Journal of Law and Health

Volume 14 | Issue 2 Note

2000

Defining Willful Remuneration: How Bryan v. United States Affects the Scienter Requirement of the Medicare/Medicaid Anti-Kickback Statute

Robb DeGraw

DEFINING "WILLFUL" REMUNERATION: HOW *BRYAN V. UNITED STATES* AFFECTS THE SCIENTER REQUIREMENT OF THE MEDICARE/MEDICAID ANTI-KICKBACK STATUTE

I. INTRODUCTION

The General Accounting Office and the Department of Health and Human Services (the "DHHS") recently estimated that Medicare pays $23 billion a year in fraudulent medical claims.[1] Not surprisingly, many health care professionals consider Medicare fraud and abuse the leading health care issue in 1999.[2] To combat the fraud abuse in the system, Congress has recently enacted several new laws and given life to some old ones. For example, Congress recently passed the Stark laws[3] the 1981 Civil Monetary Penalties Law,[4] and the Health Insurance Portability and Accountability Act.[5] In addition, the False Claims Act, originally enacted in 1863 with a qui tam provision, has become a major force in assisting the government in discovering and prosecuting fraudulent claims.[6] Considerable emphasis has also been placed on prosecuting fraud and abuse under the federal Medicare and

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[1]*HCFA's $23 Billion Error Rate Said Shows Need for Random Audits*, HEALTH L. REP. (BNA) 24.

[2]*Survey of Top Health Care Law Issues For 1999*, HEALTH L. REP. (BNA), (Dec., 1998).

[3]42 U.S.C.A. § 1395nn (West Supp. 1998). The Stark legislation consists of The Ethics in Patient Referrals Act (Stark I) and The Comprehensive Physician Ownership and Referral Act of 1993 (Stark II). Stark I prohibits physicians from referring Medicare patients to clinical laboratories in which the physician has an ownership interest. Stark II expands the prohibition against physician "self-referral" to services such as: radiology services; prosthetics; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. For a discussion of the Stark Laws, *see* Jo-Ellyn Sakowitz Klein, Note, *The Stark Laws: Conquering Physician Conflicts of Interest?* 87 GEO. L.J. 499 (1998).

[4]42 U.S.C.A. §§ 1320a-27a (West 1981). "The 1981 Civil Monetary Penalties Law gives the Inspector General the authority to seek restitution from anyone who submits a false claim to Medicare, Medicaid, or any other federally financed health or welfare program. Under [this law] providers can be fined $2000 per claim and assessed as much as twice the amount of the claim." *See Civil Monetary Penalties*, MOD. HEALTHCARE, Apr. 8, 1991, at 38.

[5]Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996). (hereinafter "HIPAA"). HIPAA provided increased funding for the Office of Inspector General (OIG) and the Department of Health and Human Services (DHHS) to investigate fraud and abuse. HIPAA allocated $70 million to the OIG, money which the Office plans to hire 250 additional investigators, auditors, attorneys and other experts. *See* Colleen Faddick, *Health Care Fraud And Abuse: New Weapons, New Penalties, And New Fears for Providers Created by the Health Insurance Portability And Accountability Act of 1996 ("HIPAA")*, 6 ANNALS HEALTH L. 77 (1997).

[6]31 U.S.C.A. §§ 3729-3733 (1995). The False Claims Act (FCA) prohibits individuals from knowingly submitting a false claim to the government for money. The FCA was originally enacted prevent contractor fraud perpetrated on the Union Army during the Civil War. Under the FCA, the U.S. Attorney General can bring a civil suit against an individual for filing a false claim against the government. The qui tam provisions of the FCA enable private individuals to sue those perpetrating fraud against the government. The FCA provisions encourage individuals to report fraud by allowing private citizens to share in the government's recovery after the defendant is successfully prosecuted or settles. *See*, Kaz Kikkawa, *Medicare Fraud and Abuse and Qui Tam: The Dynamic Duo or the Odd Couple*, 8 HEALTH MATRIX 83 (1998).

Medicaid anti-kickback statute.[7] This Note examines the recent split in federal courts' interpretation of the scienter requirement of the anti-kickback statute and how the Supreme Court's recent definition of "willfully" in *Bryan v. United States*,[8] will impact the mens rea requirement for conviction under the anti-kickback statute.

State and federal anti-kickback laws aim to prohibit the exchange of remuneration for referrals of patients, goods, or services under publicly funded health care programs. The premise of these laws is if a medical professional has a financial incentive for referring patients, he is more likely to increase the number of services performed. This incentive, in turn, will lead to an overutilization of services, the unnecessarily depletion of program funds, and a waste of taxpayer dollars.[9] Although many state laws contain similar provisions, this Note focuses solely on the federal Medicare and Medicaid anti-kickback statute.[10]

The anti-kickback statute has been the source of much controversy. Supporters of the law argue that it is necessary to punish providers who would contribute to the nation's spiraling health care costs by placing profit over the best interests of their patients. On the other hand, medical providers fear that the anti-kickback laws will punish "innocent" referral arrangements used throughout the industry. Furthermore, it has been argued that these arrangements may ultimately save taxpayers dollars because of the efficiencies which they create.[11] For example, if a hospital owns a management service organization (MSO) that furnishes support services to a

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[7]As presently amended, 42 U.S.C.A. § 1320a-7b(b)(1) and (2). For purposes of brevity, the Medicare and Medicaid anti-kickback statute will be referred to herein as the "anti-kickback statute."

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

[9]*See* James F. Blumstein, *The Fraud and Abuse in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 Am. J.L. & Med. 205, 209 (1996). This article describes a significant number of studies, primarily from Jean M. Mitchell and Elton Scott, that showes when physicians had an ownership interest or a compensation arrangement with an ancillary facility, the patients of these physicians had higher utilization rates than did the patients of other physicians.

[10]42 U.S.C.A. §§ 1320a-7b(b)(1) and (2) (1994). See discussion infra Sections II A and II B.

[11]See Blumstein, *supra* note 9:

> The fraud and abuse statute, enacted before capitation had a large market presence, clearly contemplates a world of fee for service (FFS) payment driving excessive utilization and escalating program costs. While this concern remains realistic in much of the market, the fraud and abuse law suffers from a case of hardening of the intellectual arteries because it does not adequately accommodate the evolving market-driven reforms in the health care arena. Indeed, fraud and abuse law can serve as an obstacle to the rationalization of the health care marketplace.

See also David A. Hyman & Joel V. Williamson, *Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 LOY. U. CHI. L.J., 1133, 1135 (1988).

> Although the statute was an effective and logical response to fraud and abuse under a cost-based system, it may be inappropriate to apply the same rules to the newly competitive health care environment. The statute is broadly worded and appears to prohibit many arrangements that pose little risk to the integrity of the [Medicare and Medicaid] program or the quality of medical care.

physician practice, the hospital may be in violation of the anti-kickback statute if it charges *less* than the fair market value for the services it provides to the MSO on the theory that such savings are "remuneration" to induce referrals.[12]

At the forefront of the debate over the anti-kickback statute, and the topic of this Note, is the mens rea, or mental state, that is required for a violation of the law. According to the statute, an individual must "knowingly and willfully" solicit or receive, or offer or pay, remuneration in order to induce business reimbursed under any federal health care program.[13] The interpretation of these terms by the federal courts has varied wildly, as have the underlying Supreme Court cases cited as precedent for such interpretations. However, in June of 1998, the Supreme Court defined the meaning of "willfully" under a federal criminal statute in *Bryan v. United States*.[14] Although the criminal statute in *Bryan* was unrelated to health care fraud, the Eleventh Circuit has adopted the *Bryan* Court's definition of "willfully" in a case involving the anti-kickback statute.[15] Whether *Bryan* will resolve the split between the circuit courts is unclear; however, this case is certain to significantly influence the debate.

