UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 17-cv-01719 (ECT/ECW)

United States of America, ex rel. Scott Louderback,	)	
Plaintiffs,	)	**UNITED STATES OF AMERICA'S STATEMENT OF INTEREST**
v.	)	
Sunovion Pharmaceuticals, Inc.,	)	
Defendant.	)	

I. INTRODUCTION

The United States, as the real party-plaintiff in interest in this action, submits this Statement of Interest pursuant to 28 U.S.C. § 517, with respect to Defendant's motion to dismiss. Because the United States remains the real party in interest even where it has not intervened in an action, *United States ex. rel. Thayer v. Planned Parenthood of the Heartland, Inc.,* 11 F.4th 934, 940 (8th Cir. 2021)[1], and because the False Claims Act

[1] The United States notes in this regard that its decision to decline intervention cannot be taken as a statement on the underlying merits of relators' claims. "Because the government 'may have a host of reasons for not pursuing a claim,' courts 'do not assume that in each instance in which the government declines intervention in an [FCA] case, it does so because it considers the evidence of wrongdoing insufficient or the *qui tam* relator's allegations [of] fraud to be without merit.'" *United States ex rel. Feldman v. Van Gorp*, No. 03 Civ. 8165 (WHP), 2010 WL 2911606 (S.D.N.Y. Jul. 8, 2010) (quoting *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n. 17 (11th Cir. 2006)). Indeed, "the plain language of the Act clearly anticipates that even after the Attorney General has 'diligently' investigated a violation [of the False Claims Act], the Government will not necessarily pursue all meritorious claims." *United States ex rel. Berge v. Bd. of Trustees*, 104 F.3d 1453, 1458 (4th Cir. 1997) (internal citations omitted).

("FCA"), 31 U.S.C. §§ 3729-3733, is the United States' primary tool in prosecuting fraud on the government, the government has a substantial interest in the development of the law in this area and in the correct application of that law in this, and similar, cases. The United States submits this brief to state its position on two issues: a) the confines of the statutory "discount" exception and regulatory safe harbor to the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(3)(A) (2012) and b) the standard for demonstrating causation in an AKS case.

II. ARGUMENT

A. A Price Reduction Conditioned On the Performance of Promotional or Conversion Campaign Activities Is Not a "Discount" Under 42 U.S.C. § 1320a-7b(b)(3)(A)

Under the statutory exception or regulatory safe harbor for "discounts" under the AKS, a "discount" is a price reduction or rebate conditioned on the purchase of a product or service. If a price reduction or rebate is conditioned on performance of some additional service by the buyer—*e.g.*, taking steps to generate additional business for the seller—it is not a mere "discount," regardless of how the parties might try to characterize it in their contracts. Instead, it is a form of remuneration that could implicate the AKS and would not be protected by the statutory exception or regulatory discount safe harbor.

Congress enacted the AKS to address "practices which have long been regarded by professional organizations as unethical . . . and which contribute appreciably to the cost of the [M]edicare and [M]edicaid programs." H.R. Rep. No. 92-231, at 104 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093; *see also United States v. Ruttenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980) (observing that "kickback schemes can freeze competing suppliers from

the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed"). To protect the Medicare and Medicaid programs from such practices, the AKS prohibits any entity from knowingly and willfully soliciting or receiving any remuneration "in return for . . . recommending purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §1320a-7b(b)(1). The AKS also prohibits any entity from knowingly and willfully offering or paying any remuneration to induce another entity "to purchase . . . or recommend purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

At the same time, Congress also recognized that discounts often are "a good business practice that results in savings to [M]edicare and [M]edicaid program costs." H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056; *see also United States v. Shaw*, 106 F. Supp. 2d 103, 111 (D. Mass. 2000). Accordingly, Congress created a statutory exception to the AKS for a "discount or other reduction in price." 42 U.S.C. § 1320a-7b(b)(3)(A). HHS Office of Inspector General ("HHS-OIG") later promulgated regulations implementing the AKS exception. *See* 42 C.F.R. § 1001.952(h)(5). In guidance to the pharmaceutical industry, the HHS-OIG has made clear that this exception is narrow and "covers only reductions in the product's price." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (May 5, 2003). *See also United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 296 (D. Mass. 2012) (noting that the regulatory definition of "discount" at 42 C.F.R. § 1001.952(h)(5) is

"exhaustive," and citing 42 C.F.R. § 1001.952(h)(5)(vii) (the term "discount" does not include "other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section")). Remuneration to health care providers in exchange for engaging in activities intended to switch patients from one product to another—or to prevent such switching—does not qualify as a protected price reduction, even if the parties label the remuneration as a "rebate" or "discount."

