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Healthcare Fraud Developments

By William F. Gould, Eliot T. Burriss, Nathan A. Adams IV, Gemma R. Galeoto, Jeffrey D. Anderson, David L. Haller, and Andrew I. Namkung*

The authors discuss recent enforcement developments in healthcare.

CONSPIRACY TO COMMIT HEALTHCARE FRAUD CONVICTION OVERTURNED[1]

In *United States v. Merino*,[2] the U.S. Court of Appeals for the Ninth Circuit reversed the conviction of Marina Merino of conspiracy to commit healthcare fraud in violation of 18 U.S.C. § 1349 and eight counts of healthcare fraud in violation of 18 U.S.C. § 1347.

Merino was convicted after a trial in the U.S. District Court for the Central District of California. At trial, the government presented evidence that Merino was employed as a patient recruiter and marketer at a medical clinic. The government alleged that she worked with others fraudulently to bill Medicare for unnecessary services. The government sponsored a cooperating witness at trial, Zoila O'Brien, who, like Merino, was a patient recruiter for a leader of the alleged conspiracy, Robert Glazer.

O'Brien testified that Merino was accepting kickbacks for her recruiting efforts. Notably, O'Brien did not testify that Marino had any knowledge that Glazer was billing Medicare fraudulently, nor did any other witness. There was also evidence that Merino lied to a federal agent, Agent Li, by minimizing her role as Glazer's employee.

The government's Medicare witness, Investigator Person (actual name), spent some time testifying about how detailed and complex the law and regulations are that determine whether a service is "medically necessary." Investigator Person went further, testifying that even Medicare providers "reasonably

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[1] This section was prepared by William F. Gould.

[2] *United States v. Merino*, No. 19-50291 (9th Cir. Feb. 26, 2021).

disagree about what those regulations require." At the time of her trial, Merino was a 62-year-old with no medical training.

The jury convicted Merino. She was sentenced on those convictions to 21 months in prison and three years of supervised release.

In this appeal, Merino argued that there was insufficient evidence to prove that she knew about the fraudulent billing scheme that was organized by two of her alleged codefendants.

The Ninth Circuit reviewed the sufficiency of the trial evidence *de novo*, viewing all evidence in the light most favorable to the prosecution, as is the law. Referring to the evidence as "sparse," the court determined that no rational juror could have concluded that Merino committed conspiracy to commit healthcare fraud beyond a reasonable doubt.

The court began its analysis with *Salinas v. United States*[3] and stated that the prosecution must have proved that Merino intended to pursue the same criminal objective as her conspirators. The court went on to contrast two legal rules of conspiracy law: that it is proper for the jury to draw inferences from conduct, such as coordinated action to accomplish an unlawful purpose, but that mere association with others guilty of a crime cannot, standing alone, prove guilt. In sum, the court reaffirmed that guilt by association is insufficient.

In applying this law to the Merino facts, the court started its legal analysis with the government's theory that Merino intentionally joined a scheme fraudulently to bill Medicare for services not rendered, or services that were not medically necessary.

The court began with the assumption that the evidence was sufficient to convict Merino of a violation of the Anti-Kickback Statute ("AKS").[4] Notably, Marino stood trial uncharged with any anti-kickback violation. The testimony of the cooperator witness, O'Brien, alone could bear the weight of an AKS violation in all likelihood.

Nevertheless, neither O'Brien, nor any other evidence, proved that Merino knew that Glazer's clinic was billing Medicare for patient services that were not legitimate. The government's appellate lawyers argued that Merino's lie to Agent Li about the extent of her employment with Glazer's clinic was evidence of a cover-up scheme and thus, proved guilt. The court dispatched with that argument, acknowledging that, yes, those lies may well have evidenced a guilty heart, but it was guilty of another crime, a kickback violation, or likely many such violations. This crime was uncharged in Marino's indictment.

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[3] *Salinas v. United States*, 522 U.S. 52, 63 (1997).

[4] 42 U.S.C. § 1320a-7b(b).

Last, the court dismissed the government's argument that Merino must have known that Glazer's Medicare billed services were unnecessary because of her role at the clinic—the guilt by association argument. Referring to Investigator Person's testimony about complex Medicare regulations, the court noted Merino's lack of sophistication in the complex healthcare space. The court concluded by holding that the government presented insufficient evidence that Merino agreed to peruse the specific objective of the charged conspiracy, and thus, the conspiracy conviction must fall.