The following Section of this Note briefly summarizes the legislative development of the federal anti-kickback statute including the 1980 amendment adding the mens rea requirement. Section II also summarizes the 1996 amendment requiring that the Secretary of the DHHS (Department of Health and Human Services) issue advisory opinions in response to requests for guidance about whether specific business arrangements are within the limits of the anti-kickback statute. Section III examines the various federal court interpretations of the mens rea requirement of the statute. As described in this Section, there is a split of authority as to the meaning of the word "willfully" under the statute. Because the Supreme Court has not interpreted the meaning of the mens rea requirement of the anti-kickback statute, this Section also examines the principal cases that have defined "willfully" in the context of other federal criminal statutes, that have been relied upon in interpreting the anti-kickback statute. Section IV analyzes *Bryan v. United States*, where the Supreme Court defined "willfully" under the Firearms Owners' Protection Act, as acting with a "bad purpose" or with the intent to do something which the law forbids.[16] Section V analyzes *United States v. Starks*, the first, and to date only, circuit court decision to interpret the mens rea standard of the statute in light of the Bryan decision. Section VI analyzes the alternative interpretations of the mens rea standard of the anti-kickback statute, and the reasons that federal courts will likely adopt the Bryan court's definition of "willfully." Finally, this Note concludes, that, despite its factual distinction from health care fraud and abuse

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[12]Blumstein, *supra* note 9, at 217.

[13]HIPAA § 204(a)(7). "Federal health care program" is defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," or "any State health care program, as defined in section 1128(h)." HIPAA, Pub.L.No. 104-91, Section 204(a)(7), 110 Stat. 1936, 2000 (1996).

[14]Bryan, 524 U.S. at 184.

[15]United States v. Starks, 157 F.3d 833 (11th Cir. 1998).

[16]*Id*.

litigation, the Supreme Court's recent decision in *Bryan* will greatly impact the current debate about the proper interpretation of "willfully" under the anti-kickback statute.

II. LEGISLATIVE DEVELOPMENT OF THE ANTI-KICKBACK STATUTE

A. Background

The federal anti-kickback statute was first enacted as part of the Social Security Amendments of 1972,[17] and was primarily concerned with outlawing health care referrals that were considered unethical or inappropriate. Specifically, the statute made it a misdemeanor for any individual to furnish, solicit, offer or receive any kickback, bribe or rebate in connection with any item or service for which payment could be made under the Medicare and Medicaid programs. A violation of the statute was punishable by a fine of up to $10,000, a maximum term of imprisonment of one year, or both.[18]

Shortly after its enactment, several key issues arose regarding the statute's interpretation.[19] First, it did not appear that a mens rea, or mental culpability, was required for a violation of the statute.[20] Second, it was unclear what types of business arrangements—particularly joint venture arrangements that were beginning to develop in the health care industry—were precluded by the statute.[21] Finally, terms such as "kickback," "bribe" and "rebate" were not defined in the statute. These uncertainties led to conflicting court interpretations of the statute. Consequently, government prosecutors were unsure what arrangements would be construed as a kickback and health care providers had little assurance that their commercial arrangements were properly structured.

In response to these issues, Congress enacted the Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977 (MMAAA).[22] The amendments both expanded and narrowed the reach of the statute. Congress expanded the reach of the statute by substituting the phrase "any remuneration" for the terms "rebates," "bribes" and "kickbacks."[23] In addition, a violation of the statute was increased to felony status, and the penalties were raised to a maximum fine of up to $25,000 per violation and/or five years' imprisonment.[24] The legislative history of the MMAAA indicates that these amendments were intended to be read broadly in favor of the

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[17]Social Security Amendments Act, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419-20 (1972).

[18]*Id.*

[19]*See* TIMOTHY S. JOST & SHARON DAVIES, MEDICARE AND MEDICAID FRAUD AND ABUSE §§ 88-92 (1998) (providing a detailed discussion of conflicting judicial views of the interpretation of the 1972 anti-kickback statute).

[20]*Id.*

[21]*Id.*

[22]Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, § 4(b)(1), 91 Stat. 1175, 1180 (1977).

[23]*Id.*

[24]*Id.*

government.[25] On the other hand, concern that the provisions of the statute could be construed to punish innocent business transactions likely motivated the adoption of two exceptions to the statute. First, the scope of the statute was narrowed to exclude the practice of discounts or other price reductions.[26] Second, payments made to employees under a bona fide employment relationship were also excluded from the reach of the anti-kickback statute.[27]

Instead of resolving the controversy over the interpretation and application of the anti-kickback statute, the 1977 amendments caused considerable worry among the health care industry due to their potential breadth. Again, it was argued that a broad construction of the provisions of the statute (especially the undefined phrase "any remuneration") would result in punishing not only those who had engaged in wrongful conduct, but also those providers whose conduct was innocent and socially beneficial.[28]

B. The "Willfully" Mens Rea Requirement

In 1980, Congress amended the anti-kickback statute by adding a mens rea element. Specifically, the amendment added the requirement that an individual must engage in the proscribed conduct "knowingly and willfully" to be convicted under the statute.[29] The House Budget Committee Report pointed out that the purpose of the revision was to ensure that those whose conduct may have been improper would nonetheless not be prosecuted unless they specifically intended to engage in the proscribed conduct.[30] This same mens rea element exists in the anti-kickback statute today.

The mens rea requirement was added to quiet fears of unwarranted prosecution under the statute. However, as discussed below, the interpretation and application of the requirement has been the source of considerable debate and controversy.

The 1980 amendment adding the mens rea requirement was the last amendment to the prohibitive provisions of the anti-kickback statute. Thus, the statute currently provides:

> (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–

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[25] *See* JOST & DAVIES, *supra* note 17, at § 94.

[26] *Id.*

[27] 42 U.S.C.A. §§ 1320a-7b(b)(3)(A) and (B) (1994).

[28] *See* JOST & DAVIS, *supra* note 17, at §§ 94-95 (citing David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861, 1875-76 (December 1989).

[29] *See*, Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980).

[30] Robert Salcido, *Mixing Oil and Water: The Government's Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 ANNALS HEALTH L. 105, 113 (1997).

> (A) in return for referring an individual to a person for the furnishing or arranging of any item or service for which payment may be made in whole or in part under a Federal health care program, . . . or
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> (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…[31]
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> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–
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> (A) to refer 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) to purchase, lease, order, or arrange for or recommend 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…[32]

C. Further Amendments to the Statute

The anti-kickback statute was further amended in 1987 to establish statutory exceptions to the law. These exceptions included, among others, the so-called "safe harbors."[33] The safe harbor provisions were designed to assist health care providers in understanding the legal limits of the anti-kickback statute.[34]

In 1996, as part of the Health Insurance Portability and Accountability Act, Congress mandated that the Secretary of DHHS (Health and Human Services) (the "Secretary") publish for comment and consider for final rulings any appropriate modifications to existing safe harbors, as well as promulgate additional safe harbor provisions.[35] The Secretary must also issue advisory opinions explaining: the meaning of "remuneration"; whether a transaction is legal under the statute; what constitutes "an inducement to reduce or limit services" as prohibited by the statute,

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[31]Social Security Act § 1128B(b)(1), 42 U.S.C.A. §§ 1320a-7b (b)(1)(A) and (B) (West Supp. 1997).

[32]Social Security Act § 1128B(b)(2), 42 U.S.C.A. §§ 1320a-7b (b)(2)(A) and (B) (West Supp. 1997).

[33]Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, §§ 4, 14, 101 Stat. 680, 688-89, 697-98 (1987).

[34]*See generally*, Aaron M. Altschuler, et al., *Health Care Fraud*, 35 AM. CRIM. L. REV. 841 (1998); and Brian A. Kaser, *Sailing Without Safe Harbors: Physician Recruitment and the Law of Fraud and Abuse*, 9 (3) HEALTH SPAN 9 (1992).

[35]HIPAA, § 205, 110 Stat. at 2000.

and whether an activity is subject to sanctions.[36] Also under the HIPAA, the Office of the Inspector General (the "OIG") must issue special fraud alerts in response to a request for guidance when the Secretary deems it to be appropriate.[37] Finally, HIPAA required the Secretary to issue advisory opinions in response to requests for guidance about whether a specific business arrangement violates the anti-kickback law.[38] The Secretary must issue an advisory opinion within 60 days of the receipt of a request, and the opinion is binding on both the Secretary and the party requesting the opinion.[39]

These 1996 amendments were motivated by Congress' belief that the Secretary's clarification would enable prosecutors to spend their time on the more egregious types of conduct. Congress also reasoned that while providers want to comply with the abuse statute, many are unsure of how the statute affects them and will, therefore, need to receive guidance from the government.[40]

III. JUDICIAL CONSTRUCTION OF THE MENS REA REQUIREMENT OF THE ANTI-KICKBACK STATUTE

A. Introduction

As described above, the anti-kickback statute applies only to those acts that are performed "knowingly and willfully." Circuit courts have split (or arguably splintered) on the precise meaning of these words, and particularly the word "willfully," in the context of the anti-kickback statute. This Section begins with a brief review of the primary interpretations of the word "willfully" in the context of federal criminal statutes. Following this review is an examination of the principal cases that have addressed the meaning of "knowingly and willfully" in the context of the anti-kickback statute, including the underlying cases cited in support these interpretations. The most recent case to define "knowingly and willfully" in the context of the anti-kickback statute, *United States v. Starks*, which was decided after *United States v. Bryan*, is discussed in Section V.