In a 1994 Special Fraud Alert, the HHS OIG made clear its view that the AKS prohibits manufacturers from offering financial incentives to those selling their products to effectuate "product conversion" programs where one purpose is to induce the increased use of such products covered by Federal health care programs. 59 Fed. Reg. 65,371, 65,372, 65,376 (Dec. 19, 1994). One of the examples provided in the Special Fraud Alert was of a "product conversion" program in which a drug manufacturer provided supplier pharmacies with cash awards for changing from a competitor's product to the drug manufacturer's product. *Id*. at 65,376. A price concession is functionally no different than such a cash award, regardless of the label the parties use to describe it.

Several courts have addressed the limited scope of the discount exception. For example, in *Shaw*, the government alleged that a criminal defendant offered special pricing or rebates "in exchange for receiving referrals" for laboratory testing for Medicare patients. *Id.* at 107. The defendant moved to dismiss the criminal indictment citing the discount exception. The district court denied the motion, concluding that "[a]ll of these cases confirm that the issue for a jury to decide, when faced with a defendant whose contention is that the defendant is not criminally liable under the statute due to the 'discount

exception,' is whether the reason for offering or accepting the 'discount or other reduction in price' was to induce referrals of or be reimbursed for federal health care business." *Shaw*, 106 F. Supp. 2d at 121. The court recognized that offering a price discount in exchange for receiving referrals is different in kind from merely offering escalating discounts in return for increased sales volumes in an arms-length transaction. The collusive quality of the arrangement fundamentally distorts the transparency of price competition in the healthcare market that Congress sought to promote with the discount exception. *See Shaw*, 106 F. Supp. 2d at 116 ("Discounts were only transactions made on an arms-length basis and not through a joint-venture or collusive contract.") (citing 56 Fed. Reg. 35,952, 35,977 (1991)).

In *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F.Supp.2d 112 (D. Mass. 2011), the government alleged that a drug manufacturer paid unlawful kickbacks to a long-term care pharmacy. Specifically, the pharmacy received rebates on the purchase price of the manufacturer's drug if (a) the pharmacy's purchases met a threshold share of the market compared to competitor drugs, and (b) the pharmacy successfully implemented two programs designed to shift market share (*i.e.*, switch patients) to the manufacturer's drug. *Id.* at 117. The manufacturer moved to dismiss the complaint, arguing in part that the rebates fell within the discount exception. *Id*. at 124-125. The court disagreed, observing that the pharmacy "qualified for a rebate on a specified drug only if its purchases of the drug from [the manufacturer] met market share thresholds at the expense of [the manufacturer's] competitors, and only if it succeeded in implementing the 'Active Intervention' and 'Appropriate Use' Programs with its pharmacists." *Id.* at 125.

As the courts noted in *Shaw* and *Lisitza*, a price reduction from a drug manufacturer

to a pharmacy that is conditioned on the pharmacy performing some other service, beyond merely purchasing the drug, is not a protected discount. Rather, it is illegal remuneration in exchange for conduct or services intended to give the manufacturer's products an advantage over its competitors' products. In this case, the Relator alleges that Sunovion provided remuneration to pharmacies in the form of rebates that would not qualify for any safe harbor protection. ECF No. 92, Amended Complaint at ¶¶ 8-10, ¶ 27 n.2. Specifically, the Relator alleges that as a condition of receiving the reduction in price, pharmacies had to agree to refrain from counterdetailing activities directed at Brovana. *Id*. at ¶¶ 74-75. In other words, the pharmacies would not receive the price reduction unless they agreed not to promote any drug that competed with Brovana or encourage providers or patients to switch from Brovana. Amended Complaint at ¶¶94b ("pharmacies must give Brovana an advantage over its competitors.) and 94c (pharmacies "must promote Brovana in circumstances in which they would not promote Brovana's competitors"). The Relator further alleges that Sunovion concealed what it was doing from public view. *Id.* at ¶¶ 94-95.

