DEFENDING FALSE CLAIMS ACT LAWSUITS BASED ON THE "SWAPPING" THEORY OF ANTI-KICKBACK LIABILITY

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I. Introduction to the Swapping Theory of False Claims Act Liability

The federal False Claims Act (FCA) imposes civil liability on any person or entity that "knowingly presents, or causes to be presented, to an office or employee of the United States Government . . . a false or fraudulent claim for payment or approval."[1] While historically the FCA was enacted to combat factually false or fraudulent claims submitted to the Government (*e.g.*, knowingly billing for non-existent goods), courts now frequently accept expanded theories of "legal falsity" presented by *qui tam* relators or the U.S. Department of Justice (DOJ). Where courts have accepted theories of "legal falsity," as opposed to factual falsity, the Government typically must prove that the claimant knowingly and falsely certified compliance with a statute or regulation of which compliance was a condition of government payment.[2]

Under such a theory, relators and the DOJ have long argued that defendants that violate the federal Anti-Kickback Statute (AKS) can simultaneously be held liable under the FCA based on the same underlying conduct.[3] In contrast to the FCA, the AKS is a purely criminal statute that is enforced by not only the DOJ but also U.S. Department of Health & Human Services—

[1] 31 U.S.C. § 3729(a)(1).

[2] *Gonzalez v. Fresenius Medical Care N. Am.*, 689 F.3d 470, 474-75 (5th Cir. 2012); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267-69 (5th Cir. 2010).

[3] *See, e.g., United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997).

Office of Inspector General (OIG).[4] In 2010, Congress amended the AKS to state that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."[5] But the AKS still does not contain its own civil enforcement mechanism separate from the FCA.

The AKS makes it a federal crime to "knowingly and willfully" offer or pay illegal "remuneration" to induce referrals of federal healthcare program business.[6] Remuneration is defined broadly to include the transfer of anything of value, "directly or indirectly, overtly or covertly, in cash or in kind."[7] Because the AKS is a criminal statute, the *mens rea* requirement of knowing and willful intent conditions liability on proof that the defendant acted "intentionally and purposely and with the intent to do something the law forbids, that is, with the bad purpose to disobey or to disregard the law."[8]

The swapping theory of FCA liability, as advanced by relators and the DOJ, is based on the knowing presentation of claims for payment to the Government while engaging in a swapping arrangement that violates the AKS. "Swapping" typically refers to arrangements in which providers or suppliers allegedly offer remuneration—such as discounts on goods or services—in order to induce referrals for other business that is reimbursable under a federal healthcare program. Relators and the DOJ have typically tried to apply the swapping theory of FCA liability to providers and suppliers that have contracted with inpatient facilities to serve Medicare Part A patients, and which facilities also care for Medicare Part B or Part D patients.

[4] 42 U.S.C. §§ 1320a-7b(b)(1)-(2), 1320a-7c.

[5] 42 U.S.C. § 1320a-7b(g).

[6] 42 U.S.C. §§ 1320a-7b(b)(1)-(2).

[7] *See id.*; *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 626 (N.D. Ill. 2006).

[8] *See Bryan v. United States*, 524 U.S. 184, 190 (1998).

A typical swapping allegation is that the provider or supplier has gained access to the Medicare Part B or Part D patients by discounting its Medicare Part A services to induce referrals in violation of the AKS. The AKS violation has allegedly rendered any contemporaneous claims for payment for the Medicare Part B or Part D services false or fraudulent. The companies targeted under this theory have included clinical laboratories, ambulance services, medical billing companies, pharmacies, and mobile x-ray providers.

This paper summarizes the OIG's swapping analysis for AKS enforcement, surveys the federal decisions regarding FCA liability under the swapping theory, and discusses the key defense strategies for litigating swapping cases brought by relators or the DOJ.

II. The OIG's Swapping Analysis for AKS Enforcement

As discussed above, the OIG is partly responsible for criminal enforcement of the AKS. It has set forth its swapping analysis for AKS enforcement in a series of advisory opinions and related informal guidance.[9] The advisory opinions are drafted in response to specific facts supplied by the health care providers requesting them.[10] Neither the advisory opinions nor any other informal guidance from the OIG purport to establish a legal standard for AKS compliance

[9] OIG AO 99-2, 99-3, 99-13, *available at*: http://oig.hhs.gov/compliance/advisory-opinions/index.asp (last visited Sept. 21, 2015); Discount Arrangements Between Clinical Labs and SNFs (Sept. 22, 1999), Discount Arrangements Involving Ambulance Companies, Hospitals, and Skilled Nursing Facilities (April 20, 2000), Discount Arrangements Involving Clinical Labs (April 26, 2000), *available at*: OIG Other Guidance, http://oig.hhs.gov/compliance/alerts/guidance/index.asp (last visited Sept. 21, 2015).