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[36]*Id*. at § 205, 110 Stat. at 2002.

[37]*Id*. at § 205. 110 Stat. at 2003.

[38]*Id*. at § 205, 110 Stat. at 2001-2002. Under the direction of the Attorney General, the Secretary of DHHS (Health and Human Services) will issue advisory opinions about (1) what constitutes prohibited remuneration under the anti-kickback laws; (2) whether an arrangement falls within one of the statutory exceptions to the anti-kickback law; (3) whether an arrangement falls within an applicable safe harbor established by the OIG; (4) what constitutes an inducement to reduce or limit services; and (5) whether a particular activity constitutes grounds for penalties under the anti-kickback law, civil monetary law, or exclusion statutes. The OIG must accept requests for advisory opinions between February 21, 1997 and August 21, 2000.

[39]*See*, JOST & DAVIS, *supra* note 19, at §§ 3-13.

[40]*Id*.

B. The Meaning of "Willfully" in Federal Criminal Statutes

The mens rea term "willfully" is often said to be "a word of many meanings," whose construction varies based on the context in which it appears.[41] Federal courts have generally interpreted "willfully" in one of three ways. The first interpretation merely requires that the person act "knowingly" or "purposely,"[42] which is to say that the actions are intentional rather than accidental.[43] Under this interpretation, willful does not require an evil motive.[44] The Model Penal Code adopts a similar interpretation of "willfulness" and provides that the mens rea is satisfied by the person acting "knowingly."[45]

The second interpretation of "willfully" generally requires a culpable state of mind,[46] or proof that the act was committed with the specific intent to commit an unlawful act.[47] Rather than merely committing the act "knowingly," the actor must also know the conduct is wrongful. Thus, courts frequently describe this mens rea standard as requiring proof of a "bad purpose."[48] This interpretation of "willfully" has been described by one circuit court as a "middle standard"[49] and will be referenced as such throughout this Note.

The third interpretation of "willfully" requires that the person violate a known legal duty. This interpretation is considered to be a "heightened" mens rea standard because as it requires proof that the person knows the law that he or she is charged with violating. In cases where this standard has been applied, courts have generally not required the defendant to know the specifics of the law, but he or she must be familiar with the law.[50] Because this interpretation imposes such a heavy burden on the government, its application has generally been limited to cases where a person might become innocently engaged in conduct that is not inherently evil.[51] As one

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[41]*Bryan*, 524 U.S. at 191.

[42]People v. Lee, 229 Cal. App. 3d 1504, 1508 (1981) (The word "willfully," when used in a criminal statute, implies that a person knows what he is doing and intends to do what he is doing.); *In re Jerry R*, 29 Cal. App. 4th 438 (1987) (The term "willful" requires only that the prohibited act occur intentionally).

[43]Commonwealth v. Cimino, 611 N.E.2d 738, 741 (Mass. 1993).

[44]Commonwealth v. Luna, 641 N.E.2d 1050, 1053 (Mass. 1994).

[45]Model Penal Code § 2.02(8).

[46]*See Bryan*, 524 U.S. at 191. (Defining "willfully" in the context of the federal anti-structuring laws. This case is discussed in detail in Section IV, herein).

[47]United States v. Muthana, 60 F.3d 1217, 1222 (7th Cir. 1995).

[48]United States v. Murdock, 290 U.S. 389, 396 (1933) ("[W]hen used in a criminal statute [willfully] generally means an act done with a bad purpose."); Felton v. United State, 96 U.S. 699, 702 (1877) ("Doing or omitting to do a thing knowingly and willfully, implies not only a knowledge of the thing, but a determination with a bad intent to do it or to omit doing it").

[49]United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996). This case is discussed in detail in Section III herein.

[50]Cheek v. United States, 498 U.S. 192 (1991).

[51]*Id*. at 200.

court described, the definition of "willfully" as "intentionally, deliberately, and knowingly" is appropriate for statutes criminalizing conduct that is inherently wrongful, or malum in se, whereas the heightened definition is appropriate for statutes criminalizing conduct that is not inherently nefarious, or malum prohibitum.[52]

The common law maxim that "ignorance of the law is not a defense" generally applies to the first two interpretations of "willfully." Although courts have made exceptions to this general principle,[53] persons are usually presumed to know the law.[54] However, under the heightened mens rea standard, ignorance of the law becomes a defense because the accused must be shown to know the law. If the person can demonstrate ignorance of the law, then that person cannot be convicted where the mens rea requires violation of a known legal duty.[55]

The definition given to a mens rea element in criminal law, like the degree of scrutiny in constitutional law, will often determine the outcome of a case. As described in the following Section, federal courts have split between the "middle standard" and the "heightened standard" in interpreting the meaning of the word "willfully" in the context of the anti-kickback statute. The different definitions that have been adopted affect the criminal intent the government must prove, the defenses available to the defendant, and consequently, the outcome of the case.

C. The Heightened Mens Rea Standard

1. *Hanlester Network v. Shalala*

In the much-publicized case of *Hanlester Network v. Shalala*,[56] the Ninth Circuit held that "knowingly and willfully" under the anti-kickback statute required the government to prove that the defendant had (1) a knowledge of the law and (2) engaged in the "prohibited conduct with the specific intent to disobey the law."[57] This requirement, that the defendant violate a known legal duty, can be referred to as a "heightened" mens rea standard, and is generally limited to instances where a defendant might innocently be ensnared in a complex legal arrangement.[58]

The Hanlester Network was the general partner of three limited partnership laboratories in California. Physicians in areas nearby the labs, who were in a

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[52]State v. Azneer, 526 N.W.2d 298, 299 (Iowa 1995).

[53]*See* State v. Guice, 621 A.2d 553 (N.J. Super. Ct. Law. Div. 1993) (holding that the general rule does not apply to cases where it would be counterproductive).

[54]State v. Brumback, 671 N.E.2d 1064, 1070 (Ohio Ct. App. 1996).

[55]*See* Rachael Simonoff, Ratzlaf v. United States: *The Meaning of "Willful" and the Demands of Due Process*, 28 COLUM. J.L. & SOC. PROBS. 397 (Spring 1995); Lindsey H. Simon, *The Supreme Court's Interpretation of the Word "Willful": Ignorance of the Law as an Excuse to Prosecutions for Structuring Currency Transactions*, 85 J. CRIM. L. & CRIMINOLOGY 1161 (1995); and Michael L. Travers, *Mistake of Law in Mala Prohibita Crimes*, 62 U. CHI. L. REV. 1301 (1995).

[56]51 F.3d 1390 (9th Cir. 1995).

[57]*Id*. at 1400.

[58]*See Cheek*, 498 U.S. 192 (1991); and Ratzlaf v. United States, 510 U.S. 135 (1994).

position to refer substantial quantities of tests to the labs, were sold limited partnership shares in the enterprise. The Hanlester Network contracted with Smith Kline Beecham Clinical Laboraties, Inc. (SKBL) to operate the laboratories. Under the terms of the agreement, 85 to 90 percent of the tests the physicians ordered were sent to SKBL laboratories. OIG on behalf of DHHS alleged that Hanlester Network violated the anti-kickback statute by offering and paying remuneration to the physician-investors in exchange for referrals, and by soliciting and receiving remuneration from SKBL in exchange for referrals.[59]

The Ninth Circuit unanimously disagreed with the government's assertions, and affirmed the physician joint-venture arrangement. The Court held that the "knowingly and willfully" anti-kickback standard requires the government to prove that litigants both (1) know that the statute "prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law."[60] In applying this standard to the facts in *Hanlester Network*, the court noted that the partnership arrangement was a common joint venture arrangement and that the Network did not knowingly and willfully violate the law. The court further reasoned that because dividends were paid to the limited partners based on the number of ownership shares rather than the number of lab referrals, and because they did not conceal their payments, they did not believe that their arrangement was unlawful.[61]

In reaching its interpretation of "knowingly and willfully," the Ninth Circuit relied primarily on the legislative history of the statute and the Supreme Court's definition of "willfully" in *Ratzlaf*.[62] The Ninth Circuit determined that Congress used the phrase "knowingly and willfully" to prevent prosecution of those whose conduct "while improper, was inadvertent."[63] As discussed above, there is evidence for this interpretation in that the mens rea element was added in the 1980 amendments to the statute. The Ratzlaf case relied on by the court is discussed below.