In sum, a price reduction conditioned on engaging in activities designed to switch beneficiaries to a company's product, or to lock in existing referrals, is not a "discount" within the meaning of the discount exception at 42 U.S.C. § 1320a-7b(b)(3). A price reduction that is contingent on the recipient taking steps to generate additional business for the seller or preserve the seller's existing market share does not foster price competition that inures to the benefits of the federal health care system.

B. The Relator Does Not Need to Demonstrate But-for Causation

Plaintiffs seeking to prove falsity based on the AKS have at least two alternatives. They can proceed under the traditional material falsity path, or they can pursue a supplemental theory based on 42 U.S.C. § 1320a-7b(g), the 2010 Amendment to the AKS ("2010 Amendment"). Defendants' motion assumes that the Eighth Circuit's recent holding in *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. 2022) applies to both methods of proving falsity. This is incorrect, as a court in this district recently confirmed.

1. The False Claims Act

The FCA is "the Government's primary litigative tool for combating fraud." S. Rep. No. 99-345, 99th Cong., 2d Sess. 2, reprinted in 1986 U.S.C.C.A.N. 5266. When enacting the False Claims Act, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (*quoting United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

The elements of a § 3729(a)(1)(A) claim are: (1) the defendant presented or caused the presentment of a claim for payment to the United States, (2) the claim was false or fraudulent, and (3) the defendant knew the claim was false or fraudulent. *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016). Likewise, the elements of a § 3729(a)(1)(B) claim are: (1) the defendant made or caused to me made or used a false record or statement; (2) the defendant knew the statement was false; (3) the statement was material; and (4) the statement made a claim for the government to pay money or forfeit

money due. *United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 741 (8th Cir. 2020) *citing United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500 (8th Cir. 2016).

2. False or Fraudulent Under the FCA.

Recently, the Eighth Circuit addressed FCA liability established solely through 42 U.S.C. § 1320a-7b(g), a 2010 amendment to the Anti-Kickback Statute. *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. 2022). That amendment added new subsection (g), providing "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]." *Cairns* held that the "resulting from" language of the amendment requires application of but-for causality to establish a false or fraudulent claim. *Id.* at 835 (*citing Burrage v. United States*, 571 U.S. 204, 210-11, (2014)). But as the Eighth Circuit made clear: "There are several ways to prove that a claim is 'false or fraudulent' under the False Claims Act." *Cairns*, 42 F.4th at 831 (citing 31 U.S.C. § 3729(a)(1) (emphasis added)). Only "[o]ne of them" is through the 2010 AKS amendment. *Id.* The Court specified: "Our ruling today is narrow. We do not suggest that every case arising under the False Claims Act requires a showing of but-for causation." *Cairns*, 42 F.4th at 836-37 (emphasis added). Rather, it applies only "when a plaintiff seeks to establish falsity or fraud through the 2010 amendment". *Id.* (distinguishing that it was the government's "sole theory at trial").

Thus, the government can prove that claims are false or fraudulent because they violate material terms of Medicare reimbursement. Under the FCA, the "term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or

receipt of money or property." 31 U.S.C. § 3729(b)(4). As the Supreme Court explained in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" 579 U.S. at 193 (citation omitted). Courts may analyze materiality from either the perspective of a "reasonable" person or the particular defendant. *Id.* at 193 ("[A] matter is material . . . (1) '[if] a reasonable [person] would attach importance to [it] in determining his choice of action in the transaction'; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not.") (citing Restatement (Second) of Torts § 538 (1977)).

Material omissions and misrepresentations include violations that go to "core" or "basic" requirements, *id.* at 189-90; go to the "essence of the bargain," *id.* at 193 n.5 (citation omitted); are "substantial," *id.* at 194, or are similar to where the government took action in this or other cases when it had knowledge of the violations, *id.* at 193-94. This precisely describes the materiality of the AKS requirements. By prohibiting the payment of kickbacks, the AKS ensures that the government pays only for conflict-free medical care that is provided in the best interests of the patient and that is not potentially affected by financial considerations. *See United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). "The Government does not get what it bargained for when a defendant is paid by [the Government] for services tainted by a kickback." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011). "Kickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the

functioning of the system as a whole." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53 (D. Mass. 2011).

