HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

April 2017

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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by David L. Kirman and Cameron G. Smith

McDonnell's impact on the evolution of the Anti-Kickback Statute

» The federal Anti-Kickback Statute (AKS) broadly prohibits giving, receiving, offering, or soliciting remuneration in exchange for a referral of healthcare services reimbursed by a federal healthcare program.

» In *McDonnell v. United States*, the Supreme Court held that a governmental official is not guilty of bribery if he received gifts in exchange for arranging meetings for and extending access to a constituent.

» *McDonnell* may presage new arguments for defendants against AKS allegations.

» At least one court has recently taken the position that a corporate executive does not violate the AKS where the intent is to "cultivate a business relationship or create a reservoir of goodwill."

» Companies must still be vigilant in AKS compliance and training.

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The federal Anti-Kickback Statute (the AKS) broadly prohibits giving, receiving, offering, or soliciting remuneration in exchange for a referral (or order) of healthcare services reimbursed by a federal healthcare program, such as Medicare or Medicaid. For years, the government (and whistleblowers) used the AKS as a powerful and lucrative enforcement tool. Recently, however, there has been a trend outside the context of the AKS in how courts view corruption, and the recent decision of the U.S. Supreme Court in *McDonnell v. United States*[1] may have implications for how courts view charges and claims under the AKS. Some payments are clearly illegal; some payments are clearly exempted from the AKS. But the law in the large gray area in which businesses must frequently operate may be evolving, and *McDonnell* may presage new arguments for defendants against AKS allegations.

Kirman

Smith

The *McDonnell* decision

A federal grand jury indicted Virginia Governor Bob McDonnell in January 2014. The indictment charged McDonnell and his wife with violations of federal fraud and extortion statutes based on allegations they took bribes in the form of gifts from a wealthy constituent who was the CEO of a Virginia-based company that was developing a nutritional supplement. The indictment alleged that McDonnell had been given a Rolex watch, assorted vacations, loans from the CEO, and other benefits in exchange for various "official act[s]" for the benefit of the CEO:

- "arranging meetings for [the CEO] with Virginia government officials, who were subordinates of the Governor, to discuss and promote" the supplement;
- "hosting, and . . . attending, events at the Governor's Mansion designed to encourage Virginia university researchers to initiate studies of [the supplement] and to promote [the company's] products to doctors for referral to their patients";
- "contacting other government officials in the [Governor's Office] as part of an effort to encourage Virginia state research universities to initiate studies of" the supplement;
- "promoting [the company's] products and facilitating its relationships with Virginia government officials by allowing [the CEO] to invite individuals important to [the company's] business to exclusive events at the Governor's Mansion"; and
- "recommending that senior government officials in the [Governor's Office] meet with [company] executives to discuss ways that the company's products could lower healthcare costs."[2]

The Supreme Court vacated McDonnell's convictions and, in doing so, held that the governor's actions in organizing and hosting events, setting up meetings, and talking to other officials for the benefit of the CEO—without more—did not constitute "official act[s]" within the meaning of the federal bribery statute.[3] In reaching its conclusion, the Court rejected the government's argument that "nearly anything a public official does" constitutes an official act. The Court explained that "conscientious public officials arrange meetings for constituents, contact other officials on their behalf, and include them in events all the time. The basic compact underlying representative government assumes that public officials will hear from their constituents and act appropriately on their concerns."[4] In short, the Court concluded that Governor McDonnell's conduct could not constitute a *quo* in a quid pro quo (i.e., literally "this for that" or a "something for something" exchange), which is what the bribery statute prohibited.

