UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

NO. 19-12319

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

ALAP SHAH,

Defendant-Appellant.

On Appeal from the United States District Court
for the Southern District of Florida
No. 1:16-cr-20549-RNS-1

BRIEF OF AMERICAN MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT SEEKING REVERSAL OF HIS CONVICTION

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UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

UNITED STATES OF AMERICA,	:	
	:	
Appellee,	:	
	:	
v.	:	APPEAL NO. 19-12319
	:	
ALAP SHAH,	:	
	:	
Appellant.	:	

**CERTIFICATE OF INTERESTED PERSONS
AND CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 29(a)(4)(A), 26.1, and 11th Cir. R. 26.1-1, the following persons and entities have an interest in the outcome of this appeal:

American Medical Association (AMA)[1], *Amicus Curiae*

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Goodman, Hon. Jonathan, U.S. Magistrate Judge, Southern District of Florida

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[1] Pursuant to Fed. R App. P. 26.1(a), the American Medical Association certifies that it is an incorporated non-profit professional medical association and not a publicly held corporation that issues stock.

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*Citations primarily relied upon. 11th Cir. R. 28-1(e)

INTEREST OF *AMICUS CURIAE*[2]

The American Medical Association (AMA) is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents and medical students are represented in the AMA's policymaking process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state and in every medical specialty. Unless they happen to hold a medical degree, podiatrists, such as the defendant in this case, are ineligible to become AMA members.

The AMA proffers this brief in order to provide advice and input to this Court on the proper scope of the federal anti-kickback laws. The AMA has long-recognized that "[r]elationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of

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[2] Pursuant to Fed. R. App. P. 29(a)(3), this brief is accompanied by a motion for leave to file. Pursuant to Fed. R. App. P. 29(c)(5), counsel for *amicus curiae* states that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; no person — other than the *amicus curiae*, its members, or its counsel — contributed money that was intended to fund preparing or submitting this brief.

the community to the ultimate benefit of patients and the public." American Medical Association *Code of Medical Ethics* Opinion 9.6.2 (Gifts to Physicians from Industry), *available at* https://www.ama-assn.org/delivering-care/ethics/gifts-physicians-industry. While it is important to maintain the fiscal integrity of federally funded healthcare programs, it is also important to encourage those business transactions that engender efficacious health care. The AMA hopes that this brief will help the Court find the Congressionally devised balance between these two important goals.

STATEMENT OF THE ISSUE

Whether the judicially-created "one purpose" rule should be rejected by this Court because it negates the element of "specific intent" in the anti-kickback statute, it is at odds with the AKS's Safe Harbor Regulations, and it is inconsistent with innocent business practices in the healthcare industry.

SUMMARY OF THE ARGUMENT

The "one purpose" rule permits a conviction under the federal anti-kickback statute (AKS) if any "one purpose" of an arrangement is to induce or reward referrals reimbursable by federal health care programs. This Court should reject the "one purpose" rule as both a theory of prosecution as well as an acceptable jury instruction in AKS prosecutions. It conflicts with the heightened *mens rea* requirement of the AKS by negating the element of "willfulness" (i.e., proof of specific intent to violate the law), and replacing it with proof of motive (i.e., any one purpose to induce referrals). It also runs afoul of the safe harbor regulations, which were adopted to insulate innocent business practices from strict application of this very rule. The "one purpose" rule is a flawed concept that ham-handedly interferes with the ability of healthcare systems and providers to engage in acceptable and beneficial business practices, to the detriment of the health and welfare of the general public.

ARGUMENT AND CITATIONS OF AUTHORITY

I. THE "ONE PURPOSE" RULE SHOULD BE REJECTED AS EITHER A THEORY OF PROSECUTION OR A JURY INSTRUCTION.

The Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b, makes it a federal crime for anyone to solicit or receive remuneration (including a kickback or bribe) in return for purchasing an item or service paid for, in whole or in part, by a federal healthcare program. The judicially-created "one purpose" rule provides that if any one purpose of the payment – regardless of how slight – is an expectation of referrals, the AKS is violated. This ill-conceived rule should not be sanctioned by this Court. Not only does the "one purpose" rule nullify the element of "willfulness" contained in the AKS and upend this Court's jury instructions on specific intent, it is at odds with the safe harbor regulations, 42 CFR § 1001.952, which were designed to protect innocent business practices from federal prosecution. It also thwarts the normal business relationships vital to the functioning of healthcare systems and providers, which are critical to the health and well-being of patients and the public. Application of the "one purpose" rule constitutes an unreasonable interference with the rights of healthcare systems and providers to do business.