Following the Ninth Circuit's ruling, the Department of Health and Human Services requested that the Solicitor General appeal the decision to the Supreme Court. The Inspector General refused this request due to a lack of conflict among judicial circuits.[64]

2. *Ratzlaf v. United States*

In *Ratzlaf v. United States*,[65] the Supreme Court concluded that "willfully," in the context of federal anti-structuring laws, requires knowledge of the law and the

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[59]*Hanlester*, 51 F.3d at 1394-95.

[60]*Id.* at 1400.

[61]*Id.* at 1400-1401.

[62]*Id.* at 1400.

[63]*Hanlester*, 51 F.3d at 1399 n.16 (*quoting* H.R. 96-1167, 96th Cong. (1980)).

[64]*Department of Justice Refuses to Ask for Supreme Court Review of Hanlester Anti-Kickback Case*, 5 BNA HEALTH L. REP. 6 d14 (Feb. 8, 1996) (*Cited* in JOST & DAVIS, *supra* note 17, at § 3-13).

[65]510 U.S. 135.

specific intent to violate the law.[66] Ratzlaf relied on *Cheek v. United States*[67] where the Supreme Court held that in cases involving complex statutory schemes (such as the federal tax code) knowledge of the law is required to avoid penalizing innocent behavior.

In *Ratzlaf*, the defendant owed a casino $160,000 for a gambling debt that he incurred one evening at the blackjack table. Aware that banks must report certain currency transactions over $10,000 to the Internal Revenue Service, Mr. Ratzlaf obtained multiple cashier's checks in amounts slightly less than the limit, to pay for his losses. Ratzlaf was charged however, with "structuring" his transactions to evade bank reporting requirements, which is a separate violation from the bank reporting law that he was aware. The federal structuring law requires "willful" conduct, and *Ratzlaf* argued that his knowledge of the bank reporting laws was not sufficient to convict him of violating the structuring law. The Supreme Court agreed with *Ratzlaf*, and held that the mens rea element of the statute required the government to prove that he actually knew of structuring law and acted in violation of the law.[68]

The *Hanlester Network/Ratzlaf* approach turns the American legal maxim "ignorance of the law is no excuse" on its head, and permits a person who is ignorant of the anti-kickback law to avoid conviction under it. Furthermore, under *Hanlester/Ratzlaf*, a defendant must not only know of the statute, but must also be shown to intend to violate the law, in order to be convicted. Because it sets a very high burden for conviction under the anti-kickback statute, the *Hanlester Network* decision has been applauded and criticized by health law scholars.[69]

3. The Aftermath of *Hanlester*–The Caremark Decision

The heightened mens rea standard adopted in *Hanlester* was applied by a Minnesota district court in *United States v. Caremark.*[70] In Caremark, three home health care executives were accused of paying kickbacks to a physician in exchange for prescribing a Caremark growth hormone. The district court granted defendants' motion for acquittal because the government had not met the Hanlester standard of proof that defendants knew their conduct violated the anti-kickback law.[71]

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[66]*Id.* at 149.

[67]498 U.S. 192 (1991).

[68]*Ratzlaf*, 510 U.S. at 136-140.

[69]*See* Tamsen Douglas Love, *Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid Anti Kickback Statute*, 50 VAND. L. REV. 1029 (May 1997); and Brian J. Hennigan & Arif Alikhan, *Willfulness Under the Medicare Anti-Kickback Statutes: The Continuing Debate Over Whether Ignorance of the Law is a Defense in Medicare Prosecutions*, A.B.A. CENTER FOR CONT. LEGAL ED. NAT'L INST. (Criminal Justice Section, March 6-7, 1997) (critiquing *Hanlester Network*); and William R. Kucera, Jr., Hanlester Network v. Shalala: *A Model Approach to the Medicare and Medicaid Kickback Problem*, 91 NW. U. L. REV. 413 (1996); and Andrea Tuwiner Vavonese, *The Medicare Anti-Kickback Provision of the Social Security Act—Is Ignorance of the Law an Excuse for Fraudulent and Abusive Use of the System?*, 45 CATH. U. L. REV. 943 (1996) (in defense of *Hanlester*).

[70]*See* JOST & DAVIES, *supra* note 19, at § 3-13 (discussing *Caremark* which is unpublished).

[71]*Id.*

The *Caremark* case illustrates the rigorous burden *Hanlester* places on the government to win a conviction under the anti-kickback statute. Other circuit courts however, have rejected the heightened mens rea standard, opting instead for a lesser standard of culpability.

D. The "Middle" Mens Rea Standard

When the government was defeated in the Ninth Circuit in *Hanlester Network*, its strategy was to aggressively contest its application in other circuit courts rather than appealing to the Supreme Court.[72] This strategy proved to be a success as the heightened mens rea standard of *Hanlester* was rejected at the appellate level in every circuit outside of the Ninth Circuit. This section examines three of the principal cases that focused on the mens rea standard of the anti-kickback statute. As described below, the courts in each of these cases adopted a "middle" mens rea standard that required less culpability than the heightened standard of *Hanlester/Ratzlaf*.

1. *United States v. Jain*

The Eighth Circuit was the first federal appellate court to address the mens rea requirement of the anti-kickback statute in the wake of *Hanlester*. The Eighth Circuit rejected the Ninth Circuit's requirement that the defendant know the law, and instead held that "willfully" means the defendant knew his conduct was wrongful.

In *United States v. Jain*,[73] Dr. Jain, a psychologist who operated an outpatient therapy clinic, was charged with receiving payments from a psychiatric hospital in return for patient referrals to the hospital.[74] Dr. Jain testified that the payments he received were for mental health workshops he provided and that it would be "stupid," "illegal," "unethical" and "wrong" to ever request money for referrals.[75] Two former hospital administrators testified against Dr. Jain, and a jury found him guilty of violating the anti-kickback statute.[76]

Both the government and Dr. Jain cited *Cheek* in support of the mens rea standard for "willfully". The government argued that the general rule is that "willfully" in a criminal statute "refers to consciousness of the act but not the consciousness that the act is unlawful."[77] Dr. Jain argued that the *Cheek* (and *Ratzlaf*) exceptions to the general rule–that a defendant must violate a "known legal duty"–was the proper interpretation of "willfully."[78] The Eighth Circuit affirmed the district court's definition that "the word 'willfully' means unjustifiably and wrongfully, known to be such by the defendant…"[79] The appellate court found the

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[72] *See* William R. Kucera, Jr., *supra* note 64 at 446.

[73] 93 F.3d 436 (8th Cir. 1996).

[74] *Id*.

[75] *Id*. at 438-39.

[76] *Id*.

[77] *Id*. at 440, (*citing Cheek*, 498 U.S. at 209).

[78] *Id*. (*citing Cheek*, 498 U.S. at 201 and *Ratzlaf*, 510 U.S. at 148).

[79] *Id*. at 440.

anti-kickback statute shared the complexity of the anti-structuring laws in *Ratzlaf*, as both potentially criminalize conduct that is not "inevitably nefarious."[80] However, the Court distinguished the *Ratzlaf* interpretation of willfully because the anti-structuring statute at issue in that case referred to a willful violation of another statute, and the court reasoned that one cannot willfully violate a statute without knowing the conduct proscribed by the statute. In contrast, in the anti-kickback statute, the word "willfully" specifically modifies the receipt or payment of remuneration. For this reason, the Court concluded that the proper mens rea standard is proof that the defendant "knew his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty.'"[81]

In adopting a "middle ground", the *Jain* court rejected the *Hanlester Network/Ratzlaf* mens rea construction. According to *Jain*, the government is not required to prove the defendant knew the law or had the specific intent to violate the law; rather, it is sufficient to prove that defendant knew the conduct was wrongful. This standard maintains that ignorance of the law is not a defense, but that "good faith" conduct is.[82]

2. *United States v. Davis*

In *United States v. Davis*,[83] the Fifth Circuit affirmed the district court's jury instructions that "willfully" means to disobey the law or to act with the specific intent to do something the law forbids.[84] In reaching the decision, the Fifth Circuit adopted a middle position similar to the standard set for forth by the Eighth Circuit in *Jain*.

