No. 14-14281

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

AMERITOX, LTD.,

Plaintiff-Appellee,

v.

MILLENNIUM LABORATORIES, INC.,

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING APPELLEE

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INTERESTS OF THE UNITED STATES

This appeal presents important legal questions concerning the application of the physician self-referral law, 42 U.S.C. § 1395nn (commonly known as the "Stark Law"), and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7(b). Ameritox, a clinical laboratory, filed this action against Millennium Laboratories (one of its competitors) under the Lanham Act and various state-law tort theories, alleging that Millennium engaged in unfair competition and tortiously interfered with Ameritox's business relationships by providing free point-of-care testing cups ("POCT cups") – *i.e.,* specimen-collection cups with immunoassay testing strips embedded in the cup – to physicians in violation of the Stark Law and the AKS. A jury returned a verdict in Ameritox's favor, and the district court largely denied Millennium's post-trial motions, awarding nearly $10 million in damages. Millennium appealed, advancing a variety of arguments for reversal of the judgment, including contentions that the district court misapplied the Stark Law and the AKS.

The United States enforces the Stark Law and the AKS, and therefore has a substantial interest in this Court's proper interpretation of both statutes. These statutes are critical tools in the government's ongoing efforts to contain health care costs, reduce conflicts of interests in the provision of health care services, and prevent billing for unnecessary services. In addition, violations of the Stark Law and the AKS can provide a basis for liability under the False Claims Act, 31 U.S.C. §§ 3729-33. *See, e.g, McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005)(holding that

AKS violation can provide basis for claim under the False Claims Act); *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.,* 675 F.3d 394 (4th Cir. 2012) (Stark Law); *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011) (AKS); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009) (Stark Law and AKS).

In light of these substantial interests, the United States submits this amicus brief pursuant to 28 U.S.C. § 517 and Fed. R. App. P. 29, to address three issues:

1. Whether Millennium's provision of free POCT cups to certain physicians constituted unlawful "remuneration" under the Stark Law.

2. Whether Millennium's provision of free POCT cups to certain physicians constituted unlawful "remuneration" under the Anti-Kickback Statute.

3. Whether civil claims alleging violations of the Anti-Kickback Statute must be proved by a "preponderance of the evidence," as opposed to the "beyond a reasonable doubt" standard applicable in criminal cases.

INTRODUCTION AND SUMMARY

There is no dispute in this case that Millennium entered into agreements to provide POCT cups at no cost to physicians, provided they referred specimen samples from patients, including Medicare and Medicaid patients, to Millennium for additional (and more expensive) drug testing. The sole question is whether that conduct was lawful. On appeal, Millennium contends that the jury's verdict finding its

conduct unlawful must be set aside on numerous grounds, including deficiencies in the evidence offered at trial, errors in the application of state law, and errors in the application of the Stark Law and the AKS. The United States takes no position on the case-specific, evidentiary arguments Millennium has raised or any of the state law issues. However, the United States submits this amicus brief to correct several erroneous arguments Millennium has made with respect to the Stark Law and the AKS, which rest to a large degree on a flawed understanding of the views held by the principal government entities charged with implementing and enforcing those statutes, the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General for the U.S. Department of Health and Human Services ("OIG").

First, Millennium argues (at 31-38) that it is entitled to judgment as a matter of law that its provision of free POCT cups to physicians did not constitute unlawful "remuneration" under the Stark Law. The United States does not agree. As Millennium appears to recognize, the provision of free drug-testing supplies (here, the immunoassay strips embedded in the POCT cups) to physicians falls within the broad definition of "remuneration" creating a covered "financial relationship" under the Stark Law because such supplies are plainly a direct, in-kind transfer of something with tangible value. *See* 42 U.S.C. §§ 1395nn(h)(1)(A) & (B); 42 C.F.R. § 411.354(c). The Stark Law thus applies absent an applicable exception.