[10] OIG Advisory Opinions, *available at*: http://oig.hhs.gov/compliance/advisory-opinions/index.asp (last visited Sept. 21, 2015) ("[A]dvisory opinions are binding and may legally be relied upon only by the requestor. Since each opinion will apply legal standards to a set of facts involving certain known persons who provide specific statements about key factual issues, no third parties are bound nor may they legally rely on these advisory opinions."); 42 C.F.R. § 1008.53 ("An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion."); *Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG*, 62 Fed. Reg. 7,350, 7,355 (Feb. 19, 1997) (to be codified at 42 C.F.R. pt. 1008) ("[B]y their very nature, advisory opinions, unlike the safe harbor regulations, cannot be applied generally.").

that has the force of law in federal district court.[11] Indeed, at least two district courts have held that the OIG's swapping guidance is not entitled to any judicial deference.[12] The swapping guidance is nevertheless critical for defense attorneys and corporate counsel to understand because it is a frequent starting point from which relators and the DOJ analyze FCA claims premised on the swapping theory.

When analyzing an alleged swapping arrangement, the OIG looks first for a nexus between (i) an alleged discount offered by a provider or supplier, and (ii) the referrals of federal healthcare program business from another contracting party.

According to the OIG, a nexus may exist if:

- A contracting party is in a position to direct a significant amount of non-discounted federal healthcare program business to the provider or supplier;
- The parties have financial motives to trade discounts for referrals of non-discounted federal healthcare program business; and
- The OIG has received reports that the linking of discounts and referrals is widespread throughout the industry, *or* a contracting party is likely to make the referrals to the provider or supplier as a matter of business convenience.[13]

If the OIG believes that a nexus exists, then it assesses whether the arrangement is "suspect."[14] That is, the OIG looks for "indicia" that the discount does not make "business sense 'standing alone' without reference to any other business" which the target provider may receive

[11] *See, e.g.*, OIG AO 99-13 ("This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.").

[12] Mem. Order at 21 n.10, *United States ex rel. Jamison v. McKesson Corp.*, No. 2:08cv214-SA-JMV, (N.D. Miss. Mar. 28, 2011), ECF No. 231 (explaining that statutory interpretations in opinion letters, policy statements, manuals, and enforcement guidelines, "all of which lack the force of law," do not receive judicial deference) (quoting *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000)); *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.,* 36 F. Supp. 3d 773, 780 (S.D. Ohio 2014).

[13] OIG AO 99-2, 99-13.

[14] *Id.*

from the other contracting party.[15] According to the OIG, an arrangement may be "particularly suspect" if:

- The discounted prices are below the provider or supplier's costs.
- The discounted prices are lower than the prices offered to a buyer that generates at least the same amount of business, and that has no other potentially available federal healthcare program business that it can refer.
- The discounted prices are coupled with an exclusivity arrangement.
- The provider or supplier gives the discounts on items or services for capitated or all-inclusive payment patients, in conjunction with reaching an explicit or implicit agreement for the referral of other federal health care program business.[16]

The OIG does not treat "suspect" or "particularly suspect" arrangements as *per se* violations of the AKS. Rather, they are "only 'suspect' in the sense that they may merit further investigation by the OIG depending on the facts and circumstances presented."[17] Any further investigation by the OIG is likely to focus on the intent of the provider or supplier.

III. Federal Litigation Involving the Swapping Theory of FCA Liability

A key question in the swapping cases that have proceeded to trial or summary judgment has been whether remuneration has been conferred when the services are priced at FMV and above cost. As discussed below, the few federal courts that have considered swapping cases on their merits have accepted approaches for evaluating remuneration that relators and the DOJ have argued are impermissible based on the OIG's informal guidance. Those approaches have included expert testimony that analyzes competitive bidding and market pricing, as well as evidence of pricing at or above the incremental cost of delivering the service.

[15] Discount Arrangements Between Clinical Labs and SNFs (Sept. 22, 1999); Discount Arrangements Involving Ambulance Companies, Hospitals, and Skilled Nursing Facilities (April 20, 2000).