In *Davis*, the defendant was charged with conspiracy to offer and pay inducements for Medicare patient referrals in violation of 18 U.S.C. § 371, and for offering and paying such inducements in violation of the anti-kickback statute.[85] Davis appealed his conviction on two grounds. First, he argued that the district court erred in failing to instruct the jury that it could convict him only if it found that his payments to a physician were "for no other purpose" than "inducing the referral of Medicare patients."[86] The appellate court held that this decision or holding was an erroneous statement of the law and was properly rejected. The court found that it was only necessary that the payments be in part an inducement to violate the law. [87]

Second, Davis claimed that the district court failed to properly instruct the jury regarding the mens rea terms "knowingly" and "willfully" and that the jury should have received his requested instruction concerning good faith.[88] The appeals court

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[80]*Jain*, 93 F.3d at 440.

[81]*Id*. at 441.

[82]*Id*. at 440.

[83]132 F.3d 1092 (5th Cir. 1998).

[84]*Id*. at 1094.

[85]*Id*.

[86]*Id*. at 1094.

[87]*Id*. (*citing* Polk County, Tex. v. Peters, 800 F. Supp. 1451, 1456 (E.D. Tex. 1992).

[88]*Id*. at 1094.

rejected this argument because it found that the district court's definitions of "knowingly" and "willfully" adequately explained the concept of good faith.[89] Citing *Hanlester Network*, Davis argued, however, that the anti-kickback statute contained a "heightened scienter requirement" and that the district court's definitions were therefore inadequate.[90] The district court had instructed the jury that "knowingly" means that the act was committed "voluntarily and intentionally, not because of mistake or accident," and that "willfully" means that the act was done "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."[91] The Fifth Circuit approved of these definitions, but stated that it was not deciding whether the anti-kickback statute included a heightened mens rea standard.[92]

In reaching its decision, the Fifth Circuit incorrectly read *Hanlester* as requiring only that the defendant knows that the conduct in question is unlawful.[93] As noted above, the heightened mens rea standard of *Hanlester* requires knowledge of the law as well as the specific intent to violate the law. Therefore, while the *Davis* court did not explicitly decide whether the anti-kickback statute included a heightened mens rea standard, it implicitly rejected its requirement that the defendant know the law that he or she is charged with violating. In so doing, the Fifth Circuit adopted a standard similar to the Eighth Circuit's "middle standard" in *Jain*.

3. *United States v. Neufeld*

In *United States v. Neufeld*,[94] a federal district court refused to adopt the *Ratzlaf* and *Hanslester* definitions of "willful" which required that a defendant know that his conduct was illegal. Rather, the court interpreted "willful" as the purpose to commit a wrongful act.[95]

In this case, Dr. Neufeld, who had been licensed to practice medicine in the State of Ohio since 1975, contracted with a home infusion company to act as a consultant to the company in its development of treatment and educational programs for its staff and patients.[96] Dr. Neufeld was paid by the company for services performed under the consulting agreements.[97] Based on these payments, Dr. Neufeld was indicted for conspiracy to violate and the violation of the anti-kickback statute.[98]

Interpreting the anti-kickback statute, the court declined to provide an exact definition of the scienter requirement. However, it rejected the *Ratzlaf* definition of

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[89] *Id.* (*citing* United States v. Upton, 91 F.3d 677 (5th Cir. 1996)).

[90] *Id.*

[91] *Id.* (*citing* United States v. Garcia, 762 F.2d 1222, 1224 (5th Cir. 1985) (approving substantially the same definition of "willfully")).

[92] *Id.* at 1094.

[93] *Davis*, 132 F. 3d at 1094.

[94] 908 F. Supp. 491 (S.D. Ohio 1995).

[95] *Id.* at 497.

[96] *Id.*

[97] *Id.*

[98] *Id.* at 493.

"willful" and adopted a formulation of the term which takes into account the purpose to commit a wrongful act.[99] The court reasoned that, unlike the structuring in *Ratzlaf*, taking bribes for referrals is an inherently wrongful activity of which a physician should be aware. Thus, the scienter requirement in the anti-kickback statute is satisfied by mere purposeful conduct, negating the need for the heightened scienter requirement adopted in *Ratzlaf*.[100]

E. Summary of the Judicial Constructions of the "Willfully" Mens Rea Requirement

The government's defeat in *Hanlester* proved to be short-lived, as other federal courts refused to adopt the heightened mens rea standard, choosing instead to interpret "willfully" as something short of violating a known legal duty. The Eighth Circuit Court in *Jain*, ruled that since the anti-kickback statute prohibited what would otherwise be innocent conduct, it required a more rigorous mens rea standard than a mere consciousness of the act. However, the court distinguished the anti-kickback statute from the anti-structuring statute in *Ratzlaf*, and refused the appeal on the grounds that the defendant must know the law in order to be convicted of violating the statute.[101] The Eighth Circuit approved of the district court's "middle ground" interpretation that "willfully" means "unjustifiably and wrongfully, known to be such by the defendant."[102]

In *Davis*, the Fifth Circuit court adopted a scienter requirement that could likewise be considered a "middle" standard as it required more than mere awareness of the act, but less than knowledge of the law. The court affirmed the district court definition that "willfully" is an act "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."[103] At first glance, this definition appears to be consistent with the heightened mens rea standard, however it is possible for a person to intentionally do something which the law forbids, without actually knowing the law. Therefore, while *Davis* may arguably require a greater level of culpability than *Jain* (although it is doubtful that a juror would perceive such subtle differences), it still falls within the same "middle" standard mens rea.

Similarly, in *Neufeld*, the United States District Court for the Southern District of Ohio adopted a "middle" standard that "takes into account the purpose to commit a wrongful act."[104] The court declined to follow *Hanlester/Ratzlaf* for two reasons.

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[99] *Neufeld*, 908 F. Supp. 491, 497.

[100] *Id.* at 496.

[101] *Id.* As noted above, the Eighth Circuit distinguished the anti-kickback statute from the anti-structuring statute on the basis that the mens rea requirement in the anti-kickback statute referenced a separate provision of the law. As the *Jain* court noted: "The statute at issue in *Ratzlaf* made criminal a willful violation of another anti-structuring statute. Because one cannot *willfully* violate a statute without knowing what the statute prohibits, the Supreme Court required proof that defendant intentionally violated a 'known legal duty.' 510 U.S. at 140-141. By contrast, in the Medicare anti-kickback statute, the word "willfully" modifies a series of prohibited acts." *Jain*, 93 F.3d at 441.

[102] *Jain*, 93 F.3d at 440.

[103] *Davis*, 132 F.3d at 1094.

[104] *Neufeld*, 908 F. Supp. at 497.

First, the court claimed that unlike the anti-structuring statute, the anti-kickback statute did not have parallel criminal and penalty provisions which required that a person know the law that related to the penalty provision.[105] Second, the court found that Doctor Neufeld's taking bribes for referrals was not the type of innocent behavior that the heightened standard was intended to protect against. The *Neufeld* court declined to provide an exact definition of "willfully," but relied on *Jain* for its "wrongful act" formulation.[106]

Jain, *Davis*, and *Neufeld* suggest that the "middle standard" represents the majority view of the scienter requirement of the anti-kickback statute. However, because the Supreme Court has not ruled on the issue, the "heightened standard" established in *Hanlester* is still good law. Furthermore, the *Ratzlaf* case, which was the basis for *Hanlester*, suggests that the Supreme Court has broadened the scope of the heightened mens rea standard beyond its narrow holding in *Cheek*, and may be the appropriate interpretation of "willfully" under the anti-kickback statute. The following Section analyzes the Supreme Court's most recent definition of "willfully" in the context of a federal criminal statute. Whether this definition, which is a "middle standard," or the *Hanlester/Ratzlaf* "heightened standard," is most likely to be adopted by courts interpreting the anti-kickback statute is discussed in Section VII below.

