

Defending Government Pharmaceutical Fraud Investigations: Assessing Strategic Options

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In the world of state and federal health care fraud investigations and prosecutions, business is booming. Over the past five years, the government has extracted enormous monetary payments in exchange for agreements not to exclude providers, suppliers and manufacturers from the Medicare and Medicaid programs – a corporate death sentence for most health care entities. The Office of the Inspector General (“OIG”), which works cooperatively with the Department of Justice, the Federal Bureau of Investigation, and other governmental departments in investigating allegations of civil, criminal, and administrative wrongdoing in Health and Human Services programs, reports that in fiscal year 2006, it recovered \$1.6 billion in investigative efforts, excluded 3,425 individuals and entities for fraud and abuse, and instituted 472 criminal actions and 272 civil actions against providers and others.²

Individual states have also been exacting high penalties from health care providers, suppliers and manufacturers for alleged fraud and abuse related to the Medicaid program. State Attorneys General, acutely aware of both the high costs of health care and the potential to recover some of that cost through prosecutions or civil demands, are becoming increasingly proactive in investigating potential fraud and abuse issues. While individual Medicaid Fraud Control Units (“MFCUs”) have tended to focus on the investigation and prosecution of individual health care providers, they have also proven effective partners with each other and with federal agencies. There are now active state-federal health care fraud task forces and working groups in virtually every state, in which MCFUs participate either directly or through the National Association of Medicaid Fraud Control Units.³ As a result of this coordinated effort, individual state Medicaid programs have been able to share in the billions of dollars recovered in global settlements with pharmaceutical companies, pharmacy chains, and other national providers.

But even as average settlement amounts increase, it has become less and less possible to appease the government through restitution alone. The government zest for non-monetary punishment continues to increase, as does the introduction of new investigative tactics. Both Gambro Healthcare and Serono agreed to settlements that required guilty pleas and exclusion for their subsidiary companies (five years exclusion for Serono Labs, Inc., and permanent exclusion for Gambro Supply Co.). And while the government has continued to push its theories of liability into new market segments (e.g., the

Caremark/AdvancePCS matter), it has also begun to apply hotly-debated policies and practices from other law enforcement areas to the health care context.

These enforcement trends underscore the need for sophisticated assessment of defense strategy that consider various options.

I. Statutory Framework of Pharmaceutical Fraud Investigations

In order to appreciate the significance of government enforcement efforts, and, more importantly, in order to understand the financial risks posed by the various criminal, civil and administrative remedies available, it is critical to have an understanding of the fraud and abuse statutes upon which the government relies in pursuing its investigations against pharmaceutical manufacturers. The following briefly outlines the primary weapons in the government's arsenal.

A. Off-Label Marketing and Kickbacks

For 2007, the OIG has once again identified the broad category of pharmaceutical fraud as one of its main investigative focus areas.⁴ In the past, such cases have tended to involve allegations of false claims “caused” by inappropriate or illegal marketing practices, such as offering or paying kickbacks in exchange for agreements to purchase a particular drug, or marketing a drug for uses that have not been approved by the Food and Drug Administration (“FDA”). The statutes implicated by this conduct – the Anti-kickback Statute and the Food, Drug, and Cosmetic Act⁵ – are sufficiently malleable that defense counsel are constantly challenged in effectively advocating the client's good faith attempts to comply with the law.

1. The Federal Anti-kickback Statute

The Anti-kickback Statute (“AKS”) prohibits anyone from knowingly or willfully paying or offering to pay remuneration, directly or indirectly, to another to induce that person to refer patients, or to arrange for or recommend the purchase of any facility, item or service that may be paid for by a federal health care program. It also prohibits the acceptance of such remuneration. A violation of the AKS is a felony offense punishable by a maximum sentence of five years and exclusion from federal health care programs. The Act further provides for civil penalties of \$50,000 for each violation plus three times the remuneration offered, paid, solicited or received.⁶ Courts have disagreed as to whether the AKS's “willful” intent

standard requires proof of specific intent to violate the Statute, mere knowledge that the act was unlawful, or whether willful intent can be inferred if any purpose of the remuneration was to induce a referral.

Prescription drug marketing practices that improperly affect medical decision-making are well within the reach of the Anti-kickback Statute's prohibitions. Prescription drugs are covered under a variety of federal programs. The Medicare program covers prescription drugs furnished to inpatients of hospitals, nursing homes and hospice patients under Part A of the Medicare program, and payment for such drugs is included within the facility's DRG payment rates. Medicare Part B covers few drugs on an outpatient basis, although certain enumerated drugs are covered. In contrast, the Medicaid statute allows states to cover outpatient prescription drugs, and all states have chosen to provide such coverage.⁷ Prescription drug coverage is also provided under the Civilian Health and Medical Program for the Uniformed Services ("CHAMPUS").⁸ As discussed below, the new Medicare Part D drug benefit program is perceived by the Government to bring a host of new opportunities for fraud and abuse.

While concerns about increased cost and overutilization underlie the Anti-kickback Statute's prohibitions, neither factor is required for a statutory violation to occur. Rather, it is enough if a improper incentives impair a physician's judgment so that the best interest of the patient no longer controls his decision-making. To this end, prescription drug marketing programs that encourage physicians to prescribe a manufacturer's product – not because it has any advantages for the patient – but because the physician feels an obligation to do so in exchange for a gift, violate the statute. Similarly, incentives may cause physicians to order newer, more expensive drugs without any medical justification, or even more of a particular drug than is necessary to treat the patient's condition. In each case, the medical judgment of the physician has been corrupted and the Anti-kickback Statute is implicated.

2. Off-label Marketing

The Food, Drug, and Cosmetic Act⁹ prohibits the introduction of any food, drug, device, or cosmetic that is adulterated or misbranded into interstate commerce. A drug or device is "misbranded" under the FDCA if, among other things, it contains a false or misleading label, or if the package fails to contain adequate directions and warnings for proper use.¹⁰

In addition to exercising authority over drugs and devices and their accompanying literature, the FDA limits the ability of manufacturers to market their products for unapproved uses. Thus, although physicians are free to prescribe drugs for unapproved uses, manufacturers are not allowed to promote

such uses, and may only disseminate information about unapproved uses in response to unsolicited requests from practitioners or pursuant to narrow parameters set forth by statute.¹¹

There is no intent requirement for distributing a misbranded drug or device, and it does not matter whether the statements regarding the drug or device's unapproved uses were, in fact, scientifically accurate. As a result, statutory penalties for violating the FDCA's prohibitions on marketing and selling misbranded drugs are not particularly steep, and a first time offense is considered a misdemeanor under the statute in the absence of an intent to defraud. That is not to suggest that the penalties actually imposed for FDCA violations have been minor. To the contrary, FDCA prosecutions have reaped record-making settlements from pharmaceutical corporations that have admitted to engaging in off-label promotion.

Although criminal sanctions for misbranding or off-label promotion have existed for decades, prosecutions for violations of those statutes had been rare. The FDA's historical practice was to deal with off-label promotion issues primarily through warning letters and other administrative actions. That landscape has now changed with the entry of a new "regulator" – the Department of Justice. Driven in part by a wave of *qui tam* filings, off-label has now become a burning issue in the world of health care fraud enforcement.