Moving to the eight substantive counts of healthcare fraud under Section 1347(a), the court reversed those convictions as well. Citing that statute, the court stated that the government must prove beyond a reasonable doubt that Merino knowingly and willfully executed, or attempted to execute, a scheme to defraud Medicare. Because Marino was not a healthcare provider, she could be guilty of these substantive charges if she either was a conspirator with others who committed the crimes, or an aider and abettor. The court concluded that under either theory, on the evidence admitted at trial, no rational jury could convict Marino of joining the "object of the conspiracy for which she was charged or that she had the specific intent to facilitate fraudulent billing, rather than a 'different or lesser offense.' "

It is hard to criticize the grand jury investigation in this matter because evidence often becomes more clear and focused as a case like this gets closer to trial. That said, if the grand jury had returned an anti-kickback count against Merino, it is clear that the court would have affirmed that charge based on the evidence admitted during trial.

MULTIMILLION-DOLLAR JURY VERDICT FOR KNOWING AKS AND FCA VIOLATIONS AGAINST BLOOD BANKS[5]

After ignoring counsel's memorandum warning that a sales commission arrangement may violate the AKS, two blood testing labs and their sales consultants were hit with a $111 million jury verdict affirmed by the U.S. Court of Appeals for the Fourth Circuit in *U.S. ex rel. Lutz v. Mallory*[6] for knowing and willful violations of the AKS and False Claims Act ("FCA").[7]

Blood testing labs Health Diagnostic Laboratory ("HDL") and Singulex entered into exclusive contracts with BlueWave Healthcare Consultants Inc. to market tests. HDL agreed to pay BlueWave between 13.8 to 19.8 percent of the revenue BlueWave generated for HDL based on the number of HDL tests ordered by physicians.

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[5] This section was prepared by Gemma R. Galeoto, Eliot T. Burriss, and Jeffrey D. Anderson.

[6] *United States ex rel. Lutz v. Mallory*, 988 F.3d 730 (4th Cir. 2021).

[7] 31 U.S.C. § 3729.

In a similar agreement, Singulex agreed to pay BlueWave 24 percent of the revenue generated. BlueWave assembled a sales team by contracting with independent salespeople who also obtained commissions based on volume of sales.

In addition, HDL and Singulex agreed to pay physicians a processing and handling fee (ranging from $13 to $20), purportedly to cover the costs for preserving the blood sample and shipping.

HDL submitted claims to private and government payors under its program. In a four-year period, Medicare and TRICARE paid HDL approximately $538 million, and HDL, in turn, paid BlueWave approximately $220 million. Medicare and TRICARE paid Singulex approximately $47 million, and Singulex paid BlueWave approximately $24 million.

The United States contended that the volume-based commissions paid by HDL and Singulex to BlueWave "knowingly and willfully" violated the AKS prohibition against soliciting or receiving remuneration in exchange for "arranging for the furnishing" and "recommending purchasing" a healthcare service.[8] A key component of the government's case was a BlueWave sales contractor who emphasized a physicians' ability to profit from processing and handling fees paid by the labs.

The United States also offered evidence that both in-house and outside lawyers warned all three defendants about the illegality of the commissions. HDL's general counsel also wrote a memo to HDL board members explaining there was a "high degree of risk" that BlueWave was violating AKS, and notified the board of the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"), cautioning against independent contractor sales agreements with compensation based on a percentage of sales.

Another HDL compliance lawyer told HDL that the AKS prohibited commission-based arrangements like the one with BlueWave. Outside counsel testified that they also cautioned BlueWave about the likely AKS violations. The jury returned a verdict in favor of the government, finding that the government proved that the commissions paid constituted knowing and willful violations of the AKS.

Throughout the case, the defendants attempted to rely on the advice of counsel defense. The court of appeals paid particular attention to this argument, and stated that it was not persuaded by the defendants' contention that they could not have known that the commissions were illegal because

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[8] 42 U.S.C. § 1320a-7b(b)(2).

attorneys helped draft the underlying contracts. The court pointed out that the defendants did not identify any legal opinion on which they relied in concluding that the AKS permitted commission payments to independent contractors.

The court also acknowledged the defendants' arguments regarding the AKS safe harbor for commissions paid to salespeople. The court determined the safe harbor was not applicable because it applies only to employees. The court emphasized prior legal advice from HDL's general counsel expressing concern over the independent contractor sales agreements and urging HDL to change to an employee-based sales system. Ultimately, the court affirmed the verdict for the government, concluding there was sufficient evidence to show that the commissions that the defendants paid knowingly and willfully violated the AKS and FCA.

EVIDENCE OF WILLFULNESS MISSING IN GOVERNMENT'S KICKBACK CASE AGAINST DEFENDANT[9]

In *United States v. Nora*,[10] the U.S. Court of Appeals for the Fifth Circuit ruled that the evidence was insufficient to support a finding that the defendant acted "willfully," as required to support convictions for conspiracy to commit healthcare fraud, conspiracy to pay illegal healthcare kickbacks, and aiding and abetting healthcare fraud. Although the defendant may have understood that Abide Home Health Care Services Inc. was making referral payments for new patients, there was no evidence at trial that proved that he knew these payments constituted unlawful kickbacks.