The Anti-Kickback Statute

The federal AKS, originally enacted in 1927 to combat fraud and abuse, prohibits knowingly and willfully paying or receiving remuneration in exchange for patient referrals from which payment may be made by a federal healthcare program, such as Medicare or Tricare.[5] Although the statute originally applied only to "kickbacks" and "bribes," in 1977, Congress made a violation of the AKS a felony and also expanded the scope of the statute to include "any remuneration" in return for referring a patient to a provider of covered services, directly or indirectly, overtly or covertly, or "in cash" or "in kind."[6] In 1980, Congress amended the statute to require that a violation of the AKS be committed "knowingly and willfully."[7] In 1987, Congress consolidated the AKS into Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a–7b. In its current form, the AKS punishes:

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, [and]

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—
   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 healthcare program… .[8]

Each violation of the AKS is punishable by up to five years in prison and a $25,000 fine. Moreover, violations of the AKS can result in large penalties under the False Claims Act (which permits triple damages per violation) or the Civil Monetary Penalties Law, as well as administrative exclusion from federal health benefit programs. (There are a number of so-called "safe harbors" to the AKS, such as a safe harbor for discounts in certain circumstances, some of which are statutory and others of which are regulatory, but the safe harbors are beyond the scope of this article.)

Enforcement of the AKS by the government and whistleblowers has been robust—a trend that is expected to continue, particularly in light of massive payouts in recent years by defendants and the government's conclusion that False Claims Act cases are a lucrative investment of the government's investigative and enforcement resources.

McDonnell's impact on the AKS

The *McDonnell* Court's holding (i.e., that activities designed merely to ingratiate and develop relationships do not constitute a *quo* in a quid pro quo) potentially has implications for the federal AKS.

Specifically, the reasoning of the *McDonnell* decision potentially opens up the argument that activities designed to develop long-term relationships and goodwill with customers that are not linked to referrals do not necessarily violate the AKS, because there is no prohibited quid pro quo. This potential interpretation of the statute is in contrast to the very broad view the government has taken of prohibited remuneration under the AKS. If courts (and the government) were to adopt this view of the AKS following *McDonnell*, that interpretation could have significant impact on healthcare and life sciences companies.

The Supreme Court's prior decision in *United States v. Sun-Diamond Growers of California*,[9] which the *McDonnell* Court relied upon, supports this trend. In *Sun-Diamond*, the Court threw out a trade association's conviction under the federal gratuity statute, which prohibits giving a gift to a public official for or because of an official act, where the trade association had given the Secretary of Agriculture expensive tickets, luggage, meals, and other gifts. The *Sun-Diamond Growers* Court explained that the conviction could not stand because, as instructed, the jury was not required to find that the gifts had been given because of or for an official act, but rather were given merely because of the recipient's position. The *Sun-Diamond* Court, consistent with the subsequent decision in *McDonnell*, held that a showing that the gifts were given

"to build a reservoir of goodwill that might ultimately affect one or more of a multitude of unspecified acts, now and in the future" was not sufficient to support a conviction.[10] The gratuities had to be *linked* to official acts.

McDonnell and *Sun-Diamond Growers* together may provide a compelling defense that conduct that is designed to build relationships with customers, but is not linked to specific purchase orders or referrals, may not violate the AKS. This conclusion also seems to be consistent with the Supreme Court's statement in the controversial First Amendment case *Citizens United v. Federal Election Commission*,[11] where the Court said flatly that "[i]ngratiation and access, in any event, are not corruption." Thus, just as ingratiation and access with respect to government officials are not corruption (as in the *McDonnell* case), ingratiation or relationship-building in the business context may not necessarily constitute prohibited remuneration.

Moreover, this interpretation of the AKS finds additional support in the decision of a federal appellate court in *United States v. McClatchey*,[12] an AKS case. Although the appellate court in *McClatchey* reinstated the defendant's conviction under the AKS, the court agreed with the trial court's instruction to the jury 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." Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law. There must be an offer or payment of remuneration to induce… ."[13] If the purpose of the thing of value is something other than referrals (e.g., relationship-building or ingratiation), then the AKS may not be violated.

In sum, *McDonnell* and the other cases discussed above make clear that business payments are not necessarily illicit bribes. Rather, the government must link payments to specific actions or conduct. It is this holding of *McDonnell*—a principle that, as *Sun-Diamond Growers* demonstrates, has been slowly developing over time—that may have salience for how regulators, courts, and juries view allegations of kickbacks under the AKS. Without the direct linkage between the remuneration and the alleged referral, *McDonnell* may mean that there has been no kickback.