Accordingly, long before the 2010 amendment, courts routinely held that FCA claims premised on AKS violations are false or fraudulent because they seek payment for services that are not payable by Medicare because they violate a material condition of reimbursement. *United States v. Rogan*, 459 F. Supp. 2d 692,717, 724 (N.D. Ill. 2006) ("compliance with the [AKS] is a condition of payment"); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) (claims in violation of AKS are ineligible for payment and establish FCA liability because "compliance with the [AKS] is necessary for reimbursement under the Medicare program"); *United States ex rel. Nehls v. Omnicare, Inc. et al.*, No. 07-C-05777, 2013 U.S. Dist. LEXIS 102543, at *27, (N.D. Ill. July 23, 2013) ("compliance with the AKS…is a condition of reimbursement"); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) ("Legion other cases have held violations of AKS...can be pursued under the FCA, since they would influence the Government's decision of whether to reimburse Medicare claims."); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) ("Compliance with the AKS is thus central to the reimbursement plan of Medicare."); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32 (D.D.C. 2003) ("Courts have found that kickback . . . violations affect the government's decision to pay.").

Over time, courts have used different terminology to reach these conclusions – i.e., material misrepresentation, false certification, implied certification – but the central

reasoning is the same: A claim for medical care corrupted by an AKS violation is false because compliance with the AKS is a threshold and fundamental condition of payment by the government. *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392 (1st Cir. 2011). Courts have reached the same conclusion following *Escobar.* *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817-18 (S.D.N.Y. 2017) (applying the *Escobar* "holistic" approach, the court "has no trouble concluding that compliance with the AKS is a 'material' condition of payment."), *reversed on other grounds*, 899 F.3d 163, 166 (2d Cir. 2018); *United States v. Am. at Home Healthcare & Nursing Servs.*, No. 14-cv-1098, 2017 U.S. Dist. LEXIS 94505 at *20-23 (N.D. Ill. June 20, 2017) (rejecting post-Escobar materiality challenge for AKS violations). Thus, claims can be proven false or fraudulent based on material omissions and misrepresentations without reference to the 2010 amendment. *Escobar*, 579 U.S. at 181; *Hutcheson*, 647 F.3d at 388.

3. *Cairns* Was Limited to the 2010 Amendment

Cairns unequivocally limits its holding to AKS/FCA cases solely proved through the 2010 Amendment. *Id.* at 836. The opinion is expressly predicated entirely on statutory interpretation of language in the 2010 Amendment (*id.* at 834-36), so it does not extend to other avenues for proving FCA liability, including through material falsity. *Id.* at 831. Most relevant here, it does not foreclose plaintiffs' ability to prove FCA liability through material falsity for claims that post-date the 2010 amendment. *Id.* at 836.

Accordingly, Judge Wright recently held that "if Plaintiffs can establish all the elements of their material falsity theory without reliance on the 2010 Amendment—

including that the purported AKS violations were material—Plaintiffs need not prove but-for causation to establish liability under the FCA." *United States ex. rel. Fesenmaier v. Cameron-Ehlen Group, Inc.*, 13-CV-3003 (WMW/DTS), 2023 WL 36174, at *3 (D. Minn. Jan. 4, 2023). The court ruled that way for multiple reasons. First, the court observed that nothing in the 2010 Amendment's text indicated that the amendment was intended to overrule existing caselaw that allowed parties to prove FCA claims by demonstrating that the AKS violation was materially false. *Id.* Before the 2010 Amendment, parties frequently brought FCA cases based on AKS violations under a material falsity theory. *Id.* at *2. Second, by its own express terms, *Cairns* was based entirely on the 2010 Amendment, and is explicitly limited to cases brought under that amendment. *Id.*at *3. It noted that the Eighth Circuit emphasized that its holding was "narrow" and acknowledged that there are several ways to prove falsity under the FCA. *Id.*

Therefore, provided that the relator does not rely on the 2010 Amendment in this case, he should not have to demonstrate but-for causation in order to prevail.

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Respectfully submitted,

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