy, "including relative ease of administering the test and potentially reducing the experience of unnecessary burdensome preparation and invasive procedures." Because "a large proportion" (46%) of colonoscopies reveal no polyps, CMS said, optimizing the use of a noninvasive test "would benefit the patient and also the Medicare program."

"In many instances," CMS continued, "a colonoscopy is not the most appropriate first step in colorectal cancer screening and would represent an unnecessary burden and overservicing for both the patient and the health care system."

When the company receives a prescriber's order for the test, it contacts the patient to verify the patient's address and ask the patient to return the test kit promptly. Reminders are sent by various means, including automated and nonautomated phone calls, text messages and emails. Despite the reminders, more than 30% of patients fail to return the text kit for analysis.

Details of the gift card program. Under the arrangement proposed by the company, patients who had not returned the test kit after two reminders would receive a letter between two weeks and 180 days after the patient receives the kit. The letter would state that if the patient returns the kit within a period of time stated in the letter, the patient will receive a prepaid gift card with a value of up to $75. The program would set the gift card value at the lowest amount that significantly improves patient compliance with returning the test kit to the laboratory. The gift card could not be redeemable for or convertible into cash.

Each patient would be limited to receiving one gift card every 36 months — a time period that aligns with Medicare's coverage of the test once every three years.

Apart from the letter, the company "would not engage in any patient-focused promotion of the proposed arrangement such as direct-to-consumer advertisements on third-party websites or advertisements in newspapers, on television or radio, or in magazines." Nor would the company advertise or market the gift card program to prescribers.

Beneficiary Inducements CMP analysis. The OIG concluded that the gift card program would implicate the Beneficiary Inducements CMP statute because the company would offer and transfer remuneration to federal health care program beneficiaries, and the gift card would be likely to influence patients to receive the laboratory's services.

However, the OIG said, the program would not subject the company to sanctions under the Beneficiary Inducements CMP because the statute's preventive care exception would apply, for the following reasons:

- The company would offer the gift card to promote the laboratory's services in connection with the test, which is a clinical service described in the current United States Preventive Services Task Force "Guide to Clinical Preventive Services."

- The gift card could not be converted into cash and "in this particular case" would not be disproportionately large in relationship to the value of the preventive care service.

- Although the test may result in beneficiaries obtaining additional services, such as a colonoscopy, the test would not be tied, directly or indirectly, to the provision of those additional services.

Anti-Kickback Statute analysis. The gift card program would implicate the Anti-Kickback Statute, the OIG said, because the company would offer and pay remuneration to induce the patient to return the kit to the laboratory, resulting in the purchase of laboratory services reimbursable by federal health care programs.

The OIG said that it has long-standing concerns about remuneration that could:

- influence a beneficiary's choice of a provider, supplier, item or service;

- create incentives for providers and suppliers to offset the additional costs attributable to any remuneration given to beneficiaries by providing unnecessary or subpar service; or

- favor providers and suppliers with greater financial resources over smaller entities.

"From an anti-kickback perspective," the OIG said, "the chief concern is whether an arrangement to induce patients to obtain preventive care services is intended to induce other business payable by a federal health care program." Factors to be considered with respect to this concern include:

- the nature and scope of the preventive care services;

- whether the services are tied directly or indirectly to the provision of other items or services and, if so, the nature and scope of the other services;

- the basis on which patients are selected to receive the free or discounted services; and

- whether the patient can afford the services.

For the following reasons, the OIG concluded that the gift card program "presents a minimal risk of fraud and abuse under the federal Anti-Kickback Statute."

- The program "is unlikely to lead to improperly increased costs to federal health care programs or overutilization of federally reimbursable services." The manufacturer would not offer any incentives to prescribers in connection with the program, and a prescriber would not be able to anticipate whether the company would offer or provide a gift card to any patient for whom the prescriber orders the test. Consequently, the program is unlikely to influence a prescriber to order the test in lieu of not ordering a test or ordering another screening test or procedure. Also, the test is reimbursed at a fixed rate regardless of whether the gift card is provided to a patient, thereby precluding the company from inappropriately increasing costs to federal health care programs by directly or indirectly passing on the costs associated with the gift cards to those programs.

- The gift card program would promote patient compliance with the screening test. The OIG said that it recognized that the sample collection mechanism "may be of a type where the gift card would be necessary to encourage some patients to return the kit."

- Safeguards in the gift card program reduce the risk of fraud and abuse. For example, no patient would be offered or provided a gift card if the patient had received a gift card from the company within the previous 36 months; apart from through the letter offering the gift card, the company would not promote the gift card program; the program would not be advertised or marketed to prescribers; the company would not offer to pay prescribers any remuneration in connection with the program; and the program would not apply where the test is ordered by prescribers through the company's website.

"These safeguards, in combination with all of the other factors already discussed, evidence that the proposed arrangement would provide an incentive to encourage legitimate cancer screening services, and likely would not encourage medically unnecessary services or improper utilization of the test," the OIG said.

The office added, "We appreciate that the gift card may present the opportunity for patients to receive valuable remuneration that could induce them to purchase federally reimbursable services and caution that it any of the foregoing facts were different, we likely would reach a different conclusion with respect to the risk presented by this type of arrangement."

Supreme Court Eliminates 'Objectively Reasonable' View of a Legal Duty as a False Claims Act Defense

In a unanimous decision, the U.S. Supreme Court on June 1, 2023, held that an essential element of liability under the federal False Claims Act — the defendant's knowledge of a claim's falsity — depends on whether the defendant believed that its claim for reimbursement was false, not on whether the defendant had acted using an "objectively reasonable" interpretation of the law or regulation at issue (*United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391 (2023)).

The Court's opinion, written by Associate Justice Clarence Thomas, rejected the argument — frequently seen in recent False Claims Act cases — that even if a defendant knew that a reimbursement claim that it submitted to the government was false or fraudulent, there was no liability under the False Claims Act if a legal requirement underpinning the claim was ambiguous in such a way that an objectively reasonable person could have believed that the claim was not false.

Medicare, Medicaid claims at issue. In two cases consolidated by the Court, two pharmacy chains — SuperValu and Safeway — had reacted to their competitor Walmart's offer, beginning in 2006, to offer 30-day supplies of many drugs for $4.

The two companies adopted price-match programs under which they would match a competitor's lower price at a customer's request. SuperValu pharmacies then would automatically apply the lower price to future refills of the drug for the customer. SuperValu continued the program until 2016. Safeway instead adopted a membership discount program under which customers could receive discounted generic drug prices, often $4 for a 30-day supply. Safeway's program continued until 2015.

For at last some years during the programs' operations, the discounted prices provided under the two programs allegedly constituted a majority of the companies' sales for many drugs to customers who paid with cash rather than through insurance.

The issue before the Supreme Court arose from the claims for reimbursement that the two companies submitted to the Medicare and Medicaid programs for the discounted drugs.

Qui tam relators who sued the two companies under the False Claims Act alleged that the two companies overcharged Medicare and Medicaid for years when they sought reimbursement from the health care programs for prescription drugs that their discount programs covered.