Millennium contends that its conduct falls within an exclusion from the broad definition of remuneration for the provision of items, devices or supplies "used solely

to (I) collect, transport, process or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the result of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R. § 411.351. As explained more fully in section I, however, Millennium does not use the test strips embedded in the POCT cups for *any* purpose; instead, the strips are used by physicians in the treatment of their patients. As a result, the POCT cups do not satisfy the core requirement that the relevant items be used "solely" to collect, transport, process, or store specimens for the entity that provided them (*i.e.*, Millennium). Because Millennium does not use the test strips in any way for the laboratory testing it performs on specimens, the free POCT cups do not fall within the carve-out from the Stark Law's definition of remuneration (hereafter, the "laboratory supplies carve-out"). No further analysis is necessary, and this Court may affirm the jury's Stark Law verdict on this basis alone.

Notwithstanding the plain language of the statute and regulations, which both use the term "solely," Millennium contends that CMS has construed the laboratory supplies carve-out to apply where the items provided are used "primarily" for collection, transportation and storage purposes. *See* Millen. Br. 34. As explained more fully below, that is incorrect. On the contrary, CMS has consistently reiterated that "solely" means "solely" and emphasized in regulations and advisory opinions that items, devices or supplies providing tangible benefits to physicians that are *unrelated to* permissible purposes (*i.e.*, collection, transportation, and storage for the entity providing the items, devices or supplies) do not fall within the laboratory supplies

carve-out, even if the benefits conferred are very small. *See, e.g.*, CMS Advisory Op. No. CMS-AO-2010-01 (Jun. 2010) (holding that single-use disposable specula used to collect Pap smear specimens would not fall within the laboratory supplies carve-out because they can also be used by doctors to conduct gynecological exams). Indeed, in promulgating final rules in this context in 2001, CMS categorically excluded the provision of sterile gloves by a laboratory from the laboratory supplies carve-out because "they are not items, devices, or supplies used solely to collect, transport, process, or store specimens." *Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships*, 66 Fed. Reg. 856, 948 (Jan. 4, 2001). In short, Millennium's argument that its conduct falls within the laboratory supplies carve-out is not only contrary to the plain language of the statute and regulations but also to CMS's long-held and consistent views in this context.

Second, Millennium argues (at 39-43) that it is entitled to judgment as a matter of law that its provision of free POCT cups to physicians did not constitute unlawful "remuneration" under the AKS. This argument fails for the same reasons discussed above and likewise rests on a misunderstanding of applicable regulatory guidance. As explained more fully in section II, *infra*, the principal regulatory entity charged with enforcing the statutory prohibition on kickbacks in this context, the OIG, has consistently construed the AKS to apply where an entity provides items or services for free, or below fair market value, that confer benefits on physicians (even minor ones) that are distinct from permissible services provided.

Unlike the Stark Law, the AKS has no carve-out from the definition of "remuneration" for the provision of laboratory or other supplies. Nevertheless, CMS and OIG have construed the prohibitions in those statutes similarly. *See e.g.*, 66 Fed. Reg. at 948 (noting in preamble interpreting the laboratory supplies exception that OIG guidance under the AKS is "instructive") (citing OIG Special Fraud Alert, 59 Fed. Reg. 65372 (Dec. 19, 1994)). Millennium attempts to read the functional equivalent of a laboratory supplies "carve-out" into the AKS by misinterpreting isolated comments in certain OIG advisory opinions and guidance. As explained below, however, OIG's guidance does not support Millennium's arguments, which fail for largely the same reasons as its Stark law arguments.

Third, Millennium briefly argues (at 46) that the district court erred in instructing the jury that it could find an AKS violation based upon a "preponderance of the evidence." It is well-established, however, that this is the proper standard of proof in a civil action. As the Supreme Court explained long ago, "conduct that can be punished as criminal only upon proof beyond a reasonable doubt will support civil sanctions under a preponderance standard." *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 491 (1985). The proper standard of proof in such circumstances is a matter of considerable importance to the United States because the government frequently pursues civil claims under the False Claims Act predicated upon violations of criminal statutes such as the AKS. Accordingly, we urge this Court to expressly reject Millennium's argument that a higher standard of proof applies in this context.

