

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA
ex rel. HERBERT NEVYAS and ANITA
NEVYAS-WALLACE,

Plaintiffs,

v.

ALLERGAN, INC.,

Defendant.

CIVIL ACTION No. 2:09-CV-00432

**THE UNITED STATES OF AMERICA'S STATEMENT OF INTEREST
IN RESPONSE TO ALLERGAN'S AMENDED MOTION TO DISMISS
RELATORS' SECOND AMENDED COMPLAINT**

The United States submits this Statement of Interest pursuant to 28 U.S.C. § 517 to address an argument raised in Allergan, Inc.'s Amended Motion to Dismiss Relators' Second Amended Complaint (Doc. # 62) (Def. Mot.). The United States has declined to intervene in this case but remains a real party in interest in this matter. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 930 (2009). Allergan's Motion implicates the False Claims Act (FCA), 31 U.S.C. § 3729 - 3733, and the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), both of which are essential tools used to redress fraud on the Government. The Government has a keen interest in the interpretation of these statutes and files this Statement of Interest to refute Allergan's argument that the Court should narrowly construe the AKS.¹

¹ The Government does not address the other arguments raised in Allergan's Motion but notes that if the Court accepts Allergan's arguments that the Relators' Second Amended Complaint fails to meet the requirements of Federal Rules of Procedure 9(b) and/or 12(b)(6), it need not reach the issue addressed herein.

A. Background

In their Second Amended Complaint, Relators Herbert Nevyas and Anita Nevyas-Wallace allege that since at least 2002, pharmaceutical company Allergan has violated the FCA and the AKS by providing kickbacks to eye care doctors to induce those doctors to prescribe Allergan products. Relators allege that the kickbacks include free business advisory services and education offered by Allergan's Eye Care Business Advisors, and membership to the Allergan Access website, which Relators allege offers services valued in excess of its annual fee. Allergan contends that the services it provided are commercial speech. It contends that Relators' AKS theory violates its First Amendment rights because the determination of whether its services have value and thus constitute remuneration under the AKS depends upon the content of its speech — good business advice has value and is remuneration, bad advice is not. Allergan urges the Court to narrowly construe the AKS to "conclude that activities comprising speech do not constitute remuneration under the AKS." Def. Mot. at 29.

B. The Statutory Scheme

1. The Anti-Kickback Statute

The AKS prohibits any person from "knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind. . ." to induce another to refer, purchase, order, or arrange for the furnishing of a health care item or service reimbursable under a federal health care program. 42 U.S.C.

§ 1320a-7b(b). It emanates from congressional concern that payoffs to those who can influence decisions about the delivery of health care goods and services will result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to patients and the federal fisc. By making the payment of kickbacks a felony and specifying that this prohibition covers claims "for which payment may be made in whole or in part under a Federal health care

program,” the AKS itself made compliance with its terms a condition of payment under federal health care programs. *See New York v. Amgen, Inc.*, 652 F.3d 103 (1st Cir. 2011) (AKS is a condition of payment under certain state Medicaid programs); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (AKS is a condition of payment under Medicare).

As first enacted in 1972, the AKS made it illegal to solicit, offer, or accept a kickback, bribe, or rebate for referrals, but did not include the phrase “any remuneration” in the statute. *See Social Security Amendments of 1972*, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). Congress found that this narrow formulation of the AKS proved ineffective to deal with the “disturbing degree [of] fraudulent and abusive practices associated with the provision of health services financed by the Medicare and Medicaid programs.” *See H.R. Rep. No. 95-393*, pt. 2, at 44 (1977). Determined to prohibit fraud “in whatever form it is found,” Congress amended the AKS to broaden its reach from only kickbacks, bribes, or rebates to include “any remuneration,” thus preventing defendants from evading liability by arguing that the particular form of the kickbacks they traded for referrals was excluded from the statute. Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175, 1180 (1977). Remuneration means “anything of value.” *United States ex rel. Fry v. The Health Alliance et al.*, 2008 WL 5282139 (S.D. Ohio) (Dec. 18, 2008).

2. The False Claims Act

The FCA imposes civil liability where a person “knowingly presents, or causes to be presented” to the government “a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1), or “knowingly makes, uses, or causes to be made or used, a false record or statement

material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).² In enacting the FCA, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook County, Illinois v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (citation omitted).

Because compliance with the AKS is a fundamental condition of payment in federally-funded health care programs, claims seeking payment for goods or services induced by kickbacks are "false" (*i.e.*, the goods or services are not what the government bargained for and are ineligible for payment) under the FCA. *See United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 387 (1st Cir. 2011). The government is not required to pay for goods or services tainted by kickbacks because the government has no assurance that the services were provided in the best interests of the patient rather than motivated by the financial interests of the physician, and the FCA imposes liability on defendants that knowingly cause the submission of claims tainted by kickbacks to the government for payment, regardless of whether the claims were submitted by an innocent party.³ *Id.* at 392.