Dispute over "usual and customary" prices. When the two pharmacy chains submitted reimbursement claims to Medicare and Medicaid, they often were required to disclose their "usual and customary" prices for the drugs to the health care programs. The relators alleged that the two companies reported higher prices to the programs than the prices that they usually and customarily charged to the public through their discount drug programs.

For example, the relators claimed, Safeway charged $10 for 94% of its cash sales for a 90-day supply of a cholesterol drug between 2008 and 2012, yet the company cited prices as high as $108 as the "usual and customary" prices that it reported to Medicare and Medicaid for the drug during that time.

Similarly, the relators alleged, at least at some times and for some drugs, SuperValu made more than 80% of its cash sales at prices below the prices that it disclosed to Medicare and Medicaid as its "usual and customary" prices.

"To be sure," the Court acknowledged, "the phrase 'usual and customary' on its face appears somewhat open to interpretation." However, the Court continued, the whistleblowers contended that both SuperValu and Safeway were notified in 2006 by a pharmacy benefit manager that the phrase referred to their discounted prices, and Safeway received the same message from state Medicaid agencies.

Moreover, the Court reported, "executives at both companies raised concerns about letting state agencies or pharmacy benefit managers find out about their discounted prices." For example, SuperValu executives stated in emails that the discount program was a "stealthy approach" and that they were concerned for the "integrity" of their "U&C price" claims. Similarly, Safeway officials stated, "We may have some issues with U&C," and "If you [match a] price offer, that becomes your usual and customary [price] for that day." Moreover, Safeway employees were warned not to "put any of this in writing to stores because our official policy is we do not match."

The whistleblowers contended that such evidence showed that the companies "thought that their claims were inaccurate yet submitted them anyhow," the Court noted.

"Objectively reasonable" interpretations. The Court explained that two essential elements of a False Claims Act violation are:

• the falsity of the claim; and

• the defendant's knowledge of the claim's falsity (the scienter element).

In SuperValu's case, the district court determined that the company's discounted prices were the "usual and customary" prices for its discounted drugs and that by not reporting them the company submitted Medicare and Medicaid reimbursement claims that were false. However, the district court also held that the company could not have acted "knowingly," and it granted summary judgment to the company.

The appeals court affirmed, holding that the company was entitled to summary judgment because its actions were consistent with an objectively reasonable interpretation of the phrase "usual and customary." According to the appeals court, the phrase could have been understood as referring to its retail prices rather than its discounted prices — even if the phrase, correctly understood, referred to its discounted prices.

In the SuperValu case, the issue before the Supreme Court was: If the company's claims were false and the company actually thought that its claims were false — because it believed that its reported prices were not its actual "usual and customary" prices — then would it have "knowingly" submitted a false claim within the meaning of the False Claims Act? Or was the appeals court correct in saying that SuperValu could not have "knowingly" submitted a false claim unless no hypothetical reasonable person could have thought that its higher reported prices were its "usual and customary" prices?

"Straightforward" answer. "Based on the [False Claims Act's] statutory text and its common law roots," the Court held, "the answer to the question presented is straightforward: The [False Claims Act's] scienter element refers to [the companies'] knowledge and subject beliefs — not to what an objectively reasonable person may have known or believed."

The Court said that the text of the statute (31 U.S.C. §3729(b)(1)(A)) tracks the roots of the scienter element in the common law of fraud, which can include:

• actual knowledge (what the defendant is aware of);

• deliberate ignorance (when a defendant is aware of a substantial risk that its statements are false but intentionally avoids taking steps to confirm the statement's truth or falsity); or

• reckless disregard (when the defendant is conscious of a substantial and unjustifiable risk that its claim is false but submits the claim anyway).

These forms of scienter generally focus on the defendant's lack of an honest belief in the statement's truth, the Court said. The focus is on "what a defendant thought when submitting the false claim — not what the defendant may have thought after submitting it," the Court noted.

Moreover, the Court said, even though the phrase "usual and customary" may be ambiguous on its face, that facial ambiguity alone is not sufficient to preclude a finding that the companies knew that their claims were false.

According to the Court, the appeals court in the SuperValu case "did not hold that [the company] made an honest mistake." In essence, the Court said, the appeals court had held that, because other people might make an honest mistake, the company's subjective beliefs become irrelevant to its scienter.

The Supreme Court could not support this theory.

Three arguments rejected. The Court rejected three arguments presented by the companies:

- The facial ambiguity of the phrase "usual and customary" does not by itself preclude a finding of scienter. Even if the phrase is ambiguous, the companies could have learned its correct meaning, and the relators argued that the companies did receive notice that the phrase referred to their discount prices, understood those notices, and yet tried to hide their discounted prices from Medicare and Medicaid.

- The definitions of "knowing" and "reckless" in the Fair Credit Reporting Act (FCRA), as interpreted by the Supreme Court, were inapplicable because that statute had a different mens rea standard. In addition, the Court's decision interpreting the FCRA did not set forth the purely objective safe harbor that the two pharmacy companies sought.

- The companies argued that their conduct did not create liability according to the common law incorporated into the False Claims Act because common law fraud does not encompass misrepresentations of law. If their reimbursement claims were false only because their falsity turned on the meaning of "usual and customary," the companies argued, their claims could be false only as misrepresentations of the law — and such misrepresentations do not amount to common law fraud. Countering this argument, the Court said that the companies in fact had not made a pure misrepresentation of law (saying, for example, "this is what 'usual and customary' means). Instead, the Court said, they had made statements that implied facts about their prices, essentially saying, "This is what our 'usual and customary' prices are." In this way, the companies in fact made out a valid fraud theory even under this view of the common law.

The Supreme Court vacated the lower court rulings in favor of the companies and remanded the two cases.

Court Triples False Claims Damages Against Lilly to Nearly $194 Million in Medicaid Rebate Case

In May 2023, a federal district court in Illinois tripled the damages of more than $61 million awarded by a jury in 2022 against drug maker Eli Lilly and Co. after finding the company liable under federal and state false claims acts for underpaying the rebates the company owed to state Medicaid programs (*United States ex rel. Streck v. Takeda Pharmaceuticals America, Inc.*, No. 1:14-cv-09412 (N.D. Ill.)).

The U.S. District Court for the Northern District of Illinois set the false claims trebled damages at more than $183.2 million. The court also awarded per claim civil penalties of more than $9.8 million based on the jury's findings and more than $886,000 in prejudgment interest.

Background. In November 2014, Ronald J. Streck filed a qui tam complaint in the district court alleging that more a dozen pharmaceutical manufacturers had defrauded the federal government by underpaying the rebates that they were required to pay under the Medicaid Drug Rebate Program. The DOJ declined to intervene in the case in January 2018.

Streck is a lawyer and pharmacist who worked for six years as the president and CEO of a network representing a group of regional drug wholesalers. In this capacity, he negotiated the terms of agreements between drug manufacturers and the drug wholesalers represented by the network. Streck also has served as the president and CEO of the Healthcare Distribution Management Association, now the Healthcare Distribution Alliance.

An amended complaint filed by Streck in September 2018 alleged that Eli Lilly had knowingly reported materially inaccurate Average Manufacturer's Price (AMP) data to CMS in order to lower the amount of rebates it was required to pay to state Medicaid programs.