[16] OIG AO 99-2, 99-13.

[17] Discount Arrangements Involving Ambulance Companies, Hospitals, and Skilled Nursing Facilities (April 20, 2000)

A. *Klaczak v. Consolidated Medical Transport*

Klaczak involved a *qui tam* action premised on an alleged swapping scheme between ambulance companies and nonprofit hospitals in the Chicago area. The relators alleged that the hospitals accepted remuneration in the form of below-FMV rates for Medicare Part A transports in exchange for providing preferred or exclusive access to Medicare Part B transports.[18] The rates were allegedly below FMV because they were lower than both the Medicare fee schedule (MFS) and the "usual and customary" rates charged by the ambulance companies. The hospitals moved for summary judgment, taking the position that the rates were not remuneration because they were competitive relative to the market and therefore within the range of FMV.

District Judge Mark Filip (a former federal prosecutor and former Deputy Attorney General of the United States) rejected the relators' theory that pricing below the MFS or the ambulance company's "usual and customary" rate is a discount that constitutes remuneration. Judge Filip reasoned that such a theory "is fundamentally defective because it presumes that the value of a service is defined by what one firm proposes to charge for that service, rather than by all of the participants in the market." FMV means "the price that a willing buyer would pay a willing seller," and is an "appropriate and accepted" metric for remuneration.[19] Because the relators had not conducted a competitive market analysis or adduced any other evidence showing that the rates accepted by the hospitals were below FMV, Judge Filip granted summary judgment in favor of the hospitals.

Judge Filip also found that the relators' evidence of criminal intent was insufficient. The relators had asserted that the hospitals' contract rates were so low that the only reasonable

[18] *Klaczak v. Consol. Med. Transp*., 458 F. Supp. 2d 622, 625 (N.D. Ill. 2006).

[19] *Id.* at 678-79.

inference to be drawn from them was that the hospitals knew that the discounts were illicit remuneration. The relators, however, failed to produce a "single comment, email, memo, or other indication by any relevant agent that suggest[ed] the Hospital Defendants individually or collectively were knowing and willful participations in any kickback scheme."[20] Consequently, the relators were required to prove criminal intent through "robust" circumstantial, indirect evidence which "tend[ed] to meaningfully exclude a legitimate (or negligent) explanation for the defendants' conduct—consistent with the heightened scienter requirement."[21] Because the relators' evidence of low rates did not tend to exclude both legitimate conduct and negligence as explanations for the conduct, there was no triable jury question on criminal intent.[22]

B. *United States ex rel. Jamison v. McKesson Corporation*

The *qui tam* relator in *Jamison* alleged that McKesson's subsidiary MediNet, a durable medical equipment supplier and McKesson subsidiary, offered billing services priced below total costs to a SNF chain as an inducement for referrals of Medicare Part B patients. This alleged swapping scheme supposedly violated the AKS and rendered MediNet's invoices for the Medicare Part B services false or fraudulent.[23] The Government intervened, took over the litigation from the relator, conducted several years of discovery, and then spent 14 days trying the case to District Judge Sharion Aycock (herself a former prosecutor).

The Government's position at trial was that MediNet negotiated rates with the SNF chain using cost analyses that unlawfully and improperly excluded fixed costs and overhead, *e.g.*, employee salaries born by an affiliated company. Notably, these costs would have been incurred

[20] *Id.* at 680.

[21] *Id.* at 677.

[22] *Id.* at 677-678.

[23] *United States ex rel. Jamison v. McKesson*, 900 F. Supp. 2d 683 (N.D. Miss. 2012).

regardless of whether MediNet won the contract. Instead of capturing such costs, MediNet's analyses included only the additional incremental costs that MediNet expected to incur upon winning the contract.[24] During its case-in-chief, the Government thoroughly cross-examined MediNet's executives on the company's use of incremental costs and not total costs when negotiating rates.[25]

Judge Aycock concluded that MediNet's negotiation of prices at or above what it believed to be its incremental costs did not violate the AKS. She specifically held that:

> According to the incremental cost model, fixed costs and overhead, including executive salaries and property costs, were not associated or accounted as a cost inherent in the CSMS business because such expenses would be incurred regardless of whether MediNet won the contract or not. The Government sought to highlight the fact that an incremental cost analysis was not the proper way to analyze profitability of a contract; however, Plaintiff failed to present evidence that such analysis was either illegal under the AKS or improper under standard accounting principles. John Griffiths, a financial analyst and analyst supervisor for MediNet, noted that the incremental cost analysis is a well-accepted method of analyzing opportunities and profitability.[26]

Judge Aycock rejected the argument that total or "fully loaded" costs are the only lawful measure of costs under the AKS. Because the Government failed to prove an AKS violation, Judge Aycock entered a defense verdict for MediNet and McKesson.