B. Pharmaceutical Pricing and Medicare Reimbursement

Another major aspect of pharmaceutical cases in the past has involved allegations of misconduct with respect to drug pricing. Beginning in the late 1990s, the government began investigating drug company reports of "average wholesale prices" or "AWPs," which at the time provided the benchmark for Medicare reimbursement amounts. Despite numerous indications that the government has always been aware of the disparity between reported AWPs and the prices actually paid to purchase drugs, allegations of "fraudulent" pricing continued to bring some prosecutorial success to the government in the last few years, at least insofar as settlement is concerned.¹²

AWP-based inquiries are destined to decrease, if for no other reason than the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA") replaced AWP with "averages sales price" ("ASP") as Medicare's reimbursement benchmark.¹³ This is not to say, however, that investigations into pharmaceutical pricing decisions are a thing of the past. To the contrary, unlike the prior AWP-based reimbursement system, the MMA mandates both that pharmaceutical companies report accurate ASP information to CMS and that the OIG conduct surveys into companies' methodologies for computing

ASPs. The OIG has already noticed that “the reported average sales prices for certain drugs have been rising,” a trend it intends to examine in 2007, thus paving the way for a new round of price disputes.¹⁴

C. Best Price and Medicaid Rebates

In addition, pharmaceutical companies are still obligated to pay rebates to the Medicaid program based upon the “average manufacturer’s price” (“AMP”) and the “best price” of each drug for a given quarter.¹⁵ The government has continued its success with allegations of best price violations, such as that achieved in November 2005, when King Pharmaceuticals paid \$125 million to resolve allegations that it had knowingly failed to accurately calculate its products’ AMPs and best prices in order to pay less money in rebates to Medicaid.¹⁶ The OIG intends to continue evaluating the adequacy of best price calculations “to determine whether drug manufacturers are circumventing the requirements of the Medicaid drug rebate legislation.”¹⁷

D. Medicare Part D

Finally, January 1, 2006, marked the implementation of Medicare Part D, the new drug benefit program established by the MMA for Medicare beneficiaries. By all accounts, Part D represents a whole new frontier in potential health care fraud. Under Part D, Medicare beneficiaries can choose to participate either in prescription drug plans (“PDPs”), or join Medicare Advantage or Medicare health plans through which they can obtain coverage for prescribed drugs. These new arrangements are expected to intensify the competition between pharmacists and pharmacy benefits managers (“PBMs”), which negotiate lower drug prices directly from manufacturers for participants of client health care plans.¹⁸ They will also present numerous opportunities for fraud and abuse, including potential kickbacks between PBMs and PDPs in exchange for favorable contract or formulary decisions and False Claims Act liability for marketing and pricing abuses. The OIG has already taken the position that “[b]ecause of the business relationships that will be formed under Part D, [it] is anticipating violations such as kickbacks, billing for services not rendered, false statements, prescription shorting in institutional settings, and telephone scams” To prospectively address such issues, the OIG has established a specially trained team of Special Agents dedicated to investigating potential Part D violations.¹⁹

II. Statutory Violations as False Claims

The False Claims Act (the “FCA”) is the principal weapon used by the Department of Justice (the “DOJ”) in pursuing civil fraud for pharmaceutical marketing practices, often on a parallel track to criminal prosecution under the AKS or the FDCA. Government investigations based on pharmaceutical marketing practices almost always proceed under the civil FCA, as the statute allows the government to recover not only from those providers who actually submit false claims, but from other entities such as pharmaceutical and device manufacturers who *cause* false claims to be submitted. The statute applies broadly to virtually all monetary claims submitted to federal programs, including claims for reimbursement under the various federal healthcare benefit programs including Medicare and Medicaid. An actionable claim must be submitted to the government, directly or indirectly, the claim must be false or fraudulent (the falsity element) and the claim must have been submitted with knowledge of that falsity. In the event that the government (or a whistleblower, known as a “relator” acting in the name of the United States) prevails in an FCA action, the government is entitled to treble damages plus a statutory penalty of \$5,500- \$11,000 per claim submitted, and the relator gets a percentage of the recovery as well.²⁰ Thus, the real monetary risk in most pharmaceutical investigations lies not in a finding of criminal liability, but in the treble damages and per-claim penalties provided for under the FCA. Virtually every major pharmaceutical investigation settlement has involved the government’s assertion of claims under the FCA based on improper marketing behavior that allegedly involves illegal kickbacks and/or off-label promotion.

A. Anti-kickback Statute Violations as False Claims

Historically, there has been some question as to whether violations of the Anti-kickback Statute can form the basis of a False Claims Act case. The False Claims Act does not render as actionable every claim submitted by a government contractor whose performance did not comply completely with each and every contractual and regulatory provision. To the extent that, for example, a referral that would be unlawful under the AKS resulted in the provision of inpatient medical care or the prescription of a drug that was completely medically appropriate and properly provided, the claim submitted for reimbursement would not, on its face, be false. The government has nonetheless successfully argued that the submission of such claims can form the basis of an FCA action, and will vigorously defend any attempt by defendants to convince a court otherwise. The government takes the position that FCA liability will attach for a statute or regulatory violation when compliance with the statute or regulation affects the provider’s entitlement to payment from a federal program. The government argues that the nexus between payment

and compliance with the AKS creates FCA liability for violations, and has successfully survived motions to dismiss on that basis.

In the past few years, several FCA cases have been filed against providers based at least in part on alleged violations of the Anti-kickback Statute. Those courts allowing such claims to proceed past the pleading stage have relied on two related theories – express certification and implied certification. Some cases, like *United States ex rel. Pogue v. American Healthcorp, Inc.* (“*Pogue I*”), relied on the theory that the provider implicitly certifies compliance with federal health care fraud and abuse statutes by virtue of its participation in the federal Medicare program, rendering claims submitted on referrals tainted by illegal kickbacks false.²¹ Other cases, like *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, relied on allegations that the explicit certification contained in Medicare Cost Reports constitutes an actionable false claim if there is an underlying violation of the AKS.²²

Because FCA liability will attach to a defendant’s alleged failure to comply with a particular statute or regulation that has a sufficient nexus to payment to render him ineligible to receive or retain the payment claimed from the United States, the government takes the position that a violation of the AKS can give rise to liability under the FCA. Four recent decisions have specifically agreed with the government’s position that compliance with the AKS is a prerequisite to payment of federal funds and therefore can form the basis for an FCA claim.²³ In each case, the United States convinced the court that the Social Security Act itself establishes that compliance with the AKS is a prerequisite to a provider’s right to receive or retain federal funds. While this has been the dominant trend in the case law, there have been two district court decisions that rejected the notion of applying the FCA to the AKS.²⁴ Although this issue has not been finally resolved in all circuits, the prevailing trend is in the government’s favor.

B. Off-label Promotion as False Claims

The courts seem to have had less trouble finding that off-label promotion can form the predicate act for an action under the FCA. In the first major case implicating the issue, *United States ex rel. Franklin v. Parke-Davis*, the court soundly rejected the defendant’s arguments that the relator could not prove either the existence of a false claim or that defendant’s off-label promotion had caused false claims to be submitted. The court first found that the FCA does not require that the relator demonstrate that the defendant’s marketing presentations contained any false statements in order to induce physicians to prescribe the drug for off-label uses. The court then disposed of defendant’s argument that the submission of a claim for a drug prescribed for an off-label use is not a false claim because the Medicaid statute gives

the states the discretion to provide reimbursement for off-label prescriptions. Because at least eight state Medicaid programs specifically exclude reimbursement for off-label prescriptions, the court found that compliance with the restrictions of on off-label marketing was a condition precedent to reimbursement in those states, and went on to conclude that a request for reimbursement of a non-covered drug is a false claim. Finally, the court ruled that the relator had presented evidence both of direct (or “actual”) causation in the form of rates of off-label prescriptions both before and after Parke-Davis’ off-label marketing efforts and “legal” causation because it was foreseeable that Parke-Davis’ off-label marketing efforts would lead to off-label prescriptions and the subsequent submission of claims to federal healthcare programs.²⁵

For these reasons, it may not be a productive litigation or settlement strategy to challenge the ability of the government to pursue these claims based on illegal kickbacks or off-label promotion under the FCA. Rather than challenging the applicability of the FCA, it will likely be more productive for pharmaceutical companies under investigation for improper marketing practices to focus on the hurdles that the government will have to clear to meet the FCA’s elements.

III. Challenging Falsity

To establish liability under the FCA, the government must establish: (1) that the defendant knowingly presented or caused to be presented a claim to the United States for payment or approval; (2) that the claim was false or fraudulent; and (3) that the defendant knew that the claim was false or fraudulent.²⁶ The inherent ambiguities of many healthcare statutory and regulatory schemes may make this a difficult burden.