Manufacturers must include all price increases in AMP, regardless of when they occur, the amended complaint asserted. When prices rise, so does the AMP — resulting in higher Medicaid rebate obligations for manufacturers. However, payments by manufacturers to wholesalers for bona services are excluded from AMP.

"Thus," Streck alleged, "to the extent a manufacturer can disguise a price increase by hiding it within its own self-serving contractual definition of 'service fee," the price increase will not cause the manufacturer's reported AMP — and its consequent rebate obligations to the [state Medicaid programs] — to rise."

Alleged handling of retroactive price increases. The relator alleged that Lilly disguised retroactive price increases by hiding them through "price appreciation" clauses in its service agreements with wholesalers.

"When Lilly increased its prices on a particular drug," Streck said, "the service fee owed by … Lilly to the wholesaler was lowered by the amount of the wholesaler's units in inventory of that drug, multiplied by the amount of the price increase. Thus, when Lilly raised the price of a drug, that price increase applied retroactively to the wholesaler's inventory, even though the wholesaler previously purchased that inventory at a lower price."

"Through the 'price appreciation' artifice," Streck said in the amended complaint, "Lilly disguised the revenue it received from its own price increase as a service fee. Specifically, Lilly retroactively raised the price of its products and then reduced the service fee by the amount of the price increase, dollar for dollar. But Lilly did not include this additional revenue in AMP."

"Lilly disguised post-initial-sale price increases by including them in its self-serving definition of service fee," the relator alleged. "This led to a reduction in the service fee by the amount of the price increase, rather than an increase in AMP by the amount of the price increase, thus providing Lilly with a convenient, but illegal, method to exclude price increases from its AMP calculations."

Jury award. In August 2022, a jury found in favor of Streck and ordered Eli Lilly to pay $61,229,217 in actual damages to the federal government and the Medicaid programs of 27 states and the District of Columbia.

Later that month, the relator filed a motion to amend the judgment entered by the court on the verdict. The motion sought trebled damages under the False Claims Act, prejudgment and post-judgment interest, and "maximum civil penalties."

The False Claims Act specifies that a defendant is liable for three times the amount of damage to the government because of the defendant's violative act (31 U.S.C. §3729(a)).

Damages amendments. In a May 9 memorandum opinion and order, the district court granted the relator's motion for triple damages under the false claims acts, increasing the amount of damages to $183,687,651.

The court denied Streck's motion for prejudgment interest under the federal False Claims Act but

granted prejudgment interest for claims rendered under the false claims acts of Texas and Louisiana, which include provisions expressly providing prejudgment interest.

The district court also awarded the relator post-judgment interest for his federal and state claims.

With respect to civil penalties, the court found that a civil penalty of 20% above the statutory minimum was appropriate for each offense under the false claims acts. On the basis of the 52 federal violations and 1,199 state violations found by the jury, the court determined that Eli Lilly owed $9,838,992 in civil penalties.

In June 2023, the court reduced the jury's award by $147,364 after the relator declined to consent to a remittitur (a correction to the previous award) in that amount that was previously ordered by the court. The relator asked for the reduction because he was concerned that accepting the remittitur could amount to a waiver of any possible future challenge to the overall judgment.

Streck has brought a series of false claims suits against drug companies alleging underpayments of the Medicaid rebates that they owed, including a suit against Bristol-Myers Squibb Co. that resulted in a $75 million settlement, a suit against AstraZeneca L.P. that resulted in a $46.5 million settlement, and a suit against Cephalon Inc. that resulted in a $7.5 million settlement. According to Streck's attorneys, his lawsuits have recovered more than $350 million for the Medicaid program.

Teva Denied Summary Judgment in Kickback, False Claims Case Over Funding of Medicare Drug Co-Pays

Following a July 14 ruling by a federal district court in Massachusetts, Teva Pharmaceuticals USA Inc. faced trial on the government's allegations that the drug maker violated the Anti-Kickback Statute and the False Claims Act in connection with co-pay subsidies that the company paid to Medicare beneficiaries through two contracted vendors and two foundation-operated PAPs (*United States v. Teva Pharmaceuticals USA, Inc.*, No. 1:20-cv-11548-NMG, 2023 U.S. Dist. LEXIS 122272, 2023 WL 4565105 (D. Mass. July 14, 2023)).

Teva estimated that the measure of damages adopted by the district court could result in "a devastating verdict" against the company of between $7.5 billion and $11.8 billion.

In a 16-page memorandum and order, the U.S. District Court for the District of Massachusetts granted a motion for partial summary judgment filed by the DOJ and denied a motion for summary judgment filed by Teva on the issues of materiality, causation and damages.

A trial in the case was scheduled to begin on Sept. 18. However, the court granted Teva's motion to certify for interlocutory appeal a key issue in the case.

DOJ allegations. According to the DOJ, Teva violated the Anti-Kickback Statute and caused the submission of false reimbursement claims to Medicare in violation of the False Claims Act by knowingly and willingly paying program beneficiaries' co-pays for the company's multiple sclerosis drug Copaxone.

The company allegedly made the payments through the specialty pharmacy Advanced Care Scripts Inc. (ACS), which was paid to help Medicare patients obtain Part D prescription drug coverage and to enroll them in co-pay PAPs. ACS referred the patients to two foundations, Chronic Disease Fund (CDF) and The Assistance Fund (TAF), which operated PAPs providing Copaxone co-pay assistance. Teva also allegedly funded beneficiaries' co-pays through AssistRx Inc., which helped enroll Copaxone patients in TAF's PAP.

Between December 2006 and January 2017, the DOJ alleged, Teva donated more than $350 million to CDF and TAF to cover the co-pays. During that time, Teva raised the wholesale acquisition cost of Copaxone from about $17,000 per year to more than $85,000 per year — an increase that was nearly 20 times the rate of inflation.

According to the government, Teva paid the co-pays with the intention of inducing the submission of Copaxone reimbursement claims to Medicare.

Causation. In its motion for summary judgment, Teva argued that the government could not prove that a kickback was the "but for" cause of any particular false claim — saying that there was no evidence that but for Teva's donations to CDF and TAF any Copaxone claims submitted to Medicare that were funded by the foundations would not have been submitted.

The DOJ offered various kinds of evidence to establish causation, including evidence that Teva intended to induce Copaxone prescriptions to be filled and that Medicare beneficiaries taking Copaxone told Teva that they needed financial assistance to be able to afford the drug. The department also cited Teva employee emails and other documents allegedly showing that Teva knew that it would have lost Copaxone sales if it did not provide the co-pay assistance.

In addition, a government data analysis expert identified 345,790 Medicare claims for Copaxone totaling $1.49 billion that were paid by the health care program for patients who were referred by Teva to ACS or AssistRx and enrolled for CDF or TAF assistance by ACS or AssistRx following Teva payments to the foundations.

"Resolving every doubt in favor of the government as a nonmoving party and construing the evidence in the light most favorable to it," the district court said, "the factual evidence is more than sufficient to withstand Teva's summary judgment motion on the issue of causation."