C. *United States ex rel. Gale v. Omnicare, Inc.*

Gale was a *qui tam* action in which the relator contended that Omnicare, a long term care pharmacy, provided illegal discounts on Medicare Part A business to SNFs in exchange for

[24] *Id*. at 700-01.

[25] Trial Tr. Vol. II, *Jamison*, No. 2:08cv214-SA-JMV, (Feb. 27, 2012), ECF No. 519; Trial Tr. Vol. II, *Jamison*, No. 2:08cv214-SA-JMV, (Feb. 28, 2012), ECF No. 525; Trial Tr. Vol. XI, *Jamison*, No. 2:08cv214-SA-JMV, (Mar. 7, 2012), ECF No. 533; Trial Tr. Vol. XIII, *Jamison*, No. 2:08cv214-SA-JMV, (Mar. 8, 2012), ECF No. 535.

[26] *Jamison*, 900 F. Supp. 2d at 700.

referrals of Medicare Part D patients.[27] After conducting discovery, the relator moved for summary judgment on what was essentially a test case: Omnicare's contract with a SNF called Montefiore Homes. The relator's position at summary judgment was that Omnicare conferred remuneration on Montefiore Homes by charging a per diem rate that was below Omnicare's usual and customary pricing. Omnicare was unable to say whether the per diem rate ever generated a profit.[28] Instead, Omnicare argued that its discounted rates were not remuneration because they were competitive within the market. Omnicare supported its argument with evidence showing that Montefiore announced that it was terminating its contract (and seeking a better rate in the market) after Omnicare announced a rate increase.[29]

The district court rejected the positions of both sides. Instead, it defined remuneration as "a reduction in the Part A per diem price that Omnicare charges Montefiore as compared to the price it would have charged Montefiore for the same services absent the rest of Montefiore's contract—including Part D patient referrals." The district court looked at not only what others charged for the same services, but also "the price at which an arm's-length market transaction would value these services." Under this framework, Omnicare's usual and customary price, the prices charged by Omnicare's competitors in the market, and Omnicare's costs were all relevant to the analysis of the remuneration element.[30]

The district court found a triable jury question on remuneration because the profitability of Omnicare's contract with Montefiore and the availability of similarly-priced alternatives in the

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[27] *United States ex rel. Gale v. Omnicare, Inc.*, No. 1:10-cv-127, 2012 WL 4473265, at *2 (N.D. Ohio Sept. 26, 2012) (order granting and denying mot. to dismiss in parts).

[28] *United States ex rel. Gale v. Omnicare, Inc.*, No. 1:10-cv-127, 2013 WL 3822152, at *3 n. 35, *6 (N.D. Ohio, July 23, 2013) (order granting and denying mot. for summary judgment in parts)

[29] *Id.* at *6-7.

[30] *Id.* at *6.

market were disputed.[31] The district court also found a triable jury question on inducement and criminal intent because there was testimony that any losses on the Montefiore contract resulted from corporate mismanagement rather than an effort to induce referrals.[32] Together, these rulings opened the door to a SNF-by-SNF jury trial of the relator's FCA claims. Omnicare agreed to pay $120 million to settle the action. Omnicare did not admit to any liability or wrongdoing, or to any of the conduct alleged by the relator.[33]

D. *United States ex rel. McDonough v. Symphony Diagnostics Services, Inc.*

The *qui tam* relator in *McDonough* alleged that Symphony Diagnostic Services, Inc., d/b/a Mobilex USA ("Mobilex"), a national provider of mobile x-ray services, provided Medicare Part A services to SNFs at below-FMV or below-cost rates in exchange for access to Medicare Part B patients. The relator's theory of swapping hinged on his argument that the only lawful measure of cost under the AKS is "fully-loaded cost." In other words, he asserted that Mobilex could not offer or maintain rates below an amount equal to its incremental cost of delivering the service, plus a pro rata allocation of all costs unrelated to service delivery. Anything less supposedly amounted to a *per se* violation of the AKS.[34]

Mobilex's position was that its negotiated Part A rates were at FMV—and did not constitute remuneration—because they were the product of vigorous competition.[35] Additionally, Mobilex argued that incremental cost was a lawful and appropriate measure of cost

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[31] *Id*. at *7.