According to the court, the evidence did not prove that the defendant acted with knowledge that his conduct was unlawful either. The government did not present evidence that the defendant knew that any of the patients of the home healthcare service were not actually homebound or that he knew he was assigning patients to nurses and doctors who were willing to run afoul of regulations and risk their licenses. Witnesses for the government did not testify that the defendant understood the unlawful or fraudulent purpose behind Abide's practices.

Although Abide's "ghosting" practice was inherently suspicious, and even if a reasonable person should have known that it was unlawful, the court emphasized that would make the defendant guilty of negligently participating in a fraud, rather than prove she acted "willfully" in facilitating ghosting and the fraud it furthered. The "everybody knew" testimony and the claim that Abide

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[9] This section was prepared by Nathan A. Adams IV.

[10] *United States v. Nora*, No. 18-31078 (5th Cir. Feb. 24, 2021).

had an adverse "culture" could bolster the case, but was not itself enough to convict the defendant of willful misconduct.

OIG ISSUES FAVORABLE ADVISORY OPINION ON FREE DRUGS TO PATIENTS[11]

The HHS OIG has issued a favorable advisory opinion[12] regarding an arrangement through which a pharmaceutical manufacturer offers free drugs to patients who satisfy certain criteria. The drug in question is a personalized medicine made from the patient's own cells, intended to be a one-dose and potentially curative treatment. The drug is also subject to the Risk Evaluation and Mitigation Strategy ("REMS") program of the U.S. Food and Drug Administration ("FDA") and is required to be administered only by a healthcare facility certified by the manufacturer and prescribed only by a physician trained to meet the requirements of the REMS.

Under the arrangement, patients that meet certain requirements, including the lack of insurance or denial of coverage by the patient's insurer and certain objective financial needs criteria, would qualify for the free drug. Given these requirements, no third-party payors, including federal healthcare programs, would be billed for the cost of the drug. However, third-party payors, including federal healthcare programs, may be billed for ancillary services associated with administering the free drug, including professional services and facility fees.

The OIG determined that there is a low risk of fraud and abuse under the federal AKS because:

- The drug is a potentially curative treatment that is administered only once, which negates the risk that the arrangement constitutes a "seeding" arrangement through which future referrals of a drug are induced through a free dosage.
- The drug is FDA-approved for the indications at issue and thus distinct from other arrangements where manufacturers offer a free drug for one clinical indication to maintain a high price for all of the drug's indications when paid for by federal healthcare programs.
- The arrangement is available to all eligible patients regardless of the setting in which it is administered (e.g., inpatient vs. outpatient) or payor status, which mitigates the risk that the free drug will inappropriately steer a patient to one care setting over another or inappropriately discriminate against a beneficiary due to payor status.

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[11] This section was prepared by Andrew I. Namkung.

[12] https://oig.hhs.gov/fraud/docs/advisoryopinions/2021/AdvOpn21-01.pdf.

- There is low risk that physicians would overutilize the free drugs to earn professional fees and facility fees because the drug is only administered once and approved for use only when other therapies failed.

The OIG also determined that the arrangement is also unlikely to implicate the prohibition on beneficiary inducement under the civil monetary penalty statute because it is unlikely to induce beneficiaries to select a particular provider, practitioner or supplier of federally reimbursable items or services.

Specifically, the arrangement is agnostic to the beneficiary's use of a particular provider, practitioner or a supplier because the arrangement is available regardless of which eligible physician prescribes the product or which eligible facility administers the drug.

Additionally, the eligibility of physicians who prescribe the drug, as well as facilities that administer the drug, is dependent solely on the FDA's REMS criteria and not the remuneration offered under the arrangement.

While the requestor in the advisory opinion was able to obtain a favorable opinion, the provision of free drugs in general may implicate both AKS and the prohibition on beneficiary inducement, depending on the particular circumstances of each arrangement. Each arrangement should be carefully analyzed to ensure that the arrangement poses a low risk of fraud, waste or abuse and to avoid scrutiny of the OIG, the U.S. Department of Justice and other enforcement authorities.

FDCA NO BAR TO FCA CLAIM DURING 510(k)-CLEARANCE PROCESS IN NINTH CIRCUIT[13]

In *United States ex rel. Dan Abrams Co. LLC v. Medtronic Inc.*,[14] the U.S. Court of Appeals for the Ninth Circuit affirmed in part and reversed in part the district court's dismissal of the relator's FCA lawsuit. The relator alleged that Medtronic:

(1) Fraudulently obtained FDA approval for several devices used for spinal surgery;

(2) Illegally marketed the devices for off-label and contraindicated uses; and

(3) Unlawfully compensated physicians to use the devices.