Ultimately it is the government’s burden under the FCA to establish that claims are knowingly “false.” In statutory enforcement actions, this will require proof that the claims at issue were in fact submitted in violation of the underlying statutory prohibitions – either AKS’s inducement prohibitions or, in the case of off-label marketing, the prohibitions of the FDCA – and were not protected by a safe harbor. When the falsity of a claim is based upon a violation of statute or contract, the government has the burden of establishing that the representations are false under *any reasonable interpretation* of the underlying statute or contract.²⁷ Recent case law affirms that this standard applies in the context of complex Medicare regulations.

The Eleventh Circuit’s decision in *United States v. Whiteside* confirms that the government has the burden to show that statements concerning compliance with complex Medicare statutory schemes are false under any reasonable interpretation of the rules. *Whiteside* overturned the false statement convictions of two hospital executives in connection with the submission of Medicare cost reports.

Whiteside involved a single allegedly false statement classifying debt interest as 100% capital-related on cost reports submitted to the government for reimbursement. The government contended that the classification of the interest expense based on how the debt was being used at the time of the filing of the cost report, rather than how the funds were used at the time of the loan origination, was inconsistent with the Medicare regulations. The defendants responded that no Medicare regulation or other authority exists that indicates that this characterization of debt interest was incorrect, much less “knowingly and willfully” false. “In sum,” the court explained, “defendants contend that the government failed to prove that the statements at issue were not a reasonable interpretation of ambiguous Medicare reimbursement requirements; thus, the government failed to prove the statements were knowingly and willfully false.”²⁸

The court first laid out the government’s burden:

“In a case where the truth or falsity of a statement centers on an interpretive question of law, the government bears the burden of proving beyond a reasonable doubt that the defendant’s statement is not true under a reasonable interpretation of the law. *United States v. Migliaccio*, 34 F.3d 1517, 1525 (10th Cir. 1994) (holding that the government bears the burden to negate any reasonable interpretations that would make the defendant’s statement correct); *United States v. Johnson*, 937 F.2d 392, 399 (8th Cir. 1991) (holding that one cannot be guilty of a false statement beyond a reasonable doubt when his statement is a reasonable construction); *United States v. Race*, 632 F.2d 1114, 1120 (4th Cir. 1980) (same); *United States v. Anderson*, 579 F.2d 455, 460 (8th Cir. 1978) (same); *see also United States v. Calhoon*, 97 F.3d 518, 526 (11th Cir. 1996) (noting that even though the Medicare regulations were clear regarding the royalty fees paid to a related party, the government failed to establish as a matter of fact that the fees claimed were actually in excess of what was clearly allowed under the regulations, and thus, had ‘failed to sustain its burden to prove the claim false by virtue of the nonreimbursable nature of the interest’).”²⁹

The Eleventh Circuit went on to find that the government could not meet its burden because “no Medicare regulation, administrative ruling, or judicial decision exists” clearly requiring the treatment urged by the government. It found the pertinent regulation failed to explain how to define the underlying debt for purposes of cost report treatment and concluded that the regulation was ambiguous and subject to

differing interpretations. It referred to testimony from government witnesses and agency publications suggesting that the regulation at issue “can be interpreted different ways,” and that the defendants’ interpretation was not unreasonable.³⁰

Ultimately, the court concluded that the government had failed to meet its burden of proving the statements false:

“Neither the regulations nor administrative authority clearly answer the dilemma the defendants faced here. As the [Fiscal Intermediary] testified, under current law, reasonable people could differ as to whether the debt interest was capital-related. The testimony indicates that the experts disagreed as to the validity of the theory of capital reimbursement suggested by the government. This contradictory evidence lends credence to defendants’ argument that their interpretation was not unreasonable. Here, ‘competing interpretations of the applicable law [are] far too reasonable to justify these convictions.’ *United States v. Mallas*, 762 F.2d 361, 363 (4th Cir. 1985). As such, the government failed to meet its burden of proving the *actus reus* of the offense – actual falsity as a matter of law.”³¹

This analytical framework is equally applicable in a civil FCA action. In *Hagood v. Sonoma County Water Agency*,³² the court was presented with allegations of violations of the FCA based upon the manner in which various costs allocations were made under a contract with the Army Corps of Engineers. Noting that there were both statutory and contractual ambiguities with respect to the cost allocation issue, the court granted summary judgment dismissing the allegations under the FCA due to the government’s failure to establish “falsity,” stating:

“Even viewing *Hagood’s* evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was *false* within the meaning of the false claims act.”³³

Similarly, *United States ex. rel. Swafford v. Borgess Medical Center* involved allegations under the FCA relating to whether physicians’ involvement in the interpretation of certain diagnostic tests was sufficient to permit them to bill Medicare. Noting a lack of clarity in the requirements for such billings, the court, on a motion for summary judgment, dismissed the action stating:

“A defendant’s decision in the face of a dispute over the requirements of governing regulations is insufficient, without more, to constitute falsity.”³⁴

IV. Challenging Intent

A. Challenging the Intent Elements of the Anti-kickback Statute

In order to successfully prosecute a pharmaceutical manufacturer of illegal kickbacks – and in order to use the FCA to recover civilly for such violations – the government needs to prove that the defendant acted with the required mental state. The AKS contains two scienter requirements. One is the “standard requirement of knowing and willful acts.”³⁵ The key to an AKS conviction, however, is the second, specific scienter requirement, that requires that the offer or payment of remuneration be made with the intent to induce referrals.³⁶ Both of these scienter requirements play a role in focusing the AKS on conduct deserving of criminal and civil punishment, while at the same time protecting those who enter into financial arrangements with referral sources without the required mental state.

1. Knowing and Willfully Violating the Law

In 1980, Congress responded to the concern that “criminal penalties may be imposed under [the AKS] to an individual whose conduct, while improper, was inadvertent,”³⁷ by adding that acts committed in violation of the AKS must be performed “knowingly and willfully.”³⁸ AKS cases occurring soon after this amendment seemed to interpret the addition of the “knowingly and willfully” scienter requirement as simply stating that a defendant’s actions in paying remunerations to induce referrals must be performed knowingly and willfully.³⁹ In 1994, however, the United States Supreme Court, in *Ratzlaf v. United States*, interpreted the willfulness provision of the anti-structuring provisions of the Money Laundering Control Act of 1986 to require that the government prove that the defendant knew that his conduct was unlawful.⁴⁰

Following this Supreme Court precedent, the Ninth Circuit declared in *Hanlester Network v. Shalala* that in order to prove that a defendant violated the AKS knowingly and willfully, the government must prove: (1) that the defendant knew that the AKS prohibits offering or paying remuneration to induce referrals; and (2) that the defendant engaged in this prohibited conduct with the specific intent to disobey the law. In *Hanlester*, the Department of Health and Human Services (“HHS”) brought a civil action to exclude certain individual and corporate defendants from participating in Medicare and Medicaid, alleging violations of the AKS. The allegations included that parties associated with Hanlester Network offered or paid remuneration to physician limited partners, who were in a position to order substantial quantities of laboratory tests, in order to induce referrals to limited partner laboratories. The Ninth Circuit upheld HHS’s ruling that the AKS was violated only with regard to the one individual defendant that substantial

evidence showed acted with knowledge that her conduct was unlawful, and with the specific intent to disobey the law.⁴¹

The Fifth Circuit, in *United States v. Davis*, held that *Hanlester* “requires knowledge only that the conduct in question was unlawful, and not necessarily knowledge of which particular statute makes the conduct unlawful.” Without deciding if the AKS requires such a heightened scienter requirement, the *Davis* court ruled that jury instructions defining knowingly as meaning “that the act was done voluntarily and intentionally, not because of mistake or accident,” and defining willfully as meaning “that the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law,” met the *Hanlester* heightened scienter requirement.⁴²

Other Appellate Courts that have interpreted the “knowingly and willfully” requirement of the AKS agree it requires more than simply acting in a voluntary and conscious manner, but have stopped short of *Hanlester*’s ruling that ignorance of the law is a defense against actions under the statute. In *United States v. Jain*, the Eighth Circuit affirmed the district court’s adoption of a middle ground between these two positions, requiring that the defendant knowingly behave in a matter that is unjustifiable and wrongful. The court found Congress’s concern that inadvertent behavior might be penalized, which led them to add the “knowingly and willfully” element to the AKS, and Congress’s creation of elaborate “safe harbor” provisions, confirm that the AKS potentially penalizes conduct that is not “obviously nefarious.” “Only conduct that is inevitably nefarious, that is, obviously evil or inherently bad, warrants the traditional presumption that anyone consciously engaging in it has fair warning of a criminal violation.” Therefore, the Eighth Circuit held that a heightened *mens rea* burden for the AKS is appropriate.