This Court should reject the "one purpose" rule as a theory of prosecution, and disavow the district court's "one purpose" instruction in this case.

A. The "One Purpose" Rule Improperly Permits Willful Intent to Be Inferred If Any Purpose of Remuneration Is to Induce a Referral.

The AKS provides in relevant part:

> (1) Whoever ***knowingly and willfully*** solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> * * *
>
> shall be guilty of a felony ….

42 U.S.C. § 1320a–7b(b)(1)(A) & (B) (emphasis added). Under the law of this circuit, this heightened *mens rea* requirement of "willfully" under the AKS requires proof that that "the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law." *United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998) (quoting Eleventh Circuit Pattern Jury Instructions (Criminal Cases), Basic Instruction 9.1 (2020)). "Willfulness" thus requires that a defendant act with the specific intent to violate the law. As Appellant points out in his brief (Shah

brief at 20-21), the former Fifth Circuit recognized when analyzing a predecessor anti-kickback statute in *United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979),[3] that it is this element of corrupt intent which distinguishes a bribe from a legitimate payment for services. 591 F.2d at 1053-54.

The "one purpose" rule, as a practical matter, does away with this heightened scienter requirement. It permits intent to be inferred if any one purpose of a payment made in connection with an arrangement with a health care provider is to encourage a referral, no matter how tangential or minimal the referral is in the larger scheme of the arrangement. In practice, this allowable inference permits proof of motive (i.e., purpose to induce referrals) to overcome the strict demands of the specific intent requirement; proof that one purpose of an arrangement is to induce referrals supplants proof of specific intent.

As this Court has recognized, intent and motive are not interchangeable; proof of motive is not proof of intent:

> Intent and motive must not be confused. "Motive" is what prompts a person to act. It is why the person acts.
>
> "Intent" refers to the state of mind with which the act is done.

Eleventh Circuit Pattern Jury Instructions (Criminal Cases), Special Instruction 9 (2020). *See United States v. Southers,* 583 F.2d 1302, 1306 n.6 & 1307 (5th Cir.

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[3] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as precedent the decisions of the former Fifth Circuit decided prior to October 1, 1981.

1978) (finding virtually identical instruction "correct statement of the law"). Indeed, "the motive of the accused is immaterial except insofar as evidence of motive may aid in the determination of the state of mind or intent of the accused. *Southers,* 583 F.2d at 1306 n.6. The "one purpose" rule, however, exalts proof of motive to the position of – or, more accurately, as exceeding – proof of intent, thus deeming it sufficient to establish "willfulness" under the AKS. It, in effect, reads the word "willfully" out of the statute.

Because the "one purpose" rule contradicts the statutory language and the law of this circuit by permitting proof of motive to supplant proof of specific intent, this Court should reject as ill-conceived this judicially-created concept, regardless of whether it may have been employed in other circuits.

B. The "One Purpose" Rule Effectively Negates the AKS's Safe Harbor Provisions.

The "one purpose" rule presupposes that a payment to a health care provider may not be motivated – even in part – by a hope or expectation that the provider might be a referral source. Thus, the "one purpose" rule justifies a prosecution even if the arrangement fits squarely within the safe harbor provisions of 42 CFR § 1001.952. As such, this judicially-created concept would effectively override the safe harbors implemented by Congress to protect legitimate business arrangements. This cannot be the law. The very purpose of the safe harbor provisions of the AKS was to protect health care providers from being swept up in the broad reach of the

statute. In many (if not most) arrangements, the safe harbors will be met. Yet compliance with the AKS is threatened by the "one purpose" rule. Utilization of a "one purpose" rule reflects a misunderstanding of the history and implementation of the safe harbor regulations.