Nevertheless, there are limitations to the way in which Governor McDonnell's situation is analogous to that of a doctor who is in a position to prescribe. Specifically, there is no evidence that Governor McDonnell was in a position to take any official action (such as vetoing or signing a bill or appointing an official) for the benefit of the business executive who had provided him and his family with the gifts. By contrast, a doctor with whom a pharmaceutical company is seeking to cultivate a relationship will be in a position where he/she will have to prescribe treatment or medication for a condition. Thus, a doctor will necessarily be in a position to refer or order a pharmaceutical or device company's products. This factual distinction counsels against trying to extend McDonnell's reasoning too far in the AKS context.

Differences among the AKS, bribery, and gratuity statutes

Moreover, to be sure, the Courts in *McDonnell* and *Sun-Diamond Growers* were not construing or considering the AKS. The Court in *McDonnell* was interpreting the federal bribery statute, which makes it a crime for "a public official . . . , directly or indirectly, corruptly" to demand, seek, receive, accept, or agree "to receive or accept anything of value" "*in return for*" being "influenced in the performance of any official act."[14] The *Sun-Diamond Growers* case concerned the federal "illegal gratuity

statute," which requires a showing that something of value was given, offered, or promised to a public official (by the giver), or demanded, sought, received, accepted, or agreed to be received or accepted by a public official (as the recipient), "*for or because of* any official act performed or to be performed by such public official."[15] Thus, the federal bribery statute requires intent "to influence" an official act (or be influenced) "in return for" the thing of value, but the illegal gratuity statute requires only that the gratuity be given or accepted "for or because of" an official act.

The AKS makes it a crime to offer, give, solicit, or receive remuneration "in return for" or "to induce" a referral for a good or service reimbursed by a federal healthcare program.[16] Thus, the bribery statute and the AKS cover things of value "in return for being influenced" in "official acts" (bribery statute) or "induced" to provide referrals (AKS), and the illegal gratuity statute covers things of value "for or because of" an official act. Thus, it seems that there is important overlap between the bribery statute interpreted by the *McDonnell* Court and the AKS: both prohibit things of value "in return for" something (i.e., official acts or referrals). And just as the AKS also covers things of value "to induce" a person to refer a healthcare good or service, the bribery statute prohibits things of value in return for being "influenced," which seems to be consonant with inducements.

...there may be an evolution underway in how enforcement agencies, courts, and juries view corruption within the AKS context.

Anatomy of an Anti-Kickback Statute case post-McDonnell

A look at a recent high-profile case shows that there may be an evolution underway in how enforcement agencies, courts, and juries view corruption within the AKS context. Specifically, a federal jury recently rejected nearly identical criminal charges in the recent acquittal of a former Warner Chilcott executive for conspiracy to violate the AKS in *United States v. Reichel*.[17] The government alleged that Reichel, who had been the president of Warner Chilcott's pharmaceuticals division, created a sales strategy of providing remuneration to doctors in the form of paid speaking engagements and expensive meals to induce the doctors to prescribe Warner Chilcott's prescription drugs. The government alleged that Reichel had sales representatives, at the lavish dinners, obtain commitments from doctors that they would prescribe Warner Chilcott products, and that the sales representatives were to remind the doctors of their commitments if they did not increase their prescriptions sufficiently. The court's instructions to the jury on the law of inducement or quid pro quo within the meaning of the AKS are instructive.