The Eight Circuit also found, however, that as opposed to the statute at issue in *Ratzlaf* that prohibited willful violations of another anti-structuring statute, the AKS prohibits the willful performance of a series of prohibited acts. This led the court to rule that the plain language of the AKS, and respect for the traditional principle that ignorance of the law is no defense, suggest that the heightened *mens rea* standard should only require proof that the defendant knew his conduct was wrongful.⁴³ The Eleventh Circuit, in *United States v. Starks*, reached a similar conclusion.⁴⁴

2. Intent to Induce Referrals

The AKS prohibits the offering or paying of remuneration with the specific intent to induce referrals.⁴⁵ The phrase “to induce” was interpreted in a jury instruction quoted in *United States v. McClatchey* to mean “the intent to gain influence over the reason or judgment of a person making referral decisions.” The Tenth Circuit explained that a hospital or an individual “may lawfully enter into a business relationship with a doctor and even hope for or expect referrals from that doctor” without intending to induce referrals. The court distinguished the situation where a defendant offers or pays remuneration to a person with the capacity to make referrals back to the defendant, with an intent to gain influence over the reason or judgment of the referring party, with the situation where a defendant merely hopes, or believes, or expects that referrals may ensue from remuneration designed for wholly other purposes.⁴⁶ Under this formulation of the law, if a defendant offers or pays remuneration with the former intent, he has violated the AKS, but if he offers or pays remuneration with the latter intent, he is immune from conviction.

3. The “One Purpose” Test

Courts have suggested that the protection offered by the AKS would be vitiated if a party could avoid violating the statute by funneling payments through an otherwise legitimate services arrangement – by paying excessive remuneration over and above fair market value for legitimate consulting services, for example – even when the excessive portion of the remuneration was intended as an inducement for referrals. This was the situation raised in *United States v. Greber*. In *Greber*, the defendant paid “interpretation fees” to referring physicians to compensate them for their initial consultation and for explaining the results of Holter monitor testing. The fees paid were more than Medicare allowed for such services, and were sometimes paid when the defendant himself evaluated the monitoring data for the patients. The defendant argued that “absent a showing that the only purpose behind the fee was to improperly induce future services, compensating a physician for services actually rendered could not be a violation of the [AKS].” The Third Circuit rejected this argument, holding that if remuneration is intended to induce referrals, “the [AKS is] violated, even if the payments were also intended to compensate for professional services.” The court summarized this holding in the opinion’s first paragraph by stating, “We . . . hold that if one purpose of the payment was to induce future referrals, the medicare [sic] statute has been violated.”⁴⁷ A similar argument, that an AKS conviction requires a finding that remuneration was paid for no other purpose than inducing the referral of Medicare patients, was rejected in *Davis*.⁴⁸

The First Circuit went even farther, and held in *United States v. Bay State Ambulance & Hosp. Rental Serv.* that it is not necessary for a defendant to overpay a referring party to be found guilty of violating the AKS since the gravamen of an AKS violation is inducement. The court then considered whether the intent

to induce had to be the sole intent or the primary intent in order to trigger a violation of the AKS, or if any intent to induce is enough. Although it chose not to decide if a lesser showing of intent would be sufficient, the court held that a finding that a defendant acted with the primary purpose of inducing an act prohibited by the AKS is sufficient to meet the intent element envisioned by Congress.⁴⁹

In *United States v. Kats*, a defendant was convicted of accepting kickbacks in violation of the “solicitation or receipt” portion of the AKS. The District Court charged the jury that:

“The government must prove beyond reasonable doubt that one of the purposes for the solicitation of a remuneration was to obtain money for the referral of services which may be paid in whole or in part out of Medicare funds. It is not a defense that there might have been other reasons for the solicitation of a remuneration by the defendants, if you find beyond reasonable doubt that one of the material purposes for the solicitation was to obtain money for the referral of services. It is entirely up to you to decide whether the solicitation of a remuneration was, at least in material part, for the referral of services.”⁵⁰

The District Court further instructed the jury that a “kickback,” for purposes of the “solicitation or receipt” portion of the AKS, consists of “a payment for granting assistance to one in a position to control a source of income, unless such payment is wholly and not incidentally attributable to the delivery of goods or services.”⁵¹

As discussed above, the Tenth Circuit, in *McClatchey*, defined the AKS’s phrase “to induce” to mean “to offer or pay remuneration with the intent to gain influence over the reason or judgment of a person making referral decisions.” The District Court instructed the jury that to be found guilty, the defendant’s “intent to gain such influence must, at least in part, have been the reason the remuneration was offered or paid.” The defendant argued on appeal that in order to be convicted the jury should have been required to find that the motivation to induce referrals was the primary purpose behind the offer or payment of remuneration. The Tenth Circuit rejected this argument, based on *Davis*, *Kats*, and especially *Greber*’s formulation of the one purpose test. Although the *McClatchey* court held that a party’s hope or expectation that a lawful business relationship with a doctor will lead to referrals does not violate the AKS, it further held that the party must enter into that business relationship “for legal reasons entirely distinct from its collateral hope for referrals.”⁵²

B. Challenging the “Knowing” Elements of Civil and Criminal False Claims

The earlier discussion regarding the ambiguity defense and the instinctual tendency to involve evidence of intent in the objective falsity determination reveals the close link between falsity and scienter.⁵³ Just as ambiguity in the underlying rule or regulation makes it difficult to demonstrate that a defendant made a literally false statement or claim, it also makes it difficult for the prosecution to prove that the defendant possessed the requisite intent to submit a false claim.

A defendant may be found guilty of violating various criminal false claims statutes only if prosecutors can prove that he knew, at the time that he tendered the claim or statement, that it was false.⁵⁴ Similarly, in order to recover for civil false claims, the government generally must prove that the defendant knew that it was not entitled to payment when submitting the claim. While the circuits differ as to what precise mens rea each of the fraud statutes actually require, they generally agree that at a minimum, the defendant must have possessed “knowledge of falsity.”⁵⁵ Innocent mistakes, or negligence, are not actionable.⁵⁶ When knowledge, or something greater, is required under the statute the defendant is accused of violating, the argument that the defendant lacked this state of mind is commonly referred to as the “good faith” or “mistake” defense. A good faith defense typically proceeds along the lines of the following jury instruction:

“A person who acts . . . on a belief or opinion honestly held is not punishable . . . merely because the belief or opinion turns out to be inaccurate, incorrect, or wrong. An honest mistake in judgment or an honest error in management does not rise to the level of criminal conduct.”⁵⁷

Often, the same evidence of ambiguity that a defendant introduces to establish reasonable doubt of literal falsity supports a good faith defense. The Second Circuit in *United States v. Siddiqi* recognized that the ambiguity of the procedural code at issue implicated not only the literal falsity elements of the false claims and mail fraud counts under §§ 287 and 1341, but also the *mens rea* requirements:

“Each of the Mecca counts [false claims under § 287 and mail fraud under § 1341] required proof that Siddiqi used code 96500 with a dishonest intent. Based on the present record, inference of such an intent cannot be drawn from use of the code. As noted, code 96500 allows billing for ‘supervision,’ a term that is, on this record, unclear. The government’s principal expert on this issue was unable to provide a definition of supervision, and the government cannot be allowed to prevail on the claim that it is fraud for Siddiqi not to have anticipated the definition embodied in [the government’s] theory . . .”⁵⁸

Similarly, in *United States v. Freshour* the Sixth Circuit overturned one count of the defendant's mail fraud convictions on the ground that ambiguity in the Medicaid providers' manual prevented her from knowing that the claims she submitted for reimbursement were false. The government claimed that Freshour fraudulently billed KY jelly as skin gel. The court, however, noted that there was no specific code in the manual for KY jelly, nor was there a definition for "skin gel" that may have enlightened the defendant as to the code's proper use. The interchangeable nature of the products and general confusion in the industry over the proper billing reference further convinced the court that Freshour lacked sufficient knowledge of the falsity of her claim to sustain the conviction.⁵⁹

It is apparent that, unlike the element of objective falsity, a myriad of considerations apart from the ambiguity of the rule or regulation enter into the good faith determination. While the trier of fact will be required to put on blinders to all other evidence apart from that which pertains to the ambiguity of the underlying rule or regulation in making the objective falsity determination, scienter determinations are made with respect to all of the facts and circumstances of the case -- of which the ambiguity of the underlying rule or regulation is just one. Prosecutors may refute the ambiguity defense as it is applied to the element of objective falsity only by negating all reasonable interpretations of the underlying rule or regulation that would make the defendant's statement or claim true. With respect to a defendant's assertion that because the rule governing his conduct was ambiguous, he did not know that his statement or claim was false at the time that he made it, prosecutors have significantly more weapons in their arsenal.

The government can defuse the good faith defense premised upon ambiguity in a variety of ways. It may introduce direct or circumstantial evidence indicating that the defendant had actual knowledge of the proper interpretation of the underlying regulation, code, or rule. In *United States v. Duclos*, the defendant's direct admission that "he knew the nature of his act and he knew [its] likely effect," was sufficient to demonstrate intent.⁶⁰ In *United States v. DeSalvo*, the government successfully demonstrated that the defendant knew that the Medicare claims she filed were false by showing a videotape in which the defendant boasted of her experience and knowledge of Medicare regulations.⁶¹ Most prosecutions, however, rely upon circumstantial evidence to demonstrate that the defendant possessed sufficient knowledge of the false or fraudulent nature of his conduct. Testimony indicating that an employee of an agency that administers a health care reimbursement program instructed the defendant regarding the proper claims procedure may be introduced to prove that the defendant had actual knowledge that the reimbursement claims he filed were false. Such instruction need not be formal, official or written: courts

have inferred the requisite knowledge on the basis of evidence that oral instructions were given over the telephone by a low-level employee.⁶²

The defendant's conduct, if consistent with knowledge or a suspicion of illegality, may also be used to demonstrate the requisite intent. In *United States v. Hooshmand*, the defendant-neurologist instructed his staff to address consultation reports to doctors who never requested them, place copies in patients' files, and then destroy the originals.⁶³ Such conduct illustrates that the defendant knew that his billings for "consultations" might not be legitimate. In *United States v. Weiss*, the defendant, a supplier of medical devices, was convicted of mail fraud for filing Medicare reimbursement claims to carriers in jurisdictions other than that where the sales were made in order to receive greater reimbursement. Whenever a carrier eventually realized that the defendant's claims should have been filed in another jurisdiction, the defendant would select another jurisdiction, file his claims there until the new carrier realized the error, and so on. This conduct, combined with an elaborate mailing system designed to ensure that the proper jurisdiction's postage mark appeared on each envelope, constituted persuasive evidence that Weiss knew that he was filing claims illegally. The defendant's similar prior fraudulent acts may also supply the requisite intent.⁶⁴

Moreover, evidence that the defendant deliberately ignored, or had a reckless disregard for the truth, may be sufficient to demonstrate the defendant's lack of good faith and satisfy the knowledge requirement.⁶⁵ A "deliberate ignorance," or "ostrich"⁶⁶ jury instruction allows the jury to find the defendant guilty if it concludes that the defendant had actual knowledge *or* had adopted an attitude of "willful blindness" and kept himself "deliberately ignorant" regarding the proper rules or regulations or their interpretation.⁶⁷ Such an instruction is appropriate, however, only when the defendant claims "a lack of guilty knowledge" and there are facts in evidence that would support an inference "that the defendant may have purposely avoided learning the facts or shut his eyes to avoid learning the existence of a fact he all but knew."⁶⁸ Such an instruction was proper in *United States v. Erickson*, where the defendant physician stated that he was "not in any way involved" in billing determinations even after he was interviewed in connection with an investigation by the Health Care Financing Administration ("HFCA") into his office's billing practices and instructed regarding the proper procedures.⁶⁹ A deliberate ignorance instruction was also held to be appropriate in *United States v. Lennartz*, where the operator of an ambulatory service for Medicaid patients failed to review the actual mileage, routes, or waiting times of its drivers, or even whether scheduled trips actually took place, before filing Medicaid reimbursement claims.⁷⁰

Although some complain about the congruity of a deliberate indifference instruction with the knowledge requirement, in FCA cases based on underlying kickbacks and off-label marketing, even deliberate indifference may no longer be required. While only one court has directly addressed the subject with respect to kickbacks, many of these actions are pursued in the absence of any evidence regarding the defendant's scienter with respect to the alleged underlying violation. In fact, the Middle District of Tennessee held in *Pogue* that, even in the absence of any evidence that the defendant had knowledge of the violation underlying the false claims suit, knowledge may be implied to the extent that the defendant presumptively hid the violation from the government in order to obtain reimbursement.⁷¹ Similarly, the court in *Parke-Davis*, citing to *Pogue*, suggested that the fact that the claims were submitted by another entity will not relieve the manufacturer whose off-label marketing caused the submission of the claims from liability – regardless of the mental state of the party submitting the claims and regardless of the lack of certification of compliance by the pharmaceutical manufacturer.⁷² Such actions threaten to eviscerate the scienter requirement of the law allegedly violated.

C. Using Advice of Counsel to Negate Improper Intent

Pharmaceutical manufacturers should consider seeking legal advice of counsel before undertaking any marketing practice premised on an ambiguous rule. Although it usually requires waiver of the attorney-client privilege with respect to all communications on the matter, evidence that the defendant sought, in good faith, the advice of competent, fully informed counsel before committing the allegedly illegal act is strong evidence of the defendant's good faith and the reasonableness of his interpretation,⁷³ and may disprove willfulness.⁷⁴

If possible, when seeking the advice of counsel regarding an ambiguous statute or regulation, the company should request counsel to state his opinion in writing. Oral opinions may lack sufficient indicia of timeliness, accuracy, and credibility upon which a court may comfortably conclude that the defendant lacked the willfulness to commit fraud.⁷⁵

United States v. Lewis provides an example of how the advice of counsel defense can effectively negate the intent element. In *Lewis*, the defendants were accused in an FCA *qui tam* suit brought by a former employee of misrepresenting themselves to Medicare as a dialysis supplier and taking illegal kickbacks in the form of self-referrals. The defendants, owners of a dialysis facility and dialysis supply company, argued that they lacked knowledge of the falsity of their Medicare reimbursement claims because their attorneys, members of a single law firm, had advised them that they were in compliance with the applicable laws and regulations. With respect to each of the defendants' two businesses, the firm advised

them upon incorporation and on compliance with Medicare regulations. The defendants never specifically asked if the common ownership of their two businesses might result in regulatory violations, but nor were they ever alerted to the possibility. Although the defendants did not receive specific advice stating that their reimbursement claims were in compliance with the FCA, they were implicitly advised that their common ownership arrangement did not violate any existing statutes or regulations. After assuring itself that the defendants did not conceal any material facts from their attorneys, and noting the defendants' consistent efforts to apprise themselves of and comply with relevant statutes and regulations, the court agreed that the defendants lacked the requisite knowledge of falsity and granted summary judgment in their favor.⁷⁶

Lewis demonstrates that the advice of counsel defense need not be based on specific, affirmative advice. A provider who routinely receives legal advice, and *reasonably* delegates compliance issues to its attorneys, may invoke the advice of counsel defense if it is prosecuted for a violation of which it was justifiably unaware. It is doubtful, however, that a court would be as likely to accept the advice of counsel defense had there been evidence of bad faith or deliberate ignorance on the part of the defendants.