IV. THE SUPREME COURT'S MOST RECENT INTERPRETATION OF "WILLFUL"

A. Bryan v. United States

The Supreme Court has not addressed the meaning of "knowingly and willfully" in the context of the anti-kickback statute. Therefore, the split in the circuit courts continues. However, the High Court's recent decision in *Bryan v. United States*,[107] involving a federal firearms trafficing law, is certain to impact this debate. At issue in *Bryan* was whether the Court would maintain the heightened *mens rea* requirement established in *Cheek/Ratzlaf*, or whether a lesser mens rea standard would support a conviction. The Court chose the latter, holding "willfully" is the intent to do something the law forbids without knowledge of the specific law.[108]

In *Bryan,* the defendant was convicted of violating the Firearms Owners' Protection Act (FOPA), which prohibits anyone from "willfully" violating, inter alia, Section 922(a)(1)(A), which forbids dealing in firearms without a federal license. The trial court evidence, which was accepted by the Supreme Court, showed that: the defendant did not have a license to deal in firearms; he used "straw purchasers" in Ohio to acquire hand guns; and he resold the guns on Brooklyn street corners known for drug dealing.[109] According to the Court, the evidence proved the defendant was

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[105]This was the same argument that the Eighth Circuit court raised in *Jain*. *See* discussion *infra*.

[106]*Neufeld*, 908 F. Supp. 491 at 497.

[107]524 U.S. 184 (1998).

[108]*Bryan*, 524 U.S. 190.

[109]*Id*.

dealing in firearms and that he knew that his conduct was illegal, but there was no evidence that he was specifically aware of the federal licensing requirement.[110]

At trial, the defendant requested the jury be instructed that he could only be convicted if he had actual knowledge of the federal firearms law.[111] The trial judge refused the requested jury instructions and explained that the term "willfully" required intent to do something unlawful, but that it did not require a specific knowledge of the law or rule alleged to have been violated.[112]

On appeal, the defendant raised two primary arguments in support of a heightened mens rea requirement. First, he argued that since the statute included three categories of acts that required "knowing" conduct, Congress must have intended a higher standard for "willful" conduct.[113] The Court found that "knowledge" meant merely a knowledge of the facts that constitute the offense and not knowledge of the law.[114] More is required with respect to "willful" conduct, which the Court held required a finding that the defendant "acted with an evil-meaning mind, that is to say, that he acted with knowledge that his conduct was unlawful."[115]

Second, the defendant argued that the Supreme Court's decisions in *Cheek* and *Ratzlaf* defined the statutory construction of "willful" as requiring specific awareness of the law under which the defendant was charged. However, the Court distinguished these cases as exceptions to the general rule that "ignorance of the law is no excuse" because they were highly technical and presented the danger of ensnaring individuals engaged in apparently innocent conduct.[116] According to the Court, this danger was not present in *Bryan*, as the defendant knew his conduct was unlawful and because the FOPA statute itself was designed to protect law-abiding citizens who inadvertently violate the law.[117]

In a rather strange conclusion to these primary challenges by the defendant, the Court stated, "[t]hus, the willfulness requirement of § 924(a)(1)(D) does not carve

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[110]*Id.* at 196.

[111]*Id.* at 1944 n.10. (*citing* Ratzlaf v. United States, 510 U.S. 135 (1994), the defendant requested that the jury instructions state that "[Y]ou must be persuaded that with the actual knowledge of the federal firearms licensing laws Defendant acted in knowing and intentional violation of them.").

[112]118 S. Ct. at 1944, FN 11, *citing* App. 18-19. Specifically, the trial judge stated: "A person acts willfully if he acts intentionally and purposely and with the intent to do something the law forbids, that is, with the bad purpose to disobey or to disregard the law. Now, the person need not be aware of the specific law or rule that his conduct may be violating. But he must act with the intent to do something that the law forbids."

[113]Although the defendant did not raise this issue, it should be noted that the scienter requirements of "knowing" and "willful" were added after the fact. This is analogous to the anti-kickback statute which also added the scienter requirement several years after the original act was passed.

[114]*Bryan*, 524 U.S. at 193.

[115]*Id.*

[116]*Id.*, *citing Ratzlaf* at 144-45.

[117]*Id.*, *see* FN 23 *citing* United States v. Andrade, 135 F.3d 104, 108-109 (C.A.1 1998).

out an exception to the traditional rule that ignorance of the law is no excuse; knowledge that the conduct is unlawful is all that is required."[118] While it may seem contradictory for the Court to state in the same sentence that ignorance is no excuse, but that knowledge is required, it appears that what the Court is saying that the defendant does not need to know the specifics of the law in order to be convicted. In other words, it is sufficient that the defendant know that his conduct is unlawful in a general sense.

In addition to the two primary challenges, the defendant also raised arguments based on the legislative history of FOPA. The defendant argued that when the scienter requirement was added to the legislation, at least some legislators understood the term willfully as requiring that a defendant would have to know the details of the law in order to be convicted under it. The Court rejected this argument as the legislators cited by the defendant were in opposition to amending the legislation, and the opposition is not an authoritative guide to the construction of the legislation.[119]

Finally, the defendant argued that, at the time FOPA was passed, the lower courts uniformly interpreted "willfulness" in other sections of the statute as a knowledge of the law.[120] The Court rejected any such uniformity among the lower courts and noted that in each of the cases where knowledge of the law was required, it had been established that the defendants had had a knowledge of the law when committing the crime.[121]

In dissent, Justice Scalia, joined by Chief Justice Rehnquist and Justice Ginsberg, argued that the statute is ambiguous, and the presumption should be that Congress intended a willful violation of the law to require specific knowledge of the offense.[122] Scalia pointed out that the government concedes that the defendant must know that the conduct violates the law, as the jury instructions stated that defendant "acted with knowledge that his conduct was unlawful."[123] However, Scalia criticized the majority for allowing any unlawful act–even one that is unrelated to the licensing law–to stand in the place of a violation of the anti-trafficing law. For example, he noted Mr. Bryan would be guilty of violating the anti-trafficing law based on filing off serial numbers or using straw purchasers, even if he had never heard of the licensing requirement. Scalia argued that the majority would convict if the defendant "…knew that the car out of which he sold the guns was illegally double-parked, or if, in order to meet the appointed time for sale, he intentionally violated Pennsylvania's speed limit on the drive back from the gun purchase in Ohio."[124] Finally, Justice Scalia argued that there is precedence for the heightened mens rea requirement based on the *Cheek* and *Ratzlaf* decisions.[125] He disputed the majority's explanation,

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[118]*Id*. at 195.

[119]*Id*.

[120]*Bryan*, 524 U.S. at 195.

[121]*Id*.

[122]*Id*. at 201-202.

[123]*Id*. at 205.

[124]*Id*. at 202.

[125]*Bryan*, 524 U.S. at 203.

however, that the higher standard applies in those cases because of the complexity of the tax and currency laws.[126] Rather, he bases the mens rea standard on the presumption that Congress intended the word "willfully" to mean a knowledge of the law violated.

B. The Potential Impact of Bryan

Bryan defines willfully as requiring both an evil-meaning mind, and knowledge that the conduct is unlawful.[127] The first element is satisfied by the purposeful conduct of the defendant. The second element can be satisfied by an unlawful act, even if the act is remotely related to the statute. As noted by the dissent, there does not appear to be a nexus requirement between the unlawful act and the statute under which the defendant is charged. This is evidenced by the Court's approval of the trial judges statement that "the government is not required to prove that the defendant knew that a license was required, nor is the government required to prove that he had knowledge that he was breaking the law."[128] Based on the evidence in *Bryan*–straw purchases, filed-down serial numbers, and pistol sales on notoriously high-crime street corners–there was a relationship to the federal licensing requirement. Therefore, the rule from *Bryan* appears to be that a defendant can be convicted for willfully violating a criminal statute where the defendant knowingly and with an evil mind engages in unlawful conduct that is related to, or suggests a knowledge of, the proscribed acts of the statute.