[32] *Id*. at *8.

[33] Press Release, DOJ, Nation's Largest Nursing Home Pharmacy Company to Pay $124 Million to Settle Allegations Involving False Billings to Federal Health Care Programs (June 25, 2014), available at: http://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving (last visited Sept. 26, 2015).

[34] *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.,* 36 F. Supp. 3d 773, 776 (S.D. Ohio 2014).

[35] *Id.* at 778.

because it represented the direct cost of delivering the service. The use of the relator's fully-loaded cost measure would also have led to absurd results given variability in service delivery, different competitive pressures across geographic markets, and other factors.[36]

The parties filed cross motions for summary judgment after discovery. District Judge Algenon Marbley, a former attorney for the U.S. Department of Health & Human Services, rejected the relator's argument on fully-loaded cost, and followed Judge Aycock's holding in *Jamison* that the use of the "incremental cost analysis to calculate anticipated profits was a permissible measure of costs under the AKS." Judge Marbley reasoned that the relator's approach was premised largely on the OIG's advisory opinions, which were nonbinding and limited to their narrow facts. Additionally, Judge Marbley agreed with Mobilex that the relator's approach would lead to absurd results by retroactively criminalizing contracts based on nothing more than the relator's preferred cost accounting method.[37]

Judge Marbley likewise rejected the relator's effort to prove criminal intent through circumstantial evidence. Citing *Klaczak*, Judge Marbley found that the relator's evidence was nothing more than a "chain of inferences" lacking a factual basis. Accordingly, he granted summary judgment in favor of Mobilex.[38]

E. *United States ex rel. Carlisle v. Pacific Ambulance Inc.*

The relator in *Carlisle* was the CEO of an ambulance company in Southern California who alleged that five of his competitors engaged in swapping schemes with hospitals and

[36] *Id. at* 775.

[37] *Id.* at 780-781.

[38] *Id.* at 781.

SNFs.[39] He claimed that his competitors offered the facilities discounts of 50 to 100 percent on Medicare Part A transports in exchange for access to Medicare Part B business. Such discounts were supposedly widespread in the market, and the relator's own company had previously given such discounts to facilities. But the relator's company changed its business practices after learning of the DOJ's settlement of a swapping case with an ambulance company in Texas named American Medical Response, Inc.[40] After changing its business practices, the relator's company purportedly lost contracts because the five defendant ambulance companies continued to engage in swapping schemes. The defendants collectively paid more than $11.5 million to resolve the allegations by the relator.[41]

IV. Key Defenses to FCA Claims Based on the Swapping Theory

Relators and the DOJ have continued to argue that illegal remuneration is conferred in an alleged swapping arrangement even when services are priced at FMV and above cost, notwithstanding the federal district court rulings in *Klaczak*, *Jamison*, and *McDonough*. In other words, relators and the DOJ continue to argue that a supplier or provider may be *criminally* liable for an arm's length, FMV exchange if one of the purposes of the exchange is to induce referrals.[42] The DOJ's advocacy for such an expansive interpretation of the AKS underscores

[39] Compl. ¶ 25, *United States ex rel. Carlisle v. Pac. Ambulance Inc.*, No. 3:09-cv-02628, (S.D. Cal. May 7, 2015), ECF No. 1.

[40] *Id*. at ¶¶ 25 – 34. The settlement with American Medical Response became public on October 5, 2006. Press Release, DOJ, American Medical Response Pays $9 Million to Settle Civil Fraud Case (Oct. 5, 2006), *available at*: http://www.justice.gov/archive/opa/pr/2006/October/06_civ_679.html (last visited Sept. 23, 2015).

[41] Press Release, DOJ, Five Southern California Ambulance Companies to Pay More than $1.5 Million to Resolve Kickback Allegations (May 4, 2015), *available at*: http://www.justice.gov/usao-sdca/pr/five-southern-california-ambulance-companies-pay-more-115-million-resolve-kickback; Jeff Overley, *Ambulance Cos. Ink $11.5M FCA Deal Over Kickbacks*, Law360, May 5, 2015, http://www.law360.com/articles/651783/ambulance-cos-ink-11-5m-fca-deal-over-kickbacks.