V. Challenging Damages

In FCA cases based on violations of the Anti-kickback Statute, the Department of Justice has repeatedly taken the position at the negotiation stage and in its public appearances that the appropriate measure of damages subject to trebling is the total amount of the affected claims paid. While DOJ has never actually litigated, or even briefed, this point, the theory espoused by the government is that these claims are “tainted” by the underlying statutory violation, that the government would not pay such claims had it known of the violation, and that the amounts paid are therefore damage. According to DOJ, Congress has defined the types of services for which it would pay. Services rendered as a result of illegal kickbacks are simply non-covered—and program participants are not entitled to reimbursement. To the extent that the government pays such claims, DOJ takes that position that the government is damaged for FCA purposes.

While the government widely espouses this position, no court has yet had an opportunity to rule on the proper measure of damages in an FCA case alleging false claims based on Anti-kickback Statute violations. It is, however, well-established that no damages can be awarded under the False Claims Act where the plaintiffs have failed to make a showing of an actual loss having been sustained by the government.⁷⁷ This circumstance has frequently arisen in such “false certification” cases, where the

government premises its claim on the theory that the claims are false because – had the government known about the false certifications of compliance – it would not have paid any funds. While a growing number of courts have recognized false certification as a valid theory sufficient to state a claim under the FCA, those same courts have rejected the government’s argument that damages in such cases should be equivalent to all funds received by the defendant. But applying basic FCA damages principles, the appropriate measure of damages in such cases should be the difference between what the government actually paid and what it would have paid had there been no statutory violation – that is, what the government would have paid had the referrals not been tainted by improper financial relationships. Those few courts that have calculated the amount of loss to the government as a result of government program referrals tainted by prohibited financial relationships have utilized this method. Each of these courts concluded that the government suffered no actual loss arising out of the payment of claims for such services because it got exactly what it paid for. And many other courts – including *Thompson* and *Pogue* – have acknowledged that, because Medicare pays the same amount for each service no matter where provided, there are no true “overpayments” or “inflated” Medicare payments caused by improper referrals.⁷⁸ This is particularly true when there is no evidence of overutilization.⁷⁹

While no court has yet ruled on the proper way to calculate damages under the FCA for false claims based on improper referrals, analogous decisions exist in the criminal sentencing context under the AKS, where courts have looked to the “actual loss” suffered by the government in determining the amount of restitution owed. These decisions uniformly reject the notion that the government has suffered “loss” in the amount of all funds paid on claims infected by improper referrals.

In *United States v. Anderson*, the court found that the government’s only “actual loss” as a result of an illegal referral arrangement is the Cost Report impact of any illegal or improper payments. In sentencing the defendants who had been convicted of violating the AKS, the *Anderson* court determined an appropriate restitution penalty. Like the FCA, the applicable sentencing guidelines and interpretive case law require that the restitution order be “based on the amount of loss actually caused by the defendant’s offense.” As under the FCA, the government has the burden to prove the amount of the loss. Applying this criteria, the court ultimately concluded that the appropriate restitution damages consisted of the Cost Report effect of illegal payments to physicians, which the court concluded were the only “amounts the government would not have had to pay but for the illegal remuneration schemes.”

The government had urged that the *Anderson* court issue a restitution order in one of four possible amounts: (1) the amount of the bribe or kickback; (2) the amount Medicare paid the hospitals for inpatient

services for patients referred by the physicians, under the theory that the provider was unjustly enriched by the receipt of payments that the government did not intend for it to receive; (3) the amount Medicare reimbursed the hospitals through the Medicare Cost Reports; or (4) a percentage of the salary of the convicted hospital administrator.

The *Anderson* court soundly rejected the government’s argument that the amount of restitution should be based on the total amount Medicare paid on tainted referrals. It accurately recognized that – at least where there is no proof of unnecessary treatment – the kickback scheme affected only the location of treatment, not the amount that Medicare paid in reimbursement for those treatments, and thus that the government would have paid the same amount in reimbursement for patient care regardless of the kickbacks. It found that the government’s tainted claims theory had “no merit” because a restitution order is to be based on actual loss, not on the amount by which the defendant was unjustly enriched. In this regard, the court noted that, unlike other sentencing guideline applications, a restitution order cannot be based on the actual or intended gain to the defendant; rather, it must be “based on the amount of *loss actually* caused by the defendant’s offense.”

Anderson applied a similar analysis to reject the government’s argument that restitution be based on the amount of the kickback or bribe. Relying on the fact that the kickbacks affected only where the service was provided, and not the amount reimbursed, the court found that the amount of the kickbacks had no relation to the amount of loss suffered by the government. It held that: “It would be inappropriate to value the amount of loss on the amount of the consulting fees paid by the hospitals and received by the doctors because the government has failed to show any nexus between the amount of what it considers as the bribes and the amount of its loss.” The court further reasoned that the payment of kickbacks (other than those claimed on the Cost Reports) did not cause any loss to the government because those funds were paid out of hospital – rather than government – funds.

Focusing on actual loss, the *Anderson* court ultimately concluded that the only losses actually suffered by the government in a kickback case are the amount of bribes or kickbacks for which the provider sought and received reimbursement from Medicare on its Cost Reports because “these amounts are the only amounts the government would not have had to pay but for the illegal remuneration scheme.”⁸⁰

Application of this type of approach could drastically limit, or even eliminate FCA damages, depending on the type of remuneration that is at issue. For example, if the kickbacks are income guarantees, or practice support or fees paid to Medical Directors, damages should be limited to that portion of such fees,

if any, that is claimed on the Cost Report and actually reimbursed. In the case of a pharmaceutical manufacturer that does not file Cost Reports, that amount is likely to be zero. Similarly, if the kickbacks consist of un-repaid loans, below-market leases, or other remuneration that does not involve a direct payment to the physician, even a direct provider could argue that the government suffered no loss at all, since the government did not reimburse the provider for any additional amounts because of the kickbacks.

In *United States v. Vaghela*, the Eleventh Circuit faced the same restitution issue addressed by the *Anderson* court, although it reached a different conclusion. In *Vaghela*,² the district court had calculated the amount of restitution at approximately \$50,000, the amount for which the government was billed under Medicare for the tainted referrals. The Eleventh Circuit disagreed with this calculation, and found that the proper amount of loss for purposes of restitution was \$23,400 – the amount that the provider received in illegal kickbacks in exchange for the referrals. The court first pointed to the applicable sentencing guidelines, which limited restitution to the amount of the government’s loss, and then confirmed that it is the government’s burden to prove the amount of loss by a preponderance of the evidence. The court accurately recognized that the amount of loss suffered by the government is not the amount of revenue paid for the tainted referrals, but then went on to assume that the amount of the kickback was a reasonable reflection of the government’s loss. The court rejected the government’s speculation that kickbacks necessarily result in overutilization: “Speculation that Medicare ends up paying for some medically unnecessary treatments and tests when kickbacks are provided in exchange for the referral of Medicare patients and services is insufficient to support the government’s burden to prove actual losses in each particular case.”⁸¹

It is not yet clear that courts will accept either the *Anderson* or the *Vaghela* analysis and apply it in the FCA context. But given that the FCA, like the sentencing guidelines, requires the court to look at the government’s actual loss, and given the government’s burden under the FCA to prove the amount of actual loss with specificity, such an approach appears most appropriate, and should be a focus of settlement discussions in any pharmaceutical fraud investigation based on alleged kickbacks.