The Court's definition of "willfully" in *Bryan* will impact the mens rea requirements under the anti-kickback statute because it is on point with the statute. Both statutes were amended to include a mens rea requirement of "willfully" and both include separate definitions of "knowingly" and "willfully." Because of these similarities, and for the reasons discussed in Section VI below, the *Bryan* decision will likely be followed in cases such as *Starks*. However, because the defendant's conduct in *Bryan* was done with an evil purpose and the defendant knew he was violating a law, the case does not address situations where a defendant was mistaken about the unlawfulness of the conduct. For example, in *Hanlester*, if defendants had argued that they were aware of the anti-kickback statute, but misunderstood its application, they would have failed to satisfy the requirement of knowing the conduct is unlawful. Because of the unlawful conduct in *Bryan*, the Court does not address this issue.

V. THE ELEVENTH CIRCUIT RESPONSE TO *BRYAN–UNITED STATES V. STARKS*

Just four months after the Supreme Court's ruling in *Bryan*, the Eleventh Circuit court was confronted with the issue of interpreting the meaning of "willfully" in *United States v. Starks*,[129] a case involving the anti-kickback statute. The Eleventh Circuit was to decide whether the anti-kickback statute required the *Hanlester/Ratzlaf* "heightened" mens rea standard, or whether the *Bryan/Jain*

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[126] *Id.*

[127] *Id.*

[128] *Id.* at 200. The Court noted that the last sentence was incorrect without the words, "that required a license," but found that this error was not a basis for reversal.

[129] 157 F.3d 833 (11th Cir. 1998).

"middle" standard applied. In a decision that is certain to be closely scrutinized by those interested in the debate over the scienter requirement of the anti-kickback statute, the Eleventh Circuit adopted a "middle" culpability standard by defining "willfully" as "the specific intent to do something that the law forbids."[130]

Starks involved a kickback arrangement whereby two Florida state community health aides were paid for referring pregnant women to Future Steps, Inc., a private drug addiction treatment clinic.[131] Future Steps was operating under a contract with Florida CHS's Metropolitan General Hospital.[132] The contract contained a provision explicitly forbidding Future Steps from making any payment for patient referrals in violation of the anti-kickback statute.[133] Shortly after entering into the agreement, Future Steps was having difficulty attracting patients. When efforts to build referral relationships failed, the president of Future Steps offered to pay the defendant community health aides $250 for each patient they referred for inpatient treatment. Under the referral arrangement, the health aides were paid in cash or check, usually at a parking lot or restaurant.[134]

The defendants were convicted of violating the anti-kickback statute. At trial, the district court instructed the jury that the word "willfully" means the specific intent to act unlawfully, with a bad purpose to disobey or disregard the law.[135] On appeal, defendants claimed that the jury instructions failed to require knowledge that their referral arrangement violated the anti-kickback statute. Relying principally on *Ratzlaf*, and the Eleventh Circuit's holding in *Sanchez-Corcino*,[136] defendants argued that a heightened mens rea standard applied in cases where the statute required a "willful" violation of the law.

Based on *Bryan*, the Eleventh Circuit rejected *Ratzlaf* and its own prior holding in *Sanchez-Corcino* in denying the petitioner's appeal. The court distinguished *Ratzlaf* on the basis that the anti-kickback statute "is not a highly technical tax or financial regulation that poses the danger of ensnaring persons engaged in apparently innocent activity,"[137] and *Sanchez-Corcino* was specifically overruled in *Bryan*.[138] The trial court's definition of "willfully" in *Starks* was almost identical to the

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[130]*Id.* at 835.

[131]*Id.*

[132]*Id.*

[133]*Id.*

[134]*Sparks*, 157 F.3d at 836.

[135]*Id.* at 837-838. The district court's complete jury instructions were as follows: "The word willfully, as that term is used from time to time in these instructions, means 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."

[136]85 F.3d 549 (11th Cir. 1996). In *Sanchez-Corcino*, the Eleventh Circuit interpreted the word "willfully" in 18 U.S.C. § 922(a)(1)(D) (requiring a license to possess firearms), to mean that the person "acted with knowledge of the licensing requirement." *Id.* at 553-54. ("[k]nowledge of the general illegality of one's conduct is not the same as knowledge that one is violating a specific rule.").

[137]*Starks*, 157 F.3d at 838.

[138]*Bryan*, 524 U.S. at 192.

definition that the Supreme Court approved in *Bryan*. This definition is consistent with the "middle" standard definitions adopted by the Fifth and Eighth Circuit courts.

Proponents of *Hanlester* will take issue with the *Starks* decision for several reasons. First, the court quickly dismissed the anti-kickback statute as not being highly technical like the tax (*Cheek*) and financial regulation (*Ratzlaf*) statutes that call for the heightened standard. According to the Eleventh Circuit, "the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal."[139] The court's reasoning that kickbacks are malum in se, rather than malum prohibitum, oversimplifies the complexity of modern health care remuneration arrangements, and underestimates the potential for becoming innocently engaged in prohibited transactions. Furthermore, the *Starks* court appears to base its conclusion about the complexity of the anti-kickback statute on the facts of the case at hand. For example, the court pointed out the referral arrangements directly affected the counseling of the pregnant women who relied on the counselors for help,[140] and the defendant health aides threatened to take away indigent womens' babies if they did not receive treatment from Future Steps.[141] While these acts are malum in se, they should not be read into the court's interpretation of the scienter requirements of the statute. The meaning of "willfully" under the law should stand independent of the facts of the case.

In addition to the fact that the Starks defendants knew that they were acting unlawfully, the defendant, Future Steps, was also aware of the anti-kickback law through its contract with the hospital.[142] Because Future Steps engaged in the unlawful activity that was expressly prohibited in the contract, it is questionable whether they would have escaped conviction even under the heightened mens rea standard. Such unsympathetic defendants are hardly the type that make a good case for a more rigorous scienter standard.

The *Starks/Bryan* mens rea standard is similar to the "middle" culpability standard in *Jain*, *Davis*, and *Neufeld*. This standard represents the majority view of the meaning of "willfully" under the anti-kickback statute, but does not overrule the "heightened" standard established in *Hanlester/Ratzlaf*. Because both Supreme Court cases were interpreting the meaning of the "willful" under different criminal statutes, and because the Court has never interpreted the mens rea requirement of the anti-kickback statute, courts are able to adopt whichever standard they choose. However, for the reasons discussed below, the *Bryan* "middle" standard is most likely to be followed in cases involving the mens rea of the anti-kickback statute.

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[139] *Starks*, 157 F.3d at 838.

[140] *Id.*

[141] *Id.* at 837.

[142] *Id.* at 839 n.8. In evaluating the district court decision, the Court stated that, "[t]he government produced ample evidence, including furtive methods by which [Future Steps] remunerated Starks and Henry, from which the jury could reasonably have inferred that that [defendants] knew that they were breaking the law—even if they may not have known that they were specifically violating the Anti-Kickback statute.

VI. ANALYSIS OF THE ANTI-KICKBACK MENS REA STANDARDS

A. Understanding the Alternative Standards

As the Supreme Court noted in *Bryan*, the mens rea term "willful" is "a word of many meanings."[143] As described in Section III, these meanings generally fall into one of three definitions: a lesser degree of culpability that merely requires the person to act "knowingly," a middle standard that requires intent to violate the law or the showing of an "evil purpose," and a heightened standard of culpability that requires knowledge of the law coupled with the intent to violate the law. In interpreting "willfully" in the context of the anti-kickback statute, federal courts have generally adopted either the middle standard or the heightened mens rea standard. No federal court appears to have adopted the lesser degree of culpability. This is likely because the anti-kickback statute contains the phrase "knowingly and willfully," and were a court to give the same meaning to both terms, "willfully" would be mere surplusage.[144]

While the definitions for the middle standard and heightened standard often appear to be very similar, they are very different in application. The following hypothetical will help to illustrate the differences between these definitions. Suppose a representative from a pharmaceutical company approaches a physician and invites her to participate in a research project for a new allergy medication. Under terms of the agreement, the physician agrees to record a series of utilization outcomes of her patients using (and purchasing) the medication and to share the results with the pharmaceutical company. In exchange for the doctor's time and efforts in recording the patient data and agreeing to the share the results, the physician will receive a research stipend.

Under the first interpretation of "willfully," the physician would be liable for violating the anti-kickback statute merely because she knew that she was receiving remuneration in return for medication that she ordered for her patients.[145] Despite the fact that the physician was unaware of the anti-kickback law or that such a stipend would be considered remuneration, she will still be liable for knowingly accepting the payment. The common law principle that ignorance of the law is not a defense will impose upon her the presumption that she knows the law.[146] Therefore, since she knowingly accepted the stipend money under this scenario, she will be liable for violation of the anti-kickback statute under the first interpretation of willfully.[147]

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[143] *Bryan*, 524 U.S. at 188.