The government had established evidence of "a sufficient causal connection" between Teva's payments to CDF and ATF and the resulting claims for reimbursement submitted to Medicare for Copaxone, the court concluded.

"Knowingly," "Willfully." Teva also sought summary judgment on the basis of its contention that the government had failed to show that its officers and employees had acted "knowingly" to violate the False Claims Act or "willfully" to violate the Anti-Kickback Statute — i.e., to show that the officials had acted with the scienter required under the statutes.

Acting "knowingly" under the False Claims Act, the court noted, means that the person:

- has "actual knowledge of the information";

- "acts in deliberate ignorance of the truth or falsity of the information"; or

- "acts in reckless disregard of the truth or falsity of the information" (31 U.S.C. §3729(b)(1)(A)).

The defendant in a False Claims Act case must have acted voluntarily and deliberately, rather than by mistake or accident or even negligently, the court said.

The Anti-Kickback Statute scienter element is harder to establish, the court said. To establish a violation of the Anti-Kickback Statute, the defendant must have acted both knowingly and willfully. Under First Circuit precedent, to act willfully is "to do something purposely, with the intent to violate the law, to do something purposely that law forbids" (*United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, 874 F.2d 20 (1st Cir. 1989)).

The court noted that deposition testimony confirmed that Teva employees "knew the [Anti-Kickback Statute] prohibited Medicare patients from participating in [PAPs]." A 2010 legal analysis sent from CDF's president to Teva stated, "As a threshold matter, any knowing payments by a pharmaceutical manufacturer or other provider to satisfy a federal health care program enrollee's cost-sharing obligations would almost certainly violate [the Anti-Kickback Statute]."

In addition, in May 2012 a Teva employee circulated a law firm presentation titled "Legal Considerations in Developing Patient Assistance Programs" that stressed that "PAPs present all of the usual risks of fraud and abuse associated with kickbacks, [and] the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients."

The record cited in the parties' statements of facts, the court said, "demonstrate[s] that the government has gathered sufficient [additional] evidence to defeat Teva's motion for summary judgment based on a lack of scienter."

Materiality. In its motion for partial summary judgment, the DOJ sought validation of its view that claims submitted to Medicare that include items or services resulting from kickbacks under the Anti-Kickback Statute are per se materially false or fraudulent for purposes of the False Claims Act.

The court agreed with the DOJ. It noted that a 2010 amendment to the Anti-Kickback Statute enacted as part of the Affordable Care Act plainly stated that "a claim that includes items or services resulting from a violation [of the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]" (42 U.S.C. §1320a-7b(g)).

For claims predating the 2010 amendment, the district court said, the First Circuit has stated that the statutory change "essentially codifies the long-standing view that [Anti-Kickback Statute] violations are material in the [False Claims Act] context" (*Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019)).

On this basis, the district court held that "a violation of the [Anti-Kickback Statute] is per se material for [False Claims Act] purposes."

"A sufficient causal connection." In its motion, the government also sought summary judgment on the legal standard for False Claims Act causation for claims "resulting from" Anti-Kickback Statute violations under the 2010 amendment.

Citing First Circuit precedent, the district court held that the DOJ would not have to prove "but for" causation, as Teva had insisted. Rather, it said, under *Guilfoile*, "if there is a sufficient causal connection between an [Anti-Kickback Statute] violation and a claim submitted to the federal government, that claim is false within the meaning of the [False Claims Act]."

Damages. The DOJ also asserted in its motion that the correct measure of damages for its Anti-Kickback Statute-based FCA claims against Teva should be the entirety of the government's expenditures for claims resulting from the illegal kickbacks.

The district court said that it would apply the government's damages standard that it had applied earlier in the litigation.

In a June 2022 order in the case, a federal magistrate judge had pointed to a Seventh Circuit explanation of the basis for its measure of damages for Anti-Kickback Statute-based false claims: "[The defendant] did not furnish any medical service to the United States. The government offers

a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [the defendant] received on these … claims must be paid back" (*United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008)).

"The rationale here," the district court said, "is that the government simply would not have paid those Medicare claims had it known they were submitted in violation of certain Medicare requirements such as the [Anti-Kickback Statute] or the Stark Law" (42 U.S.C. §1395nn).

"Thus, the court will measure damages in this case as the entirety of the government's payments for the claims resulting from the illegal kickbacks," the district court held.

Interlocutory appeal allowed. On Aug. 14, the district court granted Teva's motion to certify for interlocutory appeal its July 14 order denying the company's motion for summary judgment.

"Teva contends that the causation standard when a plaintiff seeks to prove falsity by relying on the 2010 amendment to [the AKS] is 'a controlling question of law as to which there is substantial ground for difference of opinion,' and an appeal may 'materially advance the ultimate termination of [this] litigation,'" the district court noted (citing 28 U.S.C. §1292(b)). "The court agrees that certification is warranted."

Teva filed its interlocutory appeal with the U.S. Court of Appeals for the First Circuit on Aug. 23, 2023 (*United States v. Teva Pharmaceuticals USA, Inc.*, No. 23-8028 (1st Cir.)).

V. New DOJ Enforcement Policies

DOJ Toughens Stance on Companies With Histories of Misconduct, Seeks To Encourage Self-Disclosure

In September 2022, Deputy Attorney General Lisa O. Monaco announced a variety of changes in DOJ policies involving corporate criminal enforcement that are important to FDA-regulated companies.

The changes covered by the department's second-ranking official include a call for companies to disclose misconduct by individuals more quickly, a DOJ commitment to developing "a full and fair picture" of a company's past misconduct, more incentives for voluntary self-disclosure of corporate wrongdoing, new policies on independent compliance monitors, and new scrutiny of corporate compensation arrangements.

"Today's announcements are fundamentally about individual accountability and corporate responsibility," Monaco told an audience at the New York University School of Law. "But they are also about ownership and choice."

"Companies should feel empowered to do the right thing — to invest in compliance and culture, and to step up and own up when misconduct occurs," she said. "Companies that do so will welcome the announcements today. For those who don't, however, our department prosecutors will be empowered, too — to hold accountable those who don't follow the law."

Individual responsibility. Monaco first reiterated "that the department's number one priority is individual accountability …. We will hold those who break the law accountable, regardless of their position, status, or seniority."

Despite recent convictions of high corporate officials, she said, "we cannot ignore the data showing overall decline in corporate criminal prosecutions over the last decade. We need to do more and move faster."

Consequently, Monaco said, “we will require cooperating companies to come forward with important evidence more quickly.”

She criticized companies that for strategic reasons “delay the disclosure of critical documents or information while they consider how to mitigate the damage or investigate on their own.”

“Delayed disclosure undermines efforts to hold individuals accountable,” she stressed. “It limits the department’s ability to proactively pursue leads and preserve evidence before it disappears. As time goes on, the lapse of statutes of limitations, dissipation of evidence, and the fading of memories can all undermine a successful prosecution.”

Because “in individual prosecutions, speed is of the essence,” she said, “undue or intentional delay in producing information or documents — particularly those that show individual culpability — will result in the reduction or denial of cooperation credit.”

“Gamesmanship with disclosures and productions will not be tolerated,” Monaco said.