VI. Conclusion

Government investigations and whistleblower actions have become a fact of life in the health care industry. Pharmaceutical manufacturers – due in no small part to their historic profitability – are in the eye of the storm. With often hundreds of millions of dollars at stake, and the ultimate penalty of exclusion as an option, most companies choose to settle rather than to roll the dice and litigate. But reaching a

negotiated resolution – even when in a cooperative mode – does not require unconditional surrender, and pharmaceutical manufacturers and their counsel can and should consider these and other similar options when developing defense strategies.

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² Press Release, Office of Inspector General, “OIG Reports \$38 Billion in Savings and Recoveries for FY 2006” (12/5/06).

³ Testimony of N. Messuri, Assistant Attorney General; Director, Massachusetts Medicaid Fraud Control Unit; and President, National Association of Medicaid Fraud Control Units, before U.S. Senate Finance Committee (6/28/05).

⁴Office of the Inspector General, Work Plan for Fiscal Year 2006 (“2006 OIG Work Plan”) at 39.

⁵42 U.S.C. § 1320a-7b(b) and 21 U.S.C. § 331.

⁶ 42 U.S.C. § 1320a-7a(a)(7); 7b.

⁷See 42 U.S.C. § 1396(a)(10)(a), 1396d(a)(12).

⁸See 32 C.F.R. § 199.4(d)(1)(vi).

⁹21 U.S.C. §§ 301 et. seq.

¹⁰21 U.S.C. § 352.

¹¹21 U.S.C. § 360aaa – 360aaa-6.

¹²For example, in September 2005, GlaxoSmithKline elected to pay \$150,000,000 to the government to resolve allegations that it had improperly “inflated” its reported prices. However, the government’s price fraud theories have suffered some notable defeats as well. In 2004, a jury acquitted eight current and former employees of TAP Pharmaceuticals of conspiring to pay kickbacks to doctors, in part, by marketing the spread between the actual cost of TAP’s drug Lupron and its AWP-based reimbursable rate. See *United States v. MacKenzie, et al.*, Case No. 1:01-cr-10350-DPW (D. Mass. 6/13/03). And in a civil trial in December 2005, a West Virginia jury agreed with Warrick Pharmaceuticals that its practices with respect to reporting its drug’s AWP complied with all applicable state regulations.

¹³On the other hand, some pharmaceutical companies are still feeling the dead hand of AWP. For example, in Schering-Plough’s 10-K filing with the SEC for the period ending September 30, 2005, it noted that it is currently responding to an investigation by the US Attorney’s Office for the District of Massachusetts into whether the AWPs set for certain drugs resulted in “unlawful inflation” of certain drug reimbursements.

¹⁴2006 OIG Work Plan at 10.

¹⁵Determining the “best price” at which a drug is sold involves a complicated series of calculations that take into account some but not all types of price reductions. 42 U.S.C. § 1396-r.

¹⁶*United States ex rel. Edward Bogart, et al. v. King Pharmaceuticals, Inc., et al.*, Case No. 03-01538-MK (E.D. Pa 3/12/03).

¹⁷2006 OIG Work Plan at 26.

¹⁸See “PBMs Fault Independent Pharmacists for Allegedly Fixing Reimbursements,” 3 Pharmaceutical Law & Industry 22 at 577 (6/3/05).

¹⁹2006 OIG Work Plan at 39.

²⁰See 31 U.S.C. §3729(7).

²¹914 F. Supp. 1507 (M.D. Tenn. 1996).

²²20 F. Supp. 2d 1017 (S.D. Tex. 1998).

²³See *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612 (N.D. Ill. 2003); *United States ex rel. Barrett v. Columbia/HCA Health Care Corp.*, 251 F. Supp. 2d 28 (D.D.C. 2003); *Pogue II*, 238 F. Supp. 2d at 266, *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 2005 WL 2179164 (11th Cir. 9/9/05).

²⁴See *U.S. ex rel. Urbanek v. Laboratory Corp. of America Holdings, Inc.*, No. 00-CV-4863 (E.D. Pa. 8/14/03) and *U.S. ex rel. Barmack v. Sutter Corp. and Orthologic Corp.*, 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y. 2002).

²⁵2003 WL 22048255 at *4-5 (D. Mass. 8/22/03)

²⁶31 U.S.C. § 3729(a)(1),(2). See, e.g., *U.S. ex rel. Swafford v. Borgess Medical Center*, 98 F. Supp. 2d 822 (W.D. Mich. 2000).

²⁷*United States v. Whiteside*, 2002 U.S. App. LEXIS 4610 (11th Cir. 3/22/02); *United States v. Anderson*, 579 F.2d 455 (8th Cir. 1978), cert. denied by 439 U.S. 980, 99 S.Ct. 567 (1978); *United States v. Race*, 632 Fed. 2d, 1114 (4th Cir. 1980); *United States v. Adler*, 623 F.2d 12 (8th Cir. 1980).

²⁸*United States v. Whiteside*, 2002 U.S. App. LEXIS 4610 at *17 (11th Cir. 3/22/02).

²⁹*Id.* at *17–18.

³⁰*Id.* at *18-21.

³¹*Id.* at *21.

³²81 F.3d 1465 (9th Cir. 1996), cert. denied, 519 U.S. 865, 117 S.Ct. 175 (1996).

³³*Id.* at 1477. In *U.S. ex rel. Oliver v. Parsons Company*, 95 F.3d 457 (9th Cir. 1999), cert. denied, 120 S. Ct. 2657 (2000), a panel of the 9th Circuit limited *Hagood’s* interpretation of the “falsity” requirement to situations involving interpretations of statutes that are “discretionary” and stated that where a case turns on the interpretation of regulations that “while unquestionably technical and complex, are not discretionary [, falsity] is ultimately the subject of judicial interpretation.” *Id.* at 463. No other court has adopted *Parsons* novel analysis. The *Parsons* court specifically acknowledged that if a standard is so vague as to be unknowable in advance, liability is impossible. *Id.* Regardless of whether the analysis is couched in terms of falsity or scienter: “[t]o take advantage of a disputed legal question . . . is to be neither deliberately ignorant nor recklessly disregarding.” *U.S. ex rel. Hagood v. Sonoma County Water Agency*, 929 F. 2d 1416 (9th Cir. 1991); See also *U.S. ex rel. Trim v. McKean* 31 F. Supp 2d 1308, 1315 (W.D. Okla. 1998) (“for a statement to be knowingly false, it must be more than merely an innocent mistake or misinterpretation of a regulatory requirement.”); *U.S. Napco International Co., Inc.* 835 F. Supp. 493 (D. Minn. 1993).

³⁴98 F. Supp. 2d. 822, 832 (W.D. Mich. 2000). Numerous other decisions follow this line of reasoning. *United States v. Krizek*, 859 F. Supp. 5 (D.D.C. 1994), affirmed in part and remanded, 111 Fed. 3d 934 (DC Cir. 1997); *Luckey v. Baxter Healthcare Corporation*, 183 Fed 3d 730, 732 (7th Cir. 1999), cert. denied, 120 S.Ct. 562 (1999) (“As

written, the regulations do not resolve this debate. Baxter had to make a decision for itself.”); *United States ex. Rel. Cox v. Iowa Health System*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998).

³⁵*United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 33 (1st Cir. 1989).

³⁶*See id.*

³⁷H.R. Rep. No. 96-1167, at 59 (1980), as reprinted in 1980 U.S.C.C.A.N. 5526, 5572.

³⁸*See Medicare And Medicaid Amendments Of 1980*, Pub. L. No. 96-499, 94 Stat. 2625.

³⁹*See, e.g., United States v. Greber*, 760 F.2d 68, 71 (1985) (summarizing the district court’s jury instructions as simply requiring that the defendant knowingly and willfully caused a payment to be made with the intent to induce referrals).

⁴⁰*See Ratzlaf v. United States*, 510 U.S. 135, 137 (1994).