The AKS criminalizes the solicitation or receipt of any remuneration in return for referring a person to anyone for any item or service paid for by the federal government. *See* 42 U.S.C. § 1320a–7b(b)(1). In 1987, Congress became aware of concerns about the statute's broad reach, observing that, "the breadth of [the] language [in the statute] has created uncertainty among health care providers as to which commercial arrangements are legitimate and which are proscribed." S. Rep. No. 109, 100th Cong., 1st Sess. 27, *reprinted in* 1987 U.S.C.C.A.N. 682, 707–08. To address these concerns, Congress directed the Secretary of Health and Human Services ("HHS") to promulgate "safe harbor regulations" specifying payment practices that would not be subject to either criminal or civil penalties. *Id*. When HHS issued the safe harbor regulations, it explained that, "[i]f a person participates in an arrangement that fully complies with a given [safe harbor] provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision." *Background to Safe Harbor Provisions*, 56 Fed. Reg. 35952, 35958 (July 29, 1991).

The HHS Office of the Inspector General ("OIG") issued advisory opinions and promulgated regulatory safe harbors to address concerns that common, "relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952-01, 1991 WL 304395 (July 29, 1991). In carrying out its mandate, the HHS OIG recognized that the broad reach of the AKS was driven by court decisions that recognized a "one purpose" rule:

> At the time that the proposed rule was issued, the leading case interpreting the breadth of the statute was *United States v. Greber*, 760 F.2d 68 (3d Cir.) *cert. denied*, 474 U.S. 988 (1985). Since publication of the notice of proposed rulemaking on January 23, 1989, two other circuit courts have lent further support to a broad reading of the statute: *Bay State Ambulance*, which was discussed above, and *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).
>
> *　　　*　　　*
>
> In upholding Kats's conviction, the United States Court of Appeals for the Ninth Circuit became the first court specifically to adopt the holding in *Gerber* [sic] that "if one purpose of the payment is to induce future referrals, the [M]edicare statute has been violated." 760 F.2d at 69. The *Kats* court held that the statute is violated unless the payments are "wholly and not incidentally attributable to the delivery of goods or services." *Id*. 871 F.2d at 108. The court upheld a jury instruction that read, in part, "It is not a defense that there might have been other reasons for the solicitation of a remuneration by the defendants, if you find that one of the material purposes for the solicitation was to obtain money for the referral of services." *Id*. 871 F.2d at 108, n.1.

56 FR 35952-01 at 35958. The safe harbors were designed to rein in the reach of the AKS, which was viewed as overextended by these cases:

> In mandating this regulation, Congress directed us to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.

Id. *See also* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 42 CFR pt. 1001 (Jan. 23, 1989). Implicit in this language is that the safe harbors were intended to override the judicially-created "one purpose" rule fabricated in cases like *Gerber* and *Kats*.

In other words, if the provisions of the safe harbor are met, the arrangement does not fall within the reach of the AKS. The safe harbor provisions thus envision that health care providers may solicit or receive referrals even when they have entered a contract for products or services, with the assurance they will not be subject to prosecution. *See* 42 U.S.C. § 1320a–7b(b)(3)(A)-(K). *See also* 42 C.F.R. § 1001.952(f) (safe harbor for "referral services"). The "one purpose" rule does not trump the safe harbor provisions.

The "safe harbor" provision itself, 42 C.F.R. § 1001.952, "lists various circumstances under which a financial relationship between a provider and a ***referral source*** would not give rise to liability under the Anti-Kickback Statute." *United States v. Rogan*, 2006 WL 8427270, at *16 (N.D. Ill. Oct. 2, 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008) (emphasis added). *Cf.* OIG Advisory Opinion 08–06