STATEMENT

A. Regulatory Background.

1. The Stark Law.

Enacted in the 1980s in an attempt "to contain health care costs and reduce conflicts of interests," *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 937 (11th Cir. 2013), the Stark Law, Pub. L. No. 101-239, § 6204, 103 Stat. 2106 (1989), generally prohibits physicians from referring their Medicare patients to business entities, such as hospitals or laboratories, with which the physicians or their immediate family members have a "financial relationship." 42 U.S.C. § 1395nn(a)(1). Subsequent amendments later extended certain aspects of the Stark Law to Medicaid patients. *See* 42 U.S.C. § 1396b(s).

Applicable regulations reiterate this basic restriction and provide guidance regarding the kinds of financial relationships that trigger the ban on physician referrals. *See generally* 42 C.F.R. §§ 411.350 - .389 ("Subpart J – Financial Relationships Between Physicians and Entities Furnishing Designated Services").[1] The statute and regulations further prohibit any entity from submitting a Medicare claim for services rendered pursuant to a prohibited referral, 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b), prohibit Medicare from paying any such claims, 42 U.S.C. § 1395nn(g)(1);

[1] HHS promulgated the regulations interpreting the Stark Law in three major phases: the Phase I rules, 66 Fed. Reg. 856 (2001); the Phase II rules, 69 Fed. Reg. 16054 (2004); and the Phase III rules, 72 Fed. Reg. 51012 (2007). HHS intended for these three phases to be read as a unified whole. *See* 72 Fed. Reg. 51013.

42 C.F.R. § 411.353(c), and require an entity that receives payment for such a claim to reimburse such funds to the United States, 42 C.F.R. § 411.353(d).

The Stark Law defines a "financial relationship" to include a "compensation arrangement," 42 U.S.C. § 1395nn(a)(2), which means "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity," 42 U.S.C. § 1395nn(h)(1)(A). In turn, "remuneration" is broadly defined to include "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. 1395nn(h)(1)(B). *See* 42 C.F.R. § 411.351 ("Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind"). However, the statute excludes certain kinds of payments from the definition of remuneration, including "the provision of items, devices or supplies that are used solely to (I) collect, transport, process or store specimens for the entity providing the item, device or supply, or (II) order or communicate the results of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii). The regulations reiterate this statutory carve-out. *See* 42 C.F.R. § 411.351.

2. The Anti-Kickback Statute.

The Anti-Kickback Statute (AKS) prohibits "knowingly and willfully" offering or paying remuneration to induce a referral "for an item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b). The AKS specifies that "remuneration" includes "any kickback, bribe or rebate" and broadly applies to benefits provided "directly or indirectly, overtly or

covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(1) & (2). "Remuneration" is defined elsewhere to include "transfers of items or services for free or for other than fair market value." 42 U.S.C. 1320a-7a(i)(6). Courts have construed this definition to include intangible remuneration, such as the opportunity to earn a fee. *See United States v. Bay State Ambulance and Hospital Rental Co.*, 874 F.2d 20, 26 (1st Cir. 1989).