C. The AKS Does Not Regulate Speech

As set forth above, Allergan contends that the business services it provided are commercial speech and that Relators' AKS theory violates its First Amendment rights because the determination of whether those services have value and constitute remuneration may only be assessed by analyzing the content of its speech. Allergan invites the Court to construe the AKS to exclude activities

² The Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (2009), modified and renumbered the subsections of 31 U.S.C. § 3729(a), but only the amendments to former Section 3729(a)(2) were made retroactive. Pub. L. No. 111-21, § 4, 123 Stat. 1625. Allergan does not contend that this case is affected by which version of these provisions applies.

³ In 2010, Congress amended the AKS to clarify existing law that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)). The PPACA amendment is not retroactive.

comprising speech from its reach. No other court has so narrowly construed the AKS in the nearly forty years since the enactment of the statute, and this Court should refuse to do so now.

The AKS does not regulate speech. The AKS prohibits a person from knowingly and willfully soliciting or receiving any remuneration to induce another to refer or purchase a health care item or service reimbursable under a federal health care program. As one court recently stated, the AKS "does not regulate speech protected by the First Amendment. Rather, it regulates the *conduct* of paying or offering to pay remuneration in return for Medicare or Medicaid referrals." *United States v. Mathur*, 2012 WL 4742833 at *10 (D. Nev. 2012) (emphasis in original); *see also United States v. Bay State Ambulance and Hosp. Service*, 874 F.2d 20, 32 (1st Cir. 1989) ("there can be no doubt that the statute is an economic regulation which allows for greater latitude by Congress—the Medicare Fraud statute is directed at drains on the public fisc").

The fact that a person may provide remuneration comprised, in whole or in part, of speech does not immunize that person from liability under the AKS. "[I]t has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949). Thus, for example, there would be no constitutional prohibition on a person who truthfully informed a known bank robber that a bank's cameras were inoperable from being tried for aiding and abetting.

Nevertheless, Allergan contends that the assessment of whether its services have "value" and thus constitute remuneration under the AKS infringes on its First Amendment rights because the value of its services may only be assessed by analyzing the content of its speech. This obfuscates the issue. Nothing in the AKS prevents Allergan from offering services, good or bad, as long as it does not offer those services at least in part to induce referrals. The fact that the value of a service may be assessed according to the type of service provided (say, legal services as

opposed to medical services) does not infringe on a defendant's First Amendment rights, even if the service is provided through speech. Whether something has "value" and thus constitutes remuneration under the AKS is evidence of intent to induce, and the use of speech as evidence of intent is constitutionally unobjectionable, even when that determination triggers regulatory or even criminal consequences. *Wisconsin v. Mitchell*, 508 U.S. 476 (1993) (sustaining the constitutionality of a state statute enhancing a defendant's sentence based on his discriminatory motivation for conducting a battery); *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004) (the use of speech to infer intent is constitutionally valid).

Because the AKS does not regulate speech, the Court may easily reject Allergan's invitation to analyze the AKS under the framework of *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). Even if considered, however, Allergan's cursory argument is unpersuasive.⁴ Allergan urges the Court to narrowly construe the AKS to exclude "activities comprising speech" like providing "useful information to physicians, such as straightforward advice as to how they might do those things *better*," but to bar companies from providing "true 'expense relief' services, i.e. handling office work that physicians would otherwise need to do themselves to run a practice." Def. Mot. at 30 (emphasis in original). This "fix" would encourage companies to recast illegal remuneration into speech to argue that the particular form of kickbacks they traded for referrals was not covered by the statute – the exact problem Congress sought to cure when it amended the AKS in 1977.⁵ Because there are infinite ways defendants can provide remuneration, the public interest is best-served by maintaining a broad definition of remuneration under the AKS. By only imposing liability for activities that are provided knowingly and

⁴ Allergan cites to no case that has narrowly construed the AKS or held it unconstitutional. Allergan merely cites *Bailey v. Morales*, 190 F.3d 320 (5th Cir. 1999), which has nothing to do with either the AKS or the FCA.

⁵ For example, while it might prevent a company from providing the cash equivalent of business services to doctors so that the doctors might procure those exact services from a third party, it would permit the company to provide those services itself to induce referrals.

willfully, and at least in part with the intent to induce referrals, the AKS maintains the proper balance between a defendant's rights and the government's substantial interest in preventing fraud.

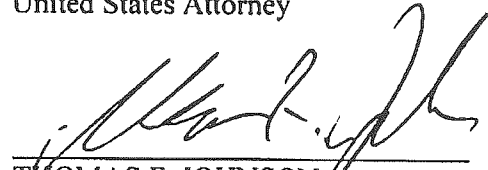
D. Conclusion

The Government respectfully requests that the Court reject Allergan's invitation to narrowly construe the AKS.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, a true and correct copy of the foregoing, The United States of America's Statement of Interest in Response to Allergan's Amended Motion to Dismiss Relators' Second Amended Complaint was served via ECF and first-class United States mail, postage prepaid, upon the following:

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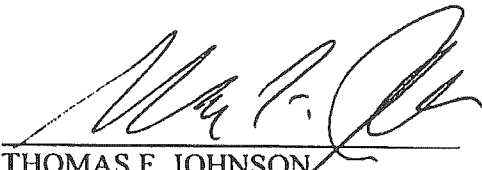
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