(May 2, 2008) ("when a laboratory offers or gives an item or service for free or less than fair market value to a ***referral source***, an inference arises that the item or service is offered to induce the referral of business") (emphasis added). Stated another way, baked into the mix is the assumption that a provider can legally contract for products or services with a referral source under the safe harbor provisions of the AKS. By definition, this means that a health care provider can enter a contract for products or services even if one purpose of the contract is, admittedly, to receive referrals. *See, e.g., U.S. ex rel. Emanuele v. Medicor Assocs*., 2017 WL 3675921, at *2 (W.D. Pa. Aug. 25, 2017) (unpublished) ("[T]he statutes giving rise to the FCA claims in this case, the Stark Act and the Anti-Kickback Statute, each generally prohibit a healthcare entity from submitting payments to Medicare based upon referrals from physicians who have a 'financial relationship' with the healthcare entity. 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b). Each statute also contains a number of statutory exceptions (or safe harbors) that ***permit those referrals if certain statutory requirements are satisfied***.") (emphasis added); *cf. United States v. Aids Healthcare Found., Inc.,* 262 F. Supp. 3d 1353 (S.D. Fla. 2017) (payments of referral bonuses to employee of health care provider for referrals of patients were for the provision of covered services, supporting application of AKS's employee safe harbor provision).

Significantly, each of the AKS's 28 safe harbor provisions begins with the introductory language, "As used in section 1128B of the Act, 'remuneration' does not include . . .." 42 C.F.R. § 1001.952(a) – (b). Once something is not considered to be "remuneration" under the safe harbor provisions, the AKS does not apply. *See, e.g., United States v. Vega*, 813 F.3d 386, 397 (1st Cir. 2016) ("The Department of Health and Human Services has promulgated regulations [at 42 C.F.R. § 1001.952] stating that certain payments are not 'remunerations' in violation of § 1320a–7b(b)(1)(B)."). If the AKS is not triggered in the first place because the payment is not "remuneration," it does not matter whether there ever was an intent to induce referrals.

Simply put, to engraft a "one purpose" rule onto the safe harbor exemptions undercuts their intent to protect bona fide business conduct.

C. The "One Purpose" Rule Conflicts with Innocent Business Practices of the Healthcare Industry that Benefit Patients.

Under the "one purpose" rule, a person violates the AKS by offering remuneration to another person for products or services when at least ***one*** purpose — not necessarily the primary purpose or even a substantial purpose — of the offer of payment is to induce referrals. *See United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (collecting cases); *Kats, supra,* 871 F.2d at 108 ("[T]he Medicare fraud statute is violated if one purpose of the payment was to induce future referrals." (quotation marks omitted); *United States v. McClatchey*, 217 F.3d 823,

835 (10th Cir. 2000) ("[A] person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals."). The "one purpose" rule – which on its face bars contracting with referral sources – reflects a lack of insight into how the healthcare industry, including physicians, hospitals, laboratories, pharmaceutical companies and medical device manufacturers, exist in the real world. It also reflects a lack of understanding of how healthcare systems and providers manage to co-exist with Government oversight and regulations, especially regulations that are antagonistic to a fundamental aspect of a commercial enterprise – business referrals. In order to maintain profitability and keep their doors open to the public, healthcare systems and providers (whether for profit or not-for-profit) must operate as business entities, and referrals are part of the lifeblood of a business. By necessity, the industry functions with the understanding that doctors, nurses, therapists and other practitioners each will be a potential source of referrals. This is the nature of the healthcare industry – indeed, it is the nature of almost any industry. To broadly criminalize the ability of a therapy service provider to refer patients to a not-for-profit hospital or a physician to refer patients to a medical device manufacturer would jeopardize routine business practices followed by the healthcare industry across the country, to the detriment of the patients benefiting from these innocuous practices.

Take, for example, Appellant Shah's case. Shah wrote his patients prescriptions for "compound" medications that were specially designed for them and supplied through "specialty" or "compounding" pharmacies. (Doc. 107-17-19). Shah prescribed compound medicines for his patients with "complicated" medical histories who needed these types of custom-designed medications. *Id*. at 19-22. Shah was interested in working with new healthcare companies to speak about and help promote their products and possibly also help develop and conduct trials of new products. *Id*. at 23-26. One of the compounding pharmacies that filled his prescriptions offered to provide Shah this opportunity through a medical "consultant/director" arrangement. *Id*. at 26-34. There is evidence that Shah firmly believed these compounding medications were beneficial to his patients, and thus it was reasonable for the compounding pharmacy to believe that Shah was in a superior position to help develop and promote its products. But application of a "one purpose" rule would prohibit this. No matter how much business sense the arrangement would have made and no matter how much patients would have benefited, the speaking services would be prohibited if "one purpose" of the payments to Shah were to induce referrals – an inevitable consequence of that arrangement.