Like the Stark Law, the AKS recognizes certain exclusions from the broad definition of "remuneration." *See* 42 U.S.C. § 1320a-7b(b)(3). The OIG has also issued guidance regarding the types of services and supplies that fall within (and outside) the definition of "remuneration" and practices that likely violate the AKS. *See e.g.*, OIG Special Fraud Alert, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994) (explaining that phlebotomy services provided by laboratories to doctors likely constitute prohibited inducement under the AKS to the extent phlebotomists perform "medical functions not directly related to the collection or processing of laboratory specimens").[2]

B. Relevant Factual Background.

1. Physicians routinely use point-of-care (POC) drug testing to screen the urine of patients who may be taking illegal drugs or who are prescribed drugs that are subject to abuse or diversion. Such testing offers considerable benefits to physicians, because it provides qualitative results in just a few minutes rather than the days

[2] Although Special Fraud Alerts are sometimes published in the Federal Register, they are also available on HHS's web site, along with OIG advisory opinions. See http://oig.hhs.gov/compliance/alerts/index.asp

typically required to send a specimen to a laboratory for testing. Unlike ordinary specimen collection cups, which cost approximately 20 cents each, POCT cups cost anywhere from $5 to $15 because they include special immunoassay testing strips in the cup itself. *See* Ameritox Br. at 7-9 (describing POCT cups).

In April 2010, CMS made an important change in the way Medicare reimburses physicians for point-of-care drug testing. That change was made in response to abusive practices (encouraged by some laboratories), where physicians billed each test strip in a POCT cup separately, which could result in total reimbursements of up to $240 for a single specimen. *See* Supp. Appendix ("SA") at 238; SA 267. In response to these practices, CMS changed its payment policy to clarify that doctors could receive only one $20 reimbursement per POCT cup. SA 239-40; *see also* Ameritox Br. at 9.

After this change to CMS's reimbursement rules, Millennium began entering into "cup agreements" with physicians under which it provided POCT cups that would be free of charge so long as physicians agreed: (1) not to bill any insurer (including federal health plans) for the urine testing service and (2) to return each test cup to Millennium for laboratory testing of the urine specimen. Under those agreements, doctors also agreed that, if they failed to comply with these requirements, Millennium would charge them for the price of the cups. Thus, under these "cup agreements," physicians had obvious financial incentives to send samples back to Millennium for further testing, regardless of whether such testing was medically necessary.

2. Ameritox, another clinical laboratory that tests urine specimens for drugs, filed this action against Millennium alleging that the latter's provision of free POCT cups to physicians violated both the Stark Law and the AKS. Based on these alleged violations, Ameritox asserted civil claims against Millennium under the Lanham Act and various state unfair competition laws.

The district court granted in part and denied in part Ameritox's motion for partial summary judgment on the question whether Millennium's cup agreements violated the Stark Law or the AKS. App. 594-607. The court concluded that a jury would have to decide whether the provision of free POCT cups was remuneration where physicians agreed not to bill for such cups but held that the provision of free POCT cups is "remuneration" within the meaning of the Stark Law and the AKS to the extent doctors could not bill for the cups for some independent reason (*e.g.*, for insurers, such as certain state Medicaid plans, that did not reimburse those tests). App. 600-01. The court also rejected Millennium's argument that the provision of free test cups fell within the laboratory supplies exclusion from the definition of remuneration. App. 601-05. The court held that this exception applies only where the items or devices supplied are used *solely* for the purpose of collecting, transporting, processing or storing specimens for the providing laboratory, and found that the POCT cups do not serve *any* function for Millennium. App. 603 (finding that "the test strips do not process the specimen *for Millennium*, nor do the test strips communicate the preliminary results *for Millennium*) (emphases in the original).

After a trial, a jury rendered a verdict in favor of Ameritox, specifically finding that Millennium's provision of free POCT cups to doctors who agreed not to bill for those cups was remuneration under the Stark Law and the AKS. The district court denied Millennium's post-trial motions for judgment as a matter of law and a new trial and entered a final judgment. The court concluded that "Ameritox showed, and the jury accepted, that Millennium's provision of free POCT cups was simply an improper way to induce referrals, as it was a violation of the AKS and Stark Law." App. 762. The court found it unnecessary to address Millennium's arguments that there was insufficient evidence to support the jury's verdict that it "knowingly and willfully" violated the AKS because "the jury found that Millennium also violated the Stark Law, which does not require a willful violation and does not contain a good faith defense." App. 768. Thus, the court grounded its post-trial ruling exclusively on the jury's verdict with respect to the Stark Law. This appeal followed.