⁴¹*See Hanlester Network v. Shalala*, 51 F.3d 1390, 1394-1400 (9th Cir. 1995). The Ninth Circuit also upheld the ruling that the AKS was violated by various corporate entities that the liable defendant acted as an agent for, under a theory of vicarious liability, but overturned the rulings against the rest of the individual defendants.

⁴²*United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998). *Davis*’s interpretation of *Hanlester* is questionable, given that the *Hanlester* court stated that a defendant is guilty of “knowingly and willingly” violating the AKS only if he: “(1) know[s] that § 1128B prohibits offering or paying remuneration to induce referrals and (2) engage[s] in prohibited conduct with the specific intent to disobey the law.” *Hanlester*, 51 F.3d at 1400 (§ 1128B refers to the section of the Social Security Act codified in the United States Code at 42 U.S.C. § 1320a-7b).

⁴³*See United States v. Jain*, 93 F.3d 436, 440-41 (8th Cir. 1996).

⁴⁴*See United States v. Starks*, 157 F.3d 833, 837-39 (11th Cir. 1998).

⁴⁵*See* 42 U.S.C. § 1320a-7b(2)(A).

⁴⁶*United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000); *see also Hanlester_Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) (interpreting the phrase “to induce” similarly).

⁴⁷*United States v. Greber*, 760 F.2d 68-72 (3d Cir. 1985). A Holter monitor is a devise which continuously measures a patient’s heart rhythm in order to detect intermittent arrhythmias.

⁴⁸*See United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (emphasis added).

⁴⁹*See United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 29-30 (1st Cir. 1989) (“Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.”).

⁵⁰*See United States v. Kats*, 871 F.2d 105, 106, 108 n.1 (9th Cir. 1989).

⁵¹*See id.* at 108 & n.2 (emphasis added).

⁵²*United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000). The Tenth Circuit, in a separate appeal arising out of the same prosecution of different defendants: (1) upheld their holding from *McClatchey* that the AKS only requires proof beyond a reasonable doubt that “one purpose,” rather than the “primary purpose,” of offering or paying remuneration was to induce referrals; (2) stated that the same reasoning mandates that the “one purpose” rule applies to the “solicitation or receipt” portion of the AKS; and (3) rejected the defendants’ vagueness challenge to the

court's "one purpose" test, as that test was applied to them. *See United States v. Lahue*, 261 F.3d 993, 1004-07 (10th Cir. 2001).

⁵³*See Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999).

⁵⁴*See United States v. Milton*, 602 F.2d 231, 233 (9th Cir. 1987); *United States v. Burke*, 1991 U.S. App. LEXIS 10119 at *6-8; *United States v. Laughlin*, 26 F.3d 1523 (10th Cir. 1994); Robert Fabrikant et al., Health Care Fraud: Criminal, Civil and Administrative Law § 3.02 (2003)

⁵⁵*See Moses*, *supra* note 3, at 505-06; Fabrikant et al., Health Care Fraud: Criminal, Civil and Administrative Law § 3.02 (2003).

⁵⁶*United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420 (9th Cir.1991); Wang ex rel. *United States v. FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992); *United States v. Nachman*, 145 F.3d 1069, 1074-76 (9th Cir. 1998).

⁵⁷*United States v. Munoz*, 233 F.3d 1117, 1131 (9th Cir. 2000).

⁵⁸98 F.3d 1427, 1439 (2d Cir. 1996).

⁵⁹*United States v. Freshour*, 1995 WL 496662 at *5 (6th Cir.)(unpublished opinion).

⁶⁰214 F.3d 27, 33 (1st Cir. 2000).

⁶¹41 F.3d 505 (9th Cir. 1994).

⁶²*United States v. Lennartz*, 948 F.2d 363, 367-68 (7th Cir. 1991); *United States v. Larm*, 824 F.2d 780, 783 (9th Cir. 1987).

⁶³*Hooshmand*, 931 F.2d at 732.

⁶⁴*United States v. Weiss*, 930 F.2d 185, 189-91, 194 (2d Cir. 1991).

⁶⁵*Moses*, *supra* note 3, at 505-06; Kim, *False Statement*, 40 Am. Crim. L. Rev. 511, 519 (2003). *See also Lennartz*, 948 F.2d at 369; *Erickson*, 75 F.3d at 480; *United States v. Nackman*, 145 F.3d 1069, 1074-76 (9th Cir. 1998); *United States v. Thomas*, 484 F.2d 909 (6th Cir. 1973); *United States v. Sarantos*, 455 F.2d 877, 881 (2d Cir. 1972); *U.S. v. Evans*, 559 F.2d 244, 246 (5th Cir. 1977).

⁶⁶*Lennartz*, 948 F.2d at 369.

⁶⁷*Erickson*, 75 F.3d at 480 (upholding use of "deliberate ignorance" instruction in § 287 false claims prosecution).

⁶⁸*Id.* (citing *United States v. Mapelli*, 971 F.2d 284, 286 (9th Cir. 1991)); *United States v. Nazon*, 940 F.2d 255, 259 (7th Cir. 1991).

⁶⁹*Id.* at 474, 480.

⁷⁰*Lennartz*, 948 F.2d at 369.

⁷¹*See United States ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996).

⁷²2003 WL 22048255 at *9-10.

⁷³*Matter of Extradition of Kulekowskis*, 881 F.Supp. 1126, 1147 (N.D.Ill. 1995).

⁷⁴*Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1579 (7th Cir. 1996) (recognizing advice of counsel as a defense to crimes involving willfulness); *United States v. Smith*, 2001 WL 371927, at *1 (9th Cir.)(unpublished)(same). *But see U.S. v. United Medical and Surgical Supply Corp.*, 989 F.2d 1390, 1403 (4th Cir. 1993) (“Good faith reliance on the advice of counsel is not a complete defense to an allegation of willful misconduct, but is merely one factor a jury may consider when determining [defendant’s] state of mind.”).

⁷⁵*See, e.g., Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals*, 2001 WL 1397304, at *19 (S.D. Ind. 2001)(unreported opinion).

⁷⁶*United States v. Lewis*, 2001 WL 32868 at *1, 7, 9-10 (N.D. Ill. 2001)(unreported).

⁷⁷*See, e.g., Commercial Contractors, Inc. v. United States*, 154 F.3d 1357, 1375 (Fed. Cir. 1998) (awarding False Claims Act penalty but no damages where no evidence of actual loss); *Ab-Tech Construction, Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994) (finding Government not entitled to damages absent showing that goods received were worth less than amount paid), *aff’d*, 57 F.3d 1084 (Fed. Cir. 1995); *United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1017 (W.D. Mo. 1995) (refusing to award False Claims Act damages where Government failed to present evidence of value of goods received).

⁷⁸*See, e.g., United States ex rel. Pogue v. American Healthcorp.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (acknowledging that Anti-kickback and self-referral violations resulted in no loss to the Government because amount paid does not vary depending on where service provided or why specific provider chosen); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1046 (S.D. Tex. 1998) (implicitly acknowledging that the allegations forming the basis for the action did not result in the Government paying more for the services than it would have paid absent the violations); *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996) (recognizing that, despite violation of Anti-kickback Statute, evidence at trial showed that patients were hospitalized appropriately, there was no substandard or unnecessary care and there was no indication that the Government paid more than it would have in the absence of the kickbacks); *United States v. Anderson*, 85 F. Supp. 2d 1084, 1102 (D. Kan. 1999) (finding that kickback scheme affected only the location of treatment, not the amount that Medicare paid in reimbursement for those treatments, and thus that the Government would have paid the same amount in reimbursement for patient care regardless of the kickbacks).

⁷⁹*See, e.g., Vaghela*, 169 F.3d at 736.

⁸⁰85 F. Supp. 2d at 1101-02 (citing *United States v. Messner*, 107 F. 3d 1448, 1455 (10th Cir. 1997) and *United States v. Guthrie*, 64 F.3d 1510, 1516 (10th Cir. 1995)).

⁸¹169 F.3d 729, 736 (11th Cir. 1999).