[42] *See* Statement of Interest of the United States in Response to Defendants' Motion for Summary Judgment at 6-8, *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.,* No. 2:08-cv-0114, (S.D. Ohio Feb. 27, 2014), ECF No. 157.

why the defenses accepted by the courts in *Klaczak*, *Jamison*, and *McDonough* are critical for healthcare companies that must litigate swapping cases. Relators and the DOJ continue to obtain settlements based on swapping allegations that fail the legal tests announced in those cases.

A. *Remuneration requires proof of pricing below FMV or incremental cost*

One of the cornerstone defenses in any swapping case is the requirement that the relator or the Government must prove the remuneration element of the AKS violation by showing that the defendant's pricing was below FMV or cost. It is not enough for the relator or the Government to show that the defendant priced below the MFS.[43] The rates in the MFS are set unilaterally by the Centers for Medicare & Medicaid Services (CMS).[44] They are not set through competitive bidding or arm's length negotiation in a competitive market. Nor are they set in relation to the specific defendant's cost structure.

Additionally, it is not enough for the relator or the Government to show that the defendant priced below its "usual and customary" rate. This is because FMV reflects how the broader market (and not any single market participant) values the service.[45] If the defendant reduces its "usual and customary" rate to meet the market, then the "usual and customary" rate may have been too high. The lower price ultimately benefits the Medicare program.

The relator or the Government may seek to prove pricing below FMV using a competitive market analysis. For example, they make take third-party discovery of the prices charged by the defendant's competitors in the market or conduct an econometric analysis. Then they may seek to show that the defendant's pricing fell below what its competitors charged.[46]

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[43] *Klaczak v. Consol. Med. Transp*., 458 F. Supp. 2d 622, 679-80 (N.D. Ill. 2006).

[44] CMS Pub. 100-04, ch. 13 §§ 10.1, 90 (Rev. 2750, Aug. 2, 2013).

[45] *Klaczak*, 458 F. Supp. 2d at 678-79.

[46] *Id*. at 626, 678-680.

To rebut such allegations, a defendant should produce its own competitive market analysis showing that its prices were the product of competitive bidding and arm's length negotiations (assuming the evidence supports such a showing). FMV is "the price that a willing buyer would pay a willing seller."[47] As the Government's own 30(b)(6) witness testified at trial in *Jamison*, a competitive market process naturally produces prices that are FMV.[48]

The defendant may also go a step further and show that its prices are FMV because they are within the range of prices charged by competitors in the market (once again, assuming the evidence supports such a showing). When faced with allegations of criminal violations based upon below-FMV pricing, the time and expense of performing such an analysis may be warranted. If there is more than one permissible method for gauging FMV, and just one of those methods supports the defendant, then judgment should be entered in favor of the defendant as to alleged AKS violations premised on below-FMV pricing.[49]

To defeat summary judgment in the defendant's favor without conducting a competitive market analysis, the relator or the Government may argue that the defendant conferred remuneration by selling at prices below its costs. The argument begs the question of what measure of cost is lawful and appropriate. As previously discussed, the incremental cost method was accepted in *Jamison* and *McDonough* because it was not "illegal under the AKS or improper under standard accounting principles," and would not produce absurd results.

Under the incremental cost method, the defendant should, if practicable, marshal testimony from an accounting expert that establishes the defendant's cost of delivering the good

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[47] *Id.* at 678-79.

[48] *United States ex rel. Jamison v. McKesson*, 900 F. Supp. 2d 683. 699-700 (N.D. Miss. 2012).

[49] *See United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.,* 36 F. Supp. 3d 773, 779 (S.D. Ohio 2014). (holding that if cost was the correct test, and defendant used one of two or more permissible methods for calculating cost, then no triable issue existed on remuneration).

or service and shows that the defendant's prices exceed those costs. A key issue in the accounting analysis is frequently how general & administrative expenses (G&A) are defined and whether the cost of delivering the good or service includes any such expenses. The inclusion of G&A has the potential to devolve the incremental cost method into the fully-loaded cost method.