The relator put forth two primary theories of liability: the "off-label/contraindicated-use theory" and the "fraud-on-the-FDA theory," each of which was dismissed by the district court.

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[13] This section was prepared by David L. Haller.

[14] *United States ex rel. Dan Abrams Co. LLC v. Medtronic Inc.*, No. 19-56377 (9th Cir. Apr. 2, 2021).

The court of appeals began with the relator's "off-label/contraindicated-use theory" of FCA liability. "The fundamental problem with this theory," the court wrote, "is that relator incorrectly assumes that the federal government will not reimburse for an off-label use of a medical device"; however, "the federal government has recognized that doctors may use medical devices for off-label purposes as long as it is medically necessary." "[T]o be reimbursable, [then,] a device must [simply] (1) have FDA approval/clearance, (2) be 'reasonable and necessary,' and (3) meet any other pertinent regulations."

The court of appeals found that Medtronic had satisfied each of the three requirements.

First, the FDA cleared the devices through the 510(k) submission process.

Second, the relator had not plausibly alleged that the devices were not "reasonable and necessary." The court observed that "a device is not reasonable and necessary—and thus is not eligible for Medicare coverage—if it is (a) not safe and effective, (b) experimental, (c) not appropriate for the individual beneficiary's needs, or (d) substantially more costly than a medically appropriate and realistically feasible alternative pattern of care." The relator, the court found, had made "no allegations about published studies demonstrating the cervical use of vertebral body replacement (VBR) is medically unsafe or ineffective." Nor had the relator alleged that "VBR use in the cervical spine is contrary to accepted stands of medical practice." The relator had merely "point[ed] to a few anecdotal examples of harm caused by the [devices] . . . [and] [m]erely showing that harm *can* occur is insufficient." Although the relator argued that this "is not a case of merely off-label use, but contraindicated use," the court found that "neither the federal government nor the judiciary appears to carve out an exception for contraindicated use in discussing off-label uses."

Third, the "[r]elator point[ed] to no statute, regulation, or administrative manual that specifically states that a contraindicated use of a device is categorically not reasonable and necessary." Based on its review, the court of appeals affirmed the district court's dismissal of the relator's off-label/contraindicated label claim.

The court of appeals then turned to the relator's "fraud-on-the-FDA theory" of FCA liability, pursuant to which the devices, which require FDA approval, would have been ineligible for reimbursement but for Medtronic's fraud.

With regard to the first group of devices at issue, the "extra-use devices," which "could be used for their stated intended use but which were contraindicated for use in the cervical spine," the court of appeals agreed with the

district court that "the materiality element cannot be met . . . because the federal government allows reimbursement for off-label and even contraindicated used."

But with regard to the second group of devices at issue, "contraindicated-only devices," which allegedly "cannot be used for their labeled intended use" and "can only be used for their contraindicated use," "Medtronic's alleged fraud went 'to the very essence of the bargain.' " Indeed, the relator alleged that, due to Medtronic's fraud, "the contraindicated-only devices were not properly cleared for any use: they cannot be used for their labeled intended use (and are thus not substantially similar to the predicate device), and they can *only* be used for their contraindicated use."

Although Medtronic argued that the Ninth Circuit should join the First Circuit in holding that the Federal Food, Drug, and Cosmetic Act ("FDCA") bars private parties from asserting FCA claims that the device manufacturer defrauded the FDA during the 510(k)-clearance process concerning a device's intended use, the Ninth Circuit rejected Medtronic's argument and reversed the district court's dismissal of the relator's "fraud-on-the-FDA theory" with respect to contraindicated-only devices.

Finally, the court of appeals addressed the relator's AKS claim, which also was dismissed by the district court. The relator first alleged that "Medtronic entered into improper rebate agreements with hospitals to buy the Subject Devices." But because the AKS exempts from its scope discounts offered to providers if properly disclosed to and reflected in charges to the federal program" and "Medicaid allows rebate agreements so long as the state Medicaid programs are offered the same pricing," the relator could not state a claim.

The relator next alleged that "Medtronic remunerated physicians by paying the costs, including food, travel, and promotional expenses, in connection with certain business development events." But because the relator's "general allegations d[id] not identify any physicians, or categories of them, who actually received payment in connection with decisions—in which they participated—to purchase or use [] any of the Subject Devices," the relator did not state a claim.

Accordingly, the court of appeals affirmed the district court's dismissal of the relator's AKS claim.