Remarkably, she suggested that “if a cooperating company discovers hot documents or evidence, its first reaction should be to notify the prosecutors.”

This new requirement, she noted, is “in addition to prior guidance that corporations must provide all relevant, nonprivileged facts about individual misconduct to receive any cooperation credit.”

Monaco also announced that DOJ prosecutors will work to complete investigations of individuals and seek any warranted criminal charges against them “prior to or at the same time as entering a resolution against a corporation.” If “it makes sense” to resolve a corporate case first, she added, “there must be a full investigative plan outlining the remaining work to do on the individual cases and a timeline for completing that work.”

History of misconduct. Monaco also announced new guidance on the DOJ’s commitment, announced in October 2021, “to consider the full criminal, civil and regulatory record of any company when deciding the appropriate resolution."

She said that the additional guidance responds to recommendations received in the wake of that announcement on “how to contextualize historical misconduct” and “to develop a full and fair picture of the misconduct and corporate culture under review.”

First, she said, “not all instances of prior misconduct are created equal.” Consequently, in the DOJ’s view, “the most significant types of prior misconduct will be criminal resolutions here in the United States” and “prior wrongdoing involving the same personnel or management as the current misconduct.”

Moreover, “dated conduct” — generally, criminal resolutions that occurred more than 10 years before the conduct currently under investigation, and civil and regulatory resolutions that took place more than five years before the current conduct — “will generally be accorded less weight.”

Monaco added that the DOJ will consider the nature and circumstances of the prior misconduct, including “whether it shared the same root causes as the present misconduct.” For example, she said, “if a corporation operates in a highly regulated industry, its history should be compared to others similarly situated, to determine if the company is an outlier.”

Also, she said, with respect to corporate acquisitions, the department "will not treat as recidivists companies with a proven track record of compliance that acquire companies with a history of compliance problems" — as long as those problems are "promptly and properly" addressed following the acquisition.

"I want to be clear that this department will disfavor multiple, successive non-prosecution or deferred prosecution agreements," Monaco added. Before DOJ prosecutors extend an offer for a successive non-prosecution or deferred prosecution agreement, she noted, "department leadership will scrutinize the proposal," and companies cannot assume that they are entitled to such agreements, "particularly when they are frequent flyers."

"If any corporation still thinks criminal resolutions can be priced in as the cost of doing business," she said, "we have a message: times have changed."

Incentives for voluntary self-disclosure. "The clearest path for a company to avoid a guilty plea or an indictment is voluntary self-disclosure," Monaco stressed, and the DOJ's goal is "to reward those companies whose historical investments in compliance enable voluntary self-disclosure and to incentivize other companies to make the same investments going forward."

"For the first time ever," she announced, "every department component that prosecutes corporate crime will have a program that incentivizes voluntary self-disclosure. If a component currently lacks a formal, documented policy, it must draft one."

The programs — like the DOJ Criminal Division's voluntary disclosure program for FCPA violations and other voluntary self-disclosure programs already in place in the department — "must provide clear expectations of what self-disclosure entails. And they must identify the concrete benefits that a self-disclosing company can expect."

The programs are to have two "common principles" for all participants, Monaco said:

- Absent aggravating factors, the DOJ will not seek a guilty plea when a company has voluntarily self-disclosed, cooperated and remediated misconduct.

- The department will not require an independent compliance monitor if, at the time of the resolution, the company has implemented and tested an effective compliance program.

She stressed that voluntary self-disclosure "can save a company hundreds of millions of dollars in fines, penalties and costs. It can avoid reputational harms that arise from pleading guilty. And it can reduce the risk of collateral consequences like suspension and debarment in relevant industries."

"I expect that resolutions over the next few months will reaffirm how much better companies fare when they come forward and self-disclose," Monaco predicted.

Independent compliance monitors. Monaco also announced that the DOJ is responding to calls for "more transparency to reduce suspicion and confusion" about the department's use of independent compliance monitors.

The DOJ, she said, will provide "new guidance for prosecutors about how to identify the need for a monitor, how to select a monitor, and how to oversee the monitor's work to increase the likelihood of success."

Also, she said, from now on "all monitor selections will be made pursuant to a documented selection process that operates transparently and consistently."

Moreover, she stated, DOJ prosecutors will ensure that the scope of every monitorship "is tailored to the misconduct and related compliance deficiencies of the resolving company." The prosecutors will get regular updates "to verify that the monitor stays on task and on budget."

Corporate culture and compensation systems. Finally, Monaco announced that when DOJ prosecutors evaluate a company's compliance program, "they will consider whether its compensation systems reward compliance and impose financial sanctions on employees, executives or directors whose direct or supervisory actions or omissions contribute to criminal conduct."

Part of the scrutiny, she said, will specifically focus on "whether, after learning of misconduct, a company actually claws back compensation or otherwise imposes financial penalties."

"An increasing number of companies are choosing to reflect corporate values in their compensation systems," she noted. "On the deterrence side, those companies employ clawback provisions, the escrowing of compensation, and other ways to hold financially accountable individuals who contribute to criminal misconduct."

Monaco said that the DOJ Criminal Division will develop guidance by the end of 2022 on "how to reward corporations that employ clawback or similar arrangements," including "how to help shift the burden of corporate financial penalties away from shareholders, who frequently pay no role in misconduct, onto those more directly responsible."

New DOJ Criminal Division Policy Offers Additional Incentives To Self-Disclose Wrongdoing

In January 2023, the DOJ's Criminal Division took steps to provide what the head of the division called "new, significant and concrete incentives" to encourage corporations to self-disclose violations of federal law.

The shift in policy, announced by Assistant Attorney General Kenneth A. Polite Jr., was a response to the DOJ's directive — announced in September 2022 by Deputy Attorney General Monaco — calling for each component of the department that prosecutes crime to develop a program that incentivizes voluntary self-disclosure.

Background. Polite noted that the Criminal Division established a voluntary self-disclosure policy in November 2017 following a pilot program designed to encourage self-disclosure during the course of prosecutions involving alleged violations of the FCPA. The FCPA Corporate Enforcement Policy (CEP) was subsequently incorporated into the department's Justice Manual.

Speaking at the Georgetown University Law Center in Washington, D.C., Polite said that the reforms being undertaken by his component of the DOJ were "the first significant changes to the Criminal Division's CEP since 2017." The changes, he said, apply "to all corporate criminal matters handled by the Criminal Division, including all FCPA cases nationwide."

"These revisions provide specific, additional incentives to companies for voluntary self-disclosures as well as for cooperation and remediation," Polite said. "The revisions make clear that there will be very different outcomes for companies that do not self-disclose, meaningfully cooperate with our investigators, or remediate."

New declination possibilities. Polite noted that in some situations companies that have identified potential wrongdoing and are considering self-disclosing the conduct to the DOJ are concerned that an aggravating factor may emerge during the course of the investigation, thereby preventing the possibility that the department would decline to prosecute.

"That concern may have led companies and their outside counsel to conclude, under the prior version of the CEP, that it is more prudent not to disclose the misconduct," he noted.