For certain defendants—such as those with nationwide operations—it may be impracticable to conduct a reliable accounting analysis below the highest corporate level because of cost allocation challenges presented by variations in service delivery and other factors. In such scenarios, the corporate-wide incremental cost may not be a reliable or appropriate proxy for the direct cost of delivering the good or service in the market or under the specific contract that is the focus of the FCA action. The analysis may shift, as in *McDonough*, to consideration of the prospective business judgments on incremental cost which the defendant made at the time of contracting using its knowledge of its own operations and any available business tools (*e.g.*, internal, sub-corporate financial data). A dispute about the reasonableness of a prospective business judgment is simply not the stuff of illegal remuneration and inducement.[50]

B. *The AKS is a criminal statute that requires knowing and willful intent*

If the remuneration element is met, then the relator or the DOJ must still prove that the defendant acted with the knowing ***and*** willful criminal intent required by the AKS. The FCA's less rigorous requirement of "knowing" intent—which may be satisfied by a showing of deliberate ignorance or reckless disregard of the truth or falsity of the claim for payment—does not override the criminal intent requirement for the alleged AKS violation. Criminal intent under the AKS must be proven as to the contract or arrangement in dispute; it would not be sufficient

[50] *See id. at* 773.

to show a general pattern and practice at the corporate level of deliberately ignoring or recklessly disregarding the possibility of below-FMV or below-cost pricing.[51]

In the absence of direct evidence of criminal intent, *e.g.*, emails containing admissions of an intent to violate the law, both *Klaczak* and *McDonough* provide that "robust" circumstantial evidence is required. That is, the circumstantial evidence must be so compelling that it "tends to meaningfully exclude a legitimate (or negligent) explanation for the defendants' conduct—consistent with the heightened scienter requirement."[52] Because the AKS criminalizes conduct that is normal and permissible in industries besides healthcare, the reasonable doubt standard is an important part of the law's protection of defendants. While the court did not find it necessary to reach the issue of whether the criminal burden of proof applies in a civil FCA case premised on a criminal AKS violation, finding that the government had not met its burden under either standard, Judge Aycock nonetheless observed in *Jamison* that "the proper course would likely be to use criminal intent to prove a civil AKS violation."[53]

C. *When elements for AKS are met, the discount statutory exception or the discount safe harbor may still apply*

If the Court finds that a defendant discounted its prices below FMV or cost, then the defendant may still prevail under the discount statutory exception. The discount statutory exception states expressly that the AKS's definition of "illegal remuneration" does not include:

> a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is ***properly disclosed*** and ***appropriately reflected*** in the costs claimed or charges made by the provider or entity under a Federal health care program.[54]

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[51] *Klaczak*, 458 F. Supp. 2d at 678; *McDonough*, 36 F. Supp. 3d at 776.

[52] *Klaczak*, 458 F. Supp. 2d at 677; *McDonough*, 36 F. Supp. 3d at 779.

[53] *Jamison*, 900 F. Supp. 2d at 698, n.7.

[54] 42 U.S.C. § 1320a-7b(b)(3)(A) (emphasis added).

If a discount by the defendant does not fall within the statutory definition of "illegal remuneration," then the defendant may lawfully provide that discount under the AKS.

The discount statutory exception is often conflated with the regulatory discount safe harbor promulgated by the OIG at 42 C.F.R. § 1001.952(h). But the regulatory safe harbor and the discount statutory exception "are separate and independent bases for which certain activities may be excluded from criminal liability under the [AKS]."[55] The defendant may invoke the statutory discount exception, the regulatory safe harbor, ***or both*** as defenses. To defeat AKS liability, the defendant must only prove that its conduct is protected by one or the other.[56]

The regulatory discount safe harbor requires the defendant to "accurately report" any discount to the inpatient facility, give reasonable notice of the cost reporting obligation, and do nothing to prevent the facility from filing an accurate cost report:

> (A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner *that is reasonably calculated* to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.[57]

The plain text of the regulation does not require the defendant to confirm that the facility understands its cost reporting obligation or confirm that the facility fulfilled that obligation. Rather, the regulation simply requires notice that is "reasonably calculated." Depending on the facts, it may be another vehicle for defeating FCA claims premised on a swapping theory.

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[55] *United States v. Shaw*, 106 F. Supp. 2d 103, 113 (D. Mass. 2000).

[56] *Id.* at 119.

[57] 42 C.F.R. § 1001.952(h)(2)(ii)(A) (emphasis added).

D. *The Future of Swapping Cases*

With cases frequently settled out of court, there have been few published judicial decisions on "swapping" theory under the FCA. As the relators' bar and the Government continue to bring FCA cases based upon alleged "swapping" violations of the AKS, we expect to see the federal case law continue to grow and develop around the issues of FMV, cost accounting, requisite *mens rea*, and the statutory discount exception and discount safe harbor.