The government requested that the jury be instructed as follows with respect to the inducement element of the AKS:

> "that the remuneration was offered or paid, or caused to be offered or paid, with the intent to gain influence over the reason or judgment of a person making decisions to order or arrange for ordering drugs. The intent to gain such influence must, at least in part, have been the reason the remuneration was offered or paid. Even if a payment or offer of payment had other purposes, if one purpose of the remuneration was to induce orders or arrangements for orders, and that purpose was not an insignificant or deminimus purpose, the payment was unlawful."[18]

The defendant on the other hand requested that the court instruct the jury as follows:

> "The Anti-Kickback Statute does not prohibit transactions that reflect the mere hope or expectation or belief that drug purchases might ultimately ensue from the business relationship. And mere oral encouragement to convince someone to purchase a drug does not itself violate the law. Rather, the statutory requirement of improper inducement is satisfied only if remuneration is offered or paid as a quid pro quo for the specific purchase of the drug. Cultivating a business relationship is not improper. A person does not violate the Anti-Kickback Statute by providing things of value solely as part of a routine cultivation of a business relationship rather than with the intent to induce specific purchases."[19]

The district court, essentially adopting the defendant's proffered instruction with respect to cultivation of a business relationship instructed the jury, using the language of the *Sun-Diamond Growers* decision, that a "defendant cannot be convicted of the Anti-Kickback statute *merely* because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more unspecified purchase or order decisions. (emphasis added)"[20] The jury acquitted the executive.

This decision and interpretation is consistent with that of the Fifth Circuit Court of Appeals just weeks ago in *U.S. ex rel. Vavra v. Kellogg Brown & Root, Inc.*,[21] where the court was construing a different statute: the government contractor Anti-Kickback Act.[22] Likewise relying on the *Sun-Diamond Growers* decision, the Fifth Circuit explained that the government contractor Anti-Kickback Act "requires a link between the kickback and some benefit being sought or already received. A kickback that has the goal of obtaining or rewarding 'favorable treatment' requires a pursuit of more than building better customer relations in the abstract."[23]

Conclusion

Consistent with the Court's prior precedent in *Sun-Diamond Growers* and as foreshadowed by the district court's jury instructions in *Reichel*, the *McDonnell* decision may have an impact on courts' construction of the AKS. Indeed, while it remains to be seen whether these developments affect the government's (or whistleblowers') charging and enforcement decisions, the *McDonnell* decision may become a significant tool in the defense arsenal of pharmaceutical, medical device, and healthcare companies. Ultimately, businesses in the healthcare industry should stay tuned to potential developments in the law and focus on strengthening their compliance programs in the meantime.

The opinions expressed in this article do not necessarily reflect the views of O'Melveny or its clients, and should not be relied upon as legal advice.

1. *McDonnell v. United States*, 136 S. Ct. 2355, 2366, 195 L. Ed. 2d 639 (2016).
2. Idem.
3. 136 S. Ct. 2355, 195 L. Ed. 2d 639 (2016).
4. Id. at 2372.
5. See Social Security Amendments Act, Pub. L. No. 92–603, §§ 242(b) (Medicare) and (c) (Medicaid), 86 Stat. 1419 (1972).
6. Medicare–Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95–142, 91 Stat. 1179, 1181 (1977).
7. See Omnibus Reconciliation Act of 1980, Pub. L. No. 96–499, 94 Stat. 2599, 2625 (1980) (codified as amended at 42 U.S.C. § 1395nn(b)(1)).
8. 42 U.S.C. § 1320a–7b.
9. 526 U.S. 398 (1999).
10. 526 U.S. at 405.
11. 558 U.S. 310, 360 (2010),
12. 217 F.3d 823 (10th Cir. 2000)
13. Id. at 834 (emphasis in original).
14. 18 U.S.C. § 201(b)(2).
15. 18 U.S.C. § 201(c)(1)(A)&(B).
16. 42 U.S.C. § 1320a-7b(b)(1) & (2).
17. No. 1:15-cr-10324 (D. Mass.).
18. No. 1:15-cr-10324 (D. Mass.), Dkt. No. 152 at 27
19. No. 1:15-cr-10324 (D. Mass.), Dkt. No. 149 at 34-35
20. No. 1:15-cr-10324 (D. Mass.), Dkt. No. 244 at 5
21. U.S Appeals Court, Fifth Circuit, No. 15-41623, decided February 3, 2017.
22. See 41 U.S.C. §§ 8701–07.
23. 2017 WL 473873, at *8.