Indeed, despite knowing that some jurisdictions recognize a "one purpose" rule, the industry out of necessity envisions that service contracts can – and will –

be entered into with referral sources. Many (if not most) hospitals issue guidelines for entering referral source arrangements; doctors routinely pay both professional and non-profit athletic organizations and schools to serve as team physicians; and pharmaceutical and medical device companies pay physicians and physical therapists to test and promote their products. Yet the expectation that these arrangements may be entered – for the benefit of both the consumer and the public – is wholly inconsistent with the "one purpose" rule, which presupposes that a violation of the AKS occurs as soon as a service contract is entered into with a referral source. *See Greber*, *supra*, 760 F.2d at 69 ("We . . . hold that if one purpose of the payment was to induce future referrals, the medicare statute has been violated."). Consequently, the industry is forced to walk a tightrope, endeavoring to engage in routine business practices, while at the same time trying to avoid running afoul of the AKS by implicating the "one purpose" rule.

One reason there exists such a great tension between the "one purpose" rule and the functioning of the healthcare industry might be because the rule has been overstated by some courts that claim to recognize it. For example, the Tenth Circuit adopted a variation of the "one purpose" rule in *McClatchey, supra*, holding that "a person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals." 217 F.3d at 835. The court rejected the defendant's

argument that the "one purpose" rule was too broad because "[e]very business relationship between a hospital and a physician is based 'at least in part' on the hospital's expectation that the physician will choose to refer patients." *Id*. at 834. But it rejected this argument only because the jury also was instructed that the defendants "*cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes*." *Id*. (italics in original). According to the Tenth Circuit, the jury was correctly instructed that "a hospital or individual may lawfully enter into a business relationship with a doctor and even hope for or ***expect*** referrals from that doctor, so long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals." *Id*. (emphasis added). In other words, the *McClatchey* court tried to mitigate the impact of the rule by adopting a more nuanced variation of the rule.

But the idea in *McClatchey* that it would not violate the AKS for a health care provider to enter a service contract with only the *expectation* that the contract will result in the flow of referrals is entirely, and obviously, inconsistent with the "one purpose" rule – under which the contract is illegal if even just one of its purposes is to induce referrals. Although the *McClatchey* court optimistically suggested that juries can fulfill the "difficult" task of distinguishing between a "motivating factor" versus a "collateral hope or expectation" for entering a services

contract, *id*. at n.7, in practicality they are not. A party's "motivation" and "expectation" for entering a contract are effectively one and the same, and an attempt to distinguish between the two requires almost superhuman powers of discernment.

Application of the "one purpose" rule impedes the research, development, promotion and delivery of health care services and products, harming both the industry and, more importantly, the public. Because this rule chills transactions beneficial to public health and stymies innovation in the healthcare industry, it should be jettisoned.

CONCLUSION

For all of these reasons, this Court should disavow the district court's "one purpose" jury instruction, reverse Mr. Shah's conviction, and remand for a new trial.

Respectfully submitted,

/s/ Amy Levin Weil______
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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R App. P. 29(a)(4)(G) and 32(g)(1), the undersigned counsel certifies that this brief:

(i) complies with the 6,500 word limitation of Fed. R. App. P. 29(a)(5), 32(a)(7)(B)(i) and 32(g)(1) because it contains 3,542 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and (6) because it has been prepared using Microsoft Office Word and is set in Times New Roman font and size 14-point.

/s/ Amy Levin Weil
Amy Levin Weil

CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2020, I electronically filed the foregoing Amicus Brief with the Clerk of the Court using the CM/ECF system, and service will be accomplished by the appellate CM/ECF system.

/s/ Amy Levin Weil
Amy Levin Weil