The revised CEP, Polite said, "presents another path for companies facing such a choice — a path that incentivizes even more robust compliance on the front end to prevent misconduct and requires even more robust cooperation and remediation on the back end if a crime occurs."

Under the new policy, even if aggravating circumstances are present — meaning that a company will not qualify for a presumption of a declination — prosecutors may nevertheless determine that a declination is appropriate if the company can demonstrate that it has satisfied three conditions:

- the voluntary self-disclosure was made immediately upon the company being made aware of the allegation of misconduct;

- at the time of the misconduct and the disclosure, the company had an effective compliance program and a system of internal accounting controls that enabled the identification of the misconduct and led to the company's voluntary self-disclosure; and

- the company provided extraordinary cooperation with the DOJ's investigation and undertook extraordinary remediation.

Incentives even when a criminal resolution is warranted. Even if a company cannot overcome the aggravating factors and so cannot receive a declination with disgorgement, the new CEP still offers incentives for self-disclosure.

Specifically, Polite said, if a company voluntarily self-discloses misconduct, fully cooperates, and timely and appropriate remediates, but a criminal resolution is still warranted, the Criminal Division "will now accord, or recommend to a sentencing court, at least 50% and up to 75% off of the low end of the U.S. Sentencing Guidelines fine range, except in the case of a criminal recidivist." For a recidivist, the reduction "will generally not be from the low end of the fine range."

Moreover, "in all cases, prosecutors will have discretion to determine the starting point within the Guidelines range."

Polite noted that this change "represents a significant increase from the previous potential maximum reduction of 50% off the Guidelines range" — "twice the maximum amount of a reduction available under the prior version of the CEP."

In these circumstances, the Criminal Division "will generally not require a corporate guilty plea — including for corporate recidivists — absent multiple or particularly egregious aggravating circumstances." Criminal recidivism, "while relevant and important," will not by itself "always mean a plea."

This policy, Polite said, applies to all Criminal Division corporate resolutions, not only voluntary self-disclosure cases. Even where there is no self-disclosure, the new policy will give federal prosecutors "a greater range of options to distinguish among companies that commit crime."

In all cases, Polite said, "prosecutors will have discretion to determine the specific percentage reduction and starting point in the range based on the particular facts and circumstances."

Qualifying for the new policy. "Each and every company starts at zero cooperation credit and must earn credit based on the parameters and factors outlined in the CEP," Polite said. "This is not a race to the bottom. A reduction of 50% will not be the new norm; it will be reserved for companies that truly distinguish themselves and demonstrate extraordinary cooperation and remediation."

As to what constitutes "extraordinary" and "full" cooperation, Polite said that "some concepts — immediacy, consistency, degree, and impact — that apply to cooperation by both individuals and cooperations … will help to inform our approach to assessing what is 'extraordinary.'"

"In many ways," Polite told the Georgetown University audience, "we know 'extraordinary cooperation' when we see it, and the differences between 'full' and 'extraordinary' cooperation are perhaps more in degree than kind."

To qualify for "extraordinary cooperation," he said, "companies must go above and beyond the criteria for full cooperation set in our policies — not just run-of-the-mill, or even gold standard cooperation, but truly extraordinary."

"This policy," Polite said, "is sending an undeniable message: Come forward, cooperate, and remediate. We are going to be closely examining how companies discipline bad actors and reward the good ones."

"Our number one goal in this area — as we have repeatedly emphasized — is individual accountability," he noted. "And we can hold accountable those who are criminally culpable — no matter their seniority — when companies come forward and cooperate with our investigation."

DOJ To Require Compliance-Related Criteria in Compensation Programs as Part of Criminal Resolutions

In March 2023, the DOJ established a three-year pilot program intended to reward corporations that incentivize compliance as part of their compensation programs, including through the use of clawback policies.

According to the DOJ, one goal of the pilot program is to explore "how policies may seek to potentially shift the burden of corporate financial penalties away from shareholders — who in many cases do not have a role in misconduct — onto those more directly responsible."

Using compensation to encourage compliance. The pilot program was announced by Deputy Attorney General Monaco, who in September 2022 announced that the DOJ would examine how to encourage compliance through corporate compensation programs.

Monaco told an audience at a Miami meeting of the American Bar Association National Institute on White Collar Crime that "every corporate resolution involving the Criminal Division will now include a requirement that the resolving company develop compliance-promoting criteria within its compensation and bonus program."

Moreover, she noted, the Criminal Division "will provide fine reductions to companies who seek to claw back compensation from corporate wrongdoers."

"At the outset of a criminal resolution," she said, "the resolving company will pay the applicable fine minus a reserved credit equaling the amount of compensation the company is attempting to claw back from culpable executives and employees."

"If the company succeeds and recoups compensation from a responsible employee," she continued, "the company gets to keep that clawback money — and also doesn't have to pay the amount it recovered."

Even where a company in good faith pursues a clawback but is unsuccessful, she said, the company is "still eligible to receive a fine reduction."

The program is intended "to encourage companies who do not already factor compliance into compensation to retool their programs and get ahead of the curve," Monaco said.

Fostering a culture of compliance. Elaborating on the pilot program, Assistant Attorney General Polite told the ABA audience, "Compensation structures that clearly and effectively impose financial penalties for misconduct can deter risky behavior and foster a culture of compliance."

"At the same time," he added, "positive incentives, such as promotions, rewards and bonuses for improving and developing a compliance program or demonstrating ethical leadership, can drive compliance."

The pilot program was launched with these principles in mind, he said.

Compliance enhancements. According to a detailed DOJ description of the pilot program, beginning March 15, 2023, when the pilot program went into effect, every corporate resolution entered into by the DOJ's Criminal Division will require that the company "implement criteria related to compliance with its compensation and bonus program."

During the term of the resolution, the company will be required to report to the Division annually about the implementation of the criteria.

The criteria may include:

- a ban on bonuses for employees who do not satisfy compliance performance requirements;
- discipline of employees who violate the law, as well as discipline of others (a) who had supervisory authority over the employees or business areas engaged in the misconduct and (b) who knew of or were blind to the misconduct; and
- incentives for employes who demonstrate "full commitment to compliance processes."

Prosecutors "will use their discretion in fashioning the appropriate requirements based on the particular facts and circumstances of the case," the department said, including applicable U.S. and foreign law. "In making this determination," the department said, "prosecutors will be mindful of, and afford due consideration to, how the company has structured its existing compensation program."

Fine reductions. In cases where a criminal resolution is called for, if a company "fully cooperates and timely and appropriately remediates" and demonstrates that before the time of the resolution it had implemented a program to recoup compensation from employee wrongdoers and their responsible supervisors that is consistent with the compliance-related compensation criteria, "an additional fine reduction may be warranted," the DOJ said.

In such circumstances, in addition to any other applicable reduction, federal prosecutors will reduce the criminal fine in the amount of 100% of compensation that is recouped during the period of the resolution. Any applicable restitution, forfeiture, disgorgement or other agreed-upon payment by the company will not be affected.

Specifically, the company will be required to pay the otherwise applicable fine reduced by 100% of the amount of compensation that the company is attempting to claw back (the "possible clawback reduction").