[144] This argument was raised in *Ratzlaf v. United States*, where the majority criticized the trial judge and the Ninth Circuit for approving of a definition of "willfully" that was essentially the same as the definition for "knowingly." *See Ratzlaf*, 510 U.S. 135, 140.

[145] Numerous courts have interpreted the language "in return for" very broadly. *See, e.g.*, United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

[146] *See Brumback*, 671 N.E. 2d 1064.

[147] This situation is distinguished from strict liability, where the physician would be liable without the government proving that she knew of the remuneration. Under strict liability, the physician would be liable under a situation where the payments were being received for the

Under the second interpretation, the government must prove that the physician had the intent to violate the law or entered into the agreement with an evil motive. The intent to violate the law is a question of fact that will be decided upon the evidence presented at trial. Under the present hypothetical, it is unclear whether the physician entered into the agreement innocently, or whether there was intent to violate the law or an evil motive. If the physician could prove she did not consider the stipend to be remuneration, then she would not be liable under the anti-kickback law. For example, if she could demonstrate that she did not increase the volume of prescriptions of the medication under the study, or that she honestly believed that her work was contributing to legitimate research in her field, she would not likely be convicted under the anti-kickback statute. However, if the government could prove that the physician knew that the stipend was really an inducement to increase utilization of the medication, or that she attempted to conceal the payment because it might be wrongful, then she would likely be guilty of violating the anti-kickback statute under the second interpretation of the mens rea requirement.

Under the third interpretation of "willfully," the physician would be liable only if the government could meet the heightened standard of proving that she violated a known legal duty. This is a difficult requirement to meet, as it requires proof that the physician knew the anti-kickback law. In cases where this standard has been adopted, the courts have generally stated that the accused need not know the specifics of the law, but must be shown to at least know of the law.[148] Under this standard, the government might win a conviction if, for example, she knew of the anti-kickback law through training from her practice group or if she were practicing under a managed care contract that specifically forbid such agreements. Short of some showing of actual knowledge of the anti-kickback statute, it will be difficult for the physician in this example to be found liable for violating the law under the third interpretation of "willfully."

B. Why Federal Courts Will Likely Follow Bryan in Anti-Kickback Cases

The Supreme Court's recent interpretation of "willfully" in *Bryan* will likely be adopted by federal courts interpreting the scienter requirement of the anti-kickback statute. Even before the Court had reached its final outcome in that case, it was anticipated to have a "dramatic" impact on future anti-kickback litigation.[149] Based on the Eleventh Circuit's adoption of *Bryan* in *United States v. Starks*, this prediction is already coming true. There are several reasons why the *Bryan* decision is likely to be followed in the context of the anti-kickback statute.

First, *Bryan* is consistent with the general interpretation of "willfully." While the word "willfully" has many different meanings, it is most commonly defined as a "bad purpose" or "intending to violate the law."[150] This definition is consistent with

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physician by the office manager without the physician being aware that she was being compensated for recording the patient outcomes.

[148]*Cheek*, 498 U.S. at 200.

[149]*See* Sharon L. Davies, *Guidance on Meaning of "Willfulness" Looming? How Bryan Might Affect the Hanlester Debate*, 10 HEALTH LAW 14 (1998).

[150]United States v. Murdock, 290 U.S. 389, 394 ("[W]hen used in a criminal statute [willfully] generally means an act done with a bad purpose . . .").

the common law understanding of the word[151] and modern statutory construction.[152] The *Bryan* decision is also consistent with the majority view of the interpretation of willfully under the anti-kickback statute. The Eighth Circuit court in *Jain*, the Fifth Circuit court in *Davis*, and the Eleventh Circuit court in *Starks* have all adopted this standard. This standard requires proof that the person knew his conduct was wrongful and chose to act contrary to the law. Furthermore, *Bryan* is also consistent with the general principle that ignorance of the law is not a defense.

Second, the heightened mens rea standard is intended to be limited to instances where a person might become innocently ensnared in a technical area of the law. Circuit Courts have split as to whether the anti-kickback statute qualifies as a highly technical area of the law. In *Hanlester*, the Ninth Circuit court considered the anti-kickback statute to be highly technical. However, the Eleventh Circuit court disagreed, claiming that the statute was not highly technical. Interestingly, the facts in each of these cases may have influenced the court's reading of the statute. *Hanlester* involved a complicated kickback arrangement, whereas *Starks* involved a strait-forward kickback scenario. However, courts should not selectively change the mens rea standard based on the facts of the case.

Even if the anti-kickback statute is considered to be highly technical, health care providers can avoid becoming innocently ensnared in its technicalities by requesting an advisory opinion. Under the HIPAA, the Secretary of the Department of Health and Human Services (HHS) is required to issue advisory opinions in response to requests for guidance about whether a specific business arrangement violates the anti-kickback law.[153] The Secretary must issue an advisory opinion within 60 days of the receipt of a request, and the opinion is binding on both the Secretary and the party requesting the opinion.[154] Thus, if a health care professional is in doubt, he or she can quickly receive clarification about a proposed financial arrangement.

Third, the heightened mens rea standard presents a very difficult burden on the government. Because this standard requires proof that the person actually knew of the anti-kickback law, it is very difficult for the government to win a conviction. Since this standard grossly favors defendants, courts will likely rely on the *Bryan* decision as a more balanced definition of "willfully." Another reason that courts may find to reject the heightened standard is that it is unclear how much the person must know about the law. In cases where this standard has been applied, courts have

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[151]Felton v. United States, 96 U.S. 669, 702 ("Doing or omitting to do a thing knowingly and willfully, implies not only a knowledge of the thing, but a determination with a bad intent to do it or to omit doing it").

[152]*Bryan*, 524 U.S. 184, 188 (1998).

[153]Pub.L.No. 104-191, Title II, § 205, 110 Stat. 1936 (1996). Under the direction of the Attorney General, the Secretary of Health and Human Services will issue advisory opinions about (1) what constitutes prohibited remuneration under the anti-kickback laws; (2) whether an arrangement falls within one of the statutory exceptions to the anti-kickback law; (3) whether an arrangement falls within an applicable safe harbor established by the (OIG); (4) what constitutes an inducement to reduce or limit services; and (5) whether a particular activity constitutes grounds for penalties under the anti-kickback law, civil monetary law, or exclusion statutes. The OIG must accept requests for advisory opinions between February 21, 1997 and August 21, 2000. *Cited* in Jost § 3-13.

[154]Jost at §§ 3-13.

stated that the person must know something of the law, but is not required to know the specifics of the law. Such an ambiguous standard will be difficult to apply where the facts do not present a clear picture of what a person knows.

Fourth, the gun trafficing statute in *Bryan* is analogous to the anti-kickback statute in that both statutes include the mens rea terms "knowingly" and "willfully." The Supreme Court defined both of these terms in *Bryan*, and noted that "willfully" requires more than "knowingly," since the person must also know that the conduct is unlawful.[155] This distinction is important because critics of the "middle standard" have argued that it proscribes the same conduct as knowingly, and therefore, courts have failed to recognize that it is a higher standard.[156]

VII. CONCLUSION

The Supreme Court's recent opinion in *Bryan* will likely have a dramatic influence on federal courts' interpretation of the mens rea requirement under the Medicare and Medicaid anti-kickback statute. Although the *Bryan* decision defined "willfully" under a different federal criminal statute, it has already been relied upon by the Eleventh Circuit court in interpreting the anti-kickback statute. However, the Court was careful not to overrule the heightened mens rea standard it approved in *Cheeks* and *Ratzlaf*. In so doing, the Court did not eliminate the possibility that the anti-kickback statute could be read as requiring a heightened standard, as the Ninth Circuit court did in *Hanlester*. Therefore, *Bryan* will significantly influence the debate about the appropriate scienter requirement, but will not completely settle it.

ROBB DEGRAW

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[155] *Bryan*, 524 U.S. 184, 193 (1998).

[156] *See* W. Bradley Tully, *Supreme Court Defines "Willfully" to Require Knowledge that the Conduct is Illegal*, 6 CAL. HEALTH L. MONITOR 2 (1998).