ARGUMENT

The "cup agreements" Millennium entered into with certain physicians create exactly the sort of intertwined financial relationships in the health care system that the Stark Law and the AKS are designed to prohibit. Under those agreements, Millennium provided POCT cups free of charge so long as doctors agreed (1) not to bill any insurer (including the federal government) for the cups, and (2) to return each cup to Millennium for laboratory testing of the patient's urine sample. However, Millennium charged the doctors for any cups they failed to return for further testing.

The purpose and effect of this arrangement was to give doctors a significant financial incentive to obtain laboratory testing of each sample collected in a POCT cup and to obtain such testing from Millennium rather than a competitor. That is precisely the sort of inducement that the Stark Law and the AKS forbid.

The district court entered judgment on a jury verdict finding that Millennium's provision of free POCT cups to physicians violated both the Stark Law and the AKS. In challenging that judgment, Millennium advances a number of case-specific, evidentiary arguments and claims of error under state law. The United States takes no position on any of these issues. However, Millennium also contends that the judgment against it must be reversed because its provision of free POCT cups to physicians was not, as a matter of law, "remuneration" within the meaning of the Stark Law or the AKS. In making this argument, Millennium relies extensively on regulatory guidance issued by CMS and OIG. Because the proper application of the Stark Law and the AKS is a matter of considerable importance to the United States, and because Millennium's interpretation of the views held by CMS and OIG is wrong, the United States submits this amicus brief to set the record straight.

I. The District Court and the Jury Correctly Concluded that Millennium's Provision of Free POCT Cups to Physicians Constituted Unlawful "Remuneration" under the Stark Law.

1. The free POCT cups Millennium provided to physicians on the condition that they return specimens to Millennium for additional laboratory testing (or be billed for those cups) were "remuneration" within the plain language of the Stark Law,

applicable regulations, and relevant CMS guidance. Millennium does not dispute that the provision of free testing strips to a doctor independent from a specimen cup satisfies the broad definition of "remuneration" under the Stark Law, because it is plainly a direct, in-kind transfer of something with tangible value. *See* 42 U.S.C. § 1395nn(h)(1)(A) & (B); 42 C.F.R. § 411.354(c). However, Millennium argues that the POCT cups it provided to physicians fall within the laboratory supplies carve-out for "[t]he provision of items, devices, or supplies that are used solely to (I) collect, transport, process or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the result of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R. § 411.351. That argument is incorrect because it ignores the word "solely" in both the statute and the regulations.

As an initial matter, Millennium appears to concede that its POCT cups do not function *solely* to collect, transport, process or store urine specimens for its own benefit. Unlike ordinary, clear specimen cups, POCT cups include immunoassay test strips that provide a valuable diagnostic tool for physicians – the immediate, qualitative identification of certain drugs in a patient – that is wholly independent from functions necessary for Millennium's purposes. As the district court recognized, there was no dispute in this case "that the provision of free test strips themselves would be remuneration under the Stark Law." App. 600. Yet Millennium nevertheless appears to believe that the act of gluing the test strips into an ordinary specimen cup

somehow nullified their independent value to physicians and placed them within the laboratory supplies carve-out.

This Court should reject Millennium's novel argument because it would create an enormous loophole in the application of the Stark Law. Were this Court to endorse that argument, it would provide a template for laboratories to funnel valuable items to doctors so long as they are attached in some way to items, devices or supplies that fall within an applicable exclusion from the definition of remuneration. But an item with independent value, such as the testing strips at issue here, does not lose its character as "remuneration" simply because it is provided at the same time (or in the same package) as a potentially permissible item. Otherwise, Millennium could simply add a five dollar bill (the approximate cost of the testing strips) to each specimen collection cup – a practice that both the Stark Law and the AKS plainly prohibit – and argue that the laboratory supplies carve-out applies because, from the laboratory's perspective, the cup was used "solely" for specimen collection.

2. Unable to argue that its POCT cups function *solely* to collect, transport, process or store urine specimens, Millennium argues "that the *primary* use of the cups is to collect specimens for analysis by Millennium." Millen. Br. at 32. But that is not the relevant inquiry under the statute and regulations, which both require that the items provided be used "solely" for transportation, collection, processing or storage purposes. *See* 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R. § 411.351. Millennium nowhere even attempts to reconcile its position with the plain language of the statute

or the regulations, but instead pivots immediately to a snippet of CMS commentary that Millennium claims supports its view that "solely" really means "primarily."

Millennium's contention that CMS has construed the laboratory supplies carve-out to apply where supplies are used "primarily" for specimen collection is incorrect. Notably, Millennium does not identify any guidance where CMS has substituted the term "primarily" for "solely" in this context. Instead, Millennium relies exclusively on a single sentence in the preamble to the 2001 final rule stating that the laboratory supplies carve-out applies to "items, supplies, and devices of low value, such as single use needles, vials, and specimen cups, that are *primarily* provided by laboratories to physicians to ensure proper collection of specimens for processing at the laboratory and that have little, if any, independent economic value to the physicians who receive them." Millen. Br. at 34 (quoting 66 Fed. Reg. 856, 947) (emphasis in the brief). This sentence cannot bear the weight that Millennium assigns to it.

As an initial matter, the use of the term "primarily" in one sentence in the preamble to a final rule cannot trump the clear language in the statute and regulation requiring items provided by a laboratory to be used "solely" for specimen collection, transportation, processing or storage in order not to constitute remuneration. Even if it is not entirely clear what the term "primarily" modifies in the sentence Millennium quotes standing alone, that term is best understood, in the context of the entire commentary, to refer to the *sources* of the items, devices or supplies, which CMS believed were typically (that is, "primarily") laboratories. That term cannot properly be

construed to reference the *use* of devices (as Millennium argues), because such a construction would directly conflict with the remainder of the preamble to the final rule and the plain language of both the statute and the regulation.

The language CMS actually adopted in the 2001 regulations makes clear that "solely" means "solely" for purposes of the laboratory supplies carve-out. *See* 66 Fed. Reg. at 956 (defining "remuneration"). Moreover, other parts of the comment on which Millennium bases its argument reiterate the "sole use" requirement, noting, for example, that "the provision of an excessive number of supplies creates an inference that the supplies are not provided *solely* to collect, transport, process or store specimens for the entity providing them." *Id.* at 948 (emphasis added). Similarly, CMS explained that, although "sterile gloves are essential to the proper collection of specimens," they would not qualify for the laboratory supplies carve-out because they "can also be used by a physician for other purposes." *Id.* This discussion is entirely consistent with the proposed regulations, published in 1998, which likewise use the term "solely" to limit this carve-out. *See Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships,* 63 Fed. Reg. 1659, 1693 (Jan. 9, 1998).

CMS's advisory opinions have also consistently explained that, in order to fall within the carve-out, supplies must be used "solely to collect, transport, process or store specimens for the entity providing them." For example, in a 2010 advisory opinion, CMS concluded that single-use disposable specula used to collect Pap smear specimens would not fall within the laboratory supplies carve-out because the

laboratory providing the specula "has no way to prevent the concurrent use of a speculum for the collection of a Pap smear specimen and the gynecological examination of a patient." Advisory Op. No. CMS-AO-2010-01, at 3 (Jun. 2010). At a minimum, the POCT cups Millennium provided to physicians serve a similar dual purpose, because they are used by physicians in the treatment of their patients – a function wholly unrelated to any testing by Millennium. *See, e.g.,* SA 64 (concession by Millennium's expert that POCT cups "are used for multiple purposes"). The cups provide a valuable financial benefit to physicians (indeed, greater than the financial value of the specula deemed "remuneration"), who would otherwise have needed to purchase them (or equivalent test strips) for use in the treatment of their patients.

3. Millennium argues (at 34) that the free POCT cups it provided to physicians cannot be "remuneration" because physicians agreed not to bill for them under the cup agreements. But the ability to bill for a device or service is not the *sine qua non* of remuneration. The provision of non-billable gifts (such as cash) or cost-avoiding items and services (such as free drug testing strips or personnel) is clearly remuneration. As CMS's guidance makes clear, benefits conferred on physicians that are *unrelated to* collecting, processing, transporting or storing specimens may be remuneration under the Stark Law, even if the value of the items or services provided is very small and not separately billed. *See* Advisory Op. No. CMS-AO-2010-01 (disposable specula worth only $1.70); 66 Fed. Reg. at 948 (sterile gloves). In short, the relevant question is not how much a free item is worth, or whether it can be billed

separately, but instead whether the item is used "solely" for the functions covered by the laboratory supplies carve-out.

In defending the judgment in this case, Ameritox emphasizes that the free POCT cups Millennium provided to physicians conferred a tangible benefit on them even if they could not bill directly for the cups. *See* Ameritox Br. at 41-42. The immediate test results provided by the cups facilitated more effective treatment of patients and physicians, of course, "billed for the overall treatment of the patients." *Id.* at 41. Moreover, the free POCT cups provided a tangible cost-savings to physicians of $5 to $15 per specimen. *Id.* at 42. Finally, the most obvious proof that the POCT cups conferred a tangible benefit on physicians was that they were willing to enter agreements to use Millennium's laboratory services in order to obtain those cups for free. *See id.* at 41(stressing that "the cups were valuable enough to induce doctors to agree to sign agreements to use Millennium's lab services"). These facts are all relevant, but they are not dispositive, because not every benefit conferred on physicians from items or services provided by laboratories constitutes "remuneration." The critical question instead is whether the supplies provided (which may or may not have significant value to doctors) are used solely for the functions specified in the laboratory supplies carve-out.

In this case, the test strips in the POCT cups served absolutely no purpose for Millennium, thereby precluding any plausible argument that the cups were used "solely" to collect, transport, process or store specimens. Indeed, if the test strips

served any function besides making POCT cups sufficiently attractive for doctors to enter agreements to obtain them for free, Millennium would have provided them to *all* physicians (as it did for plain cups), not just those willing to enter cup agreements. As the district court found, and Millennium nowhere disputes, "the test strips do not process the specimen *for Millennium*, nor do the test strips communicate the preliminary results *for Millennium*." App. 603 (emphases in the original). The district court thus correctly held that POCT cups did not fall within the regulatory carve-out.

This unexceptional result does not preclude the possibility that items, devices or supplies provided by a laboratory or other entity that fall within the laboratory supplies carve-out can confer benefits on physicians. As noted, the relevant question is not simply whether a device or service provides some benefit to a physician but whether it performs a function distinct from the functions covered by the carve-out. Millennium's POCT cups plainly fail that test because it is undisputed that the functions performed by the testing strips embedded in those cups are not necessary – or relevant in any way – for the laboratory's legitimate collection, transportation, processing or storage of specimens for its own testing. Instead, the only purpose of adding test strips to an ordinary specimen cup is to provide independent benefits to physicians (free diagnostic tests) that are sufficiently attractive to induce them to enter cup agreements, which are expressly designed to promote referrals to Millennium. That is no different from taping a five dollar bill to the inside of an ordinary specimen cup, and it is precisely what the Stark Law forbids.

II. The District Court and the Jury Correctly Concluded that Millennium's Provision of Free POCT Cups to Physicians Constituted Unlawful "Remuneration" under the Anti-Kickback Statute.

Millennium