At the end of the resolution period, if the company has not recouped the full amount of compensation that it sought to claw back, the company will be required to pay the amount that it attempted to claw back minus 100% of the compensation actually recovered.

Even if a company's good-faith attempt to recover the compensation is unsuccessful, Criminal Division prosecutors may in their discretion "accord a reduction of up to 25% of the amount of compensation the company attempted to claw back — such that the company must at the conclusion of the resolution term make an additional fine payment of the possible clawback reduction less the determined reduction percentage of the compensation sought."

Such a reduction may be appropriate, the DOJ said, where, for instance, a company has incurred significant litigation costs for shareholders or can demonstrate that it is highly likely that it will successfully recoup the compensation shortly after the end of the resolution term.

VI. Preemption

Ninth Circuit: Manufacturer Cannot Sue To Stop Compounder From Producing Purported Copy of Drug

A drug manufacturer could not sue under the unfair trade practices laws of several states to block a drug compounder from producing a purported copy of the manufacturer's product, a federal appeals court held in September 2022, because the manufacturer's claims were impliedly preempted and would violate an FD&C Act provision barring private enforcement of the federal statute's requirements (*Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022)).

Nexus Pharmaceuticals Inc. developed the FDA-approved drug Emerphed, a ready-to-use ephedrine sulfate product provided in a 5-milligram-per-milliliter vial. The drug is used to raise blood pressure immediately if an anesthetized surgical patient's blood pressure falls to a dangerously low level.

Central Admixture Pharmacy Services Inc., a drug compounder registered with the FDA as an outsourcing facility under the Drug Quality and Security Act of 2013 (DQSA) (21 U.S.C. §353b), produced ephedrine sulfate that was pre-loaded into ready-to-use syringes. The product had not been approved by the FDA but was produced under the drug compounding provisions of the DQSA.

Outsourcing facilities. Under the statute, which is part of the FD&C Act, registered outsourcing facilities meeting certain requirements can compound on a large scale and without patient-specific prescriptions. However, to prevent outsourcing facilities from producing generic drugs that are not approved by the FDA, the DQSA bars them from producing any compounding drug that is "essentially a copy of one or more approved drugs."

In August 2020, Nexus alleged in a complaint filed in the U.S. District Court for the Central District of California that the compounder violated this provision by producing its version of ephedrine sulfate. However, evidently to avoid the FD&C Act's prohibition against private enforcement of its requirements (21 U.S.C. §337(a)), Nexus did not sue under the FD&C Act but rather alleged that the compounder had violated consumer protection laws of California, Florida, Connecticut, Pennsylvania and Arizona, which prohibit the sale of drugs that are not approved by the FDA. The manufacturer sought an injunction, declaratory relief and damages.

The district court dismissed Nexus's suit, holding that because the plaintiff's state law claims "exist only because of the [FD&C Act's] requirements," they were impliedly preempted by federal law. The district court also noted the private enforcement ban in the FD&C Act, under which enforcement of the statute must be "by and in the name of the United States," and held that the determination of whether a compounded drug is "essentially a copy" of an FDA-approved drug must be left to the agency (*Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, No. SACV 20-01506-CJC(JDEx), 2020 U.S. Dist. LEXIS 220759, 2020 WL 6867069 (C.D. Cal. Nov. 18, 2020)).

Implied preemption. The U.S. Court of Appeals for the Ninth Circuit affirmed. Noting that this was the first occasion for the court to interpret 21 U.S.C. §353b, the appeals court affirmed the lower court's holding that Nexus's claims were impliedly preempted by federal law.

The lower court had relied on the Ninth Circuit's decision in Perez v. Nidek, 711 F.3d 1109 (9th Cir. 2013), where the appeals court affirmed the dismissal of a claim that a manufacturer did not warn the class members that the FDA had approved the LASIK procedure only for near-sightedness, not far-sightedness. The Ninth Circuit panel applied the FD&C Act's express preemption provision relating to medical devices (21 U.S.C. §360k(a)). However, the appeals court also held that the claims were impliedly preempted because "private enforcement of the [FD&C Act] is barred" and because the state law claim for fraud by omission "exist[s] solely by virtue of the [FD&C Act]."

Ban on private enforcement of the FD&C Act. "For Nexus to prevail in our case," the appellate panel stated, "it would … have to prove that Central Admixture's drug is 'essentially a copy,' which would amount to litigation of the alleged underlying [FD&C Act] violation even though the FDA has not itself concluded that there was a violation."

"To permit Nexus to proceed with a claim that defendants violated this law when the FDA did not so determine would, in effect, permit Nexus to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make," the Ninth Circuit continued. "Proceedings to enforce or restrain violations of the [FD&C Act], including the compounding statute, must be by and in the name of the United States, not a private party. Nexus's claim is such a proceeding, so it is barred by the exclusive enforcement statute."

"Nexus does not claim harm to a patient, where a traditional common law tort action might provide a remedy to the patient and escape preemption," the appeals court said. "Instead, the claim is that a manufacturer is harmed economically because the defendant violated the [FD&C Act]. The purported state law violation is a law that says in substance, 'comply with the [FD&C Act],' not a traditional common law tort."

"Nexus's theory is that Central Admixture's product is 'essentially a copy' of Emerphed, so it falls outside the exception to the requirement of FDA approval for safety and effectiveness for compounded drugs," the court added.

The appellate panel noted that FDA guidance has addressed the rationale for the "essentially a copy" exclusion, stated that the agency "does not intend to take action" against facilities compounding drugs that are "essentially a copy" of an approved drug that has been discontinued, and reported that the FDA "has plans to issue clarifying regulations on what 'essentially a copy' means."

"The issuance of this and other FDA documents shows that it has been attentive to the difficult issues of interpreting and enforcing the 'essentially a copy' provision," the appeals court continued. "All of Nexus's claims depend on a determination of whether Central Admixture's ephedrine sulphate is 'essentially a copy' of Nexus's Emerphed. The plain text of the [FD&C Act] leaves that determination in the first instance to the FDA's balancing of risks and concerns in its enforcement process."

"Nexus seeks to enforce its interpretation of the 'essentially a copy' exclusion from the outsourcing facilities exception, a task reserved to the FDA," the court concluded. "The prohibition of private enforcement applies squarely, as does implied preemption."

Court: State Law Claims Involving Class II Device Cleared via De Novo Process Not Expressly Preempted

In March 2023, a federal district court in Brooklyn, New York, has held that state law tort claims involving a Class II medical device cleared for marketing by the FDA through the de novo process are not expressly preempted by federal law, even when the agency's clearance of the device is accompanied by a set of special controls that the FDA said should be addressed by future devices of the same type (*Desch v. Merz North America, Inc.*, No. 1:22-cv-02688-HG, 2023 U.S. Dist. LEXIS 57618, 2023 WL 2734671 (E.D.N.Y. March 31, 2023)).

The plaintiff alleged that she was injured by the Ulthera System, a device manufactured by the defendants that used ultrasound to provide a "noninvasive alternative to face lifts." The device originally was cleared for marketing by the FDA as a Class II device for use "to lift the eyebrow."

During the 510(k) clearance process, the agency determined that the device was not substantially equivalent to previously marketed devices. As a consequence, the FDA subjected the device to de novo review. In its clearance of the device, the agency published a "special controls" document with recommendations that future devices of the same type would need to address.

Following the FDA's initial clearance of the device, the manufacturers provided additional submissions to the agency to clear the product to be marketed for other indications, including to lift skin on the neck, lift skin under the chin, and reduce lines and wrinkles on the chest. However, the FDA denied a request that the device be allowed to be marketed for use on "the full face and neck," finding the proposed indication for use not to be acceptable.

Plaintiff's allegations. The plaintiff alleged that the manufacturers' marketing of the device was misleading in several respects:

- The device allegedly was marketed for use on "the entire face," despite receiving a denial of FDA clearance for that indication.

- It allegedly was marketed as "noninvasive," and the manufacturers allegedly downplayed any possible adverse events resulting from the device as "mild and temporary in nature." In reality,

according to the plaintiff, the device had been linked to "permanent nerve injuries" before the plaintiff's treatment, and the manufacturers failed to report adverse events associated with the device to the FDA or to the medical community.

- The manufacturers allegedly marketed the device as "FDA-approved," when in fact the Class II device was cleared rather than approved for marketing by the agency.

In addition, the plaintiff alleged that the manufacturing process that produced the device was defective and that the defect caused the device to "deliver the wrong amount of energy to the wrong locations." According to the plaintiff, the defect resulted from the manufacturers' failure to establish and maintain procedures for implementing CAPAs as mandated by the cGMP requirements of the FDA's quality system regulation (21 C.F.R. §820.100(a)).

The plaintiff alleged that her physician used the device on her full face and that as a result of her treatment she suffered "permanent facial, eye and nerve damage, including significant facial fat atrophy."

In a suit against the manufacturers, she brought causes of action under New York law for breach of express warranty, breach of implied warranty, negligence, strict liability for failure to warn, strict liability for a manufacturing defect, and misrepresentation by omission.

She originally filed her suit in New York state court, but the manufacturers removed the claims to the U.S. District Court for the Eastern District of New York based on diversity jurisdiction. The manufacturers moved to have the complaint dismissed. By consent of the parties, the plaintiff filed an amended complaint, and the manufacturers filed a motion to dismiss the amended complaint.

Express preemption. Ruling on the motion to dismiss, the court determined that express preemption under 21 U.S.C. §360k(a) — which bars a state law claim that would impose an obligation that "is different from, or in addition to, any requirement" under the FD&C Act — did not apply to the manufacturers' device.

Because the product was a Class II device, the court said, "it received less regulatory scrutiny during the FDA clearance process than the types of Class III devices that the Supreme Court has held are subject to express preemption" (*Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)).

The manufacturers argued, however, that express preemption applied to the plaintiff's claims because their device had received de novo review — in their view, a heightened form of review of a Class II device — and resulted in the FDA promulgating special controls providing guidance for the device. According to the manufacturers, the special controls document imposed the type of specific requirements from the FDA that trigger express preemption under 21 U.S.C. §360k(a).

Rejecting the manufacturers' contention, the district court held that the plaintiff's claims were not expressly preempted. "The FDA's special controls document on which [the manufacturers] rely does not impose any specific requirements on the Ulthera System," the court said. "Instead, the document recommends the types of tests that other manufacturers should perform when applying to the FDA for clearance to sell substantially equivalent devices."

"To the extent that the document imposes any requirements at all," the court continued, "it requires [the] defendants (and other manufacturers) to comply with the FDA's general regulations regarding device labeling. Consistent with this interpretation, the only purportedly specific requirements that [the] defendants have attributed to the special controls document are 'specific information in the labeling' required for Ulthera System and similar devices."

Because, as described later in the court's decision, none of the plaintiff's claims that survived the manufacturers' motion to dismiss challenged the adequacy of the companies' label for the Ulthera System, the court said, there was no basis on which to apply express preemption to the plaintiff's claims.

Rulings on plaintiff's claims. However, the court went on to dismiss certain allegations brought by the plaintiff for failure to state a claim.

(1) Alleged manufacturing defect. The court held that the plaintiff's simple allegation that the manufacturers failed to comply with the quality system regulation's CAPA requirements was insufficient "because the purported process failures do not actually identify a supposed manufacturing defect." The plaintiff failed to establish "the necessary link between [the manufacturers'] alleged federal violations and her alleged causes of action because she does not allege how the failure to follow cGMPs led to a defect," the court said. As a result, it determined, the negligence and breach of implied warranty claims were dismissed to the extent that they were based on an alleged manufacturing defect.

(2) Alleged off-label marketing. The court also dismissed the plaintiff's claims to the extent that they were based on the manufacturers' alleged off-label marketing promoting the use of the Ulthera System for the "full face."

Under Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), the court said, "the FDA, rather than private plaintiffs, is responsible for deciding whether to enforce prohibitions related to off-label promotion."

Because she could not use a private cause of action to enforce federal prohibitions against off-label promotion, the court continued, the plaintiff was required to demonstrate that New York law recognized a tort that prohibits off-label promotion. The plaintiff had not provided any legal authority demonstrating that New York law allowed for such a claim, the court said, and the U.S. Court of Appeals for the Second Circuit had stated that "the weight of authority both in this circuit and elsewhere casts doubts on the viability" of state law claims related to off-label marketing of medical devices (*Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433 (2d Cir. 2015)). Consequently, the district court dismissed the plaintiffs' claims to the extent that they relied on the manufacturers' alleged off-label marketing.

(3) Alleged failure to warn the FDA about adverse events. However, the court did not dismiss the plaintiff's claims based on the manufacturers' alleged failure to warn the FDA about adverse events related to use of the Ulthera System.

"Multiple courts in this circuit have held that New York common law would impose liability on a medical device manufacturer for failing to provide the FDA with a warning required by federal law," the court noted. The manufacturers argued that the exact circumstances related to the adverse events associated with the Ulthera System made them nonreportable under the FDA's criteria, but the court determined that "that is a dispute of fact that must be resolved either on summary judgment or at trial."

(4) Alleged failure to warn the medical community. The court also declined to dismiss the plaintiff's claims based on the manufacturers' alleged failure to warn the medical community at large — again because "multiple courts" in the Second Circuit have held that such a failure gives rise to a legally cognizable claim under New York law.

(5) Alleged failure to warn the plaintiff. By contrast, the court dismissed the plaintiff's claims to the extent that they were based on the manufacturers' alleged failure to warn her personally about the risks associated with their device. "Due to New York's learned intermediary doctrine," the court said, "the manufacturer's duty to caution against a treatment's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient."

(6) Alleged false promotion of the device as "FDA-approved." On similar grounds, the court dismissed the plaintiff's claims based on allegations that the manufacturers falsely promoted their device as "FDA-approved." The learned intermediary doctrine required the plaintiff to plead her doctors' reasonable reliance on the manufacturers' alleged misrepresentations rather than her own reliance, the court said. "Unlike a patient," it continued, "any reasonable doctor would have understood that the FDA's review process for Class II devices does not represent 'approval,' so no doctor would have reasonably relied on these alleged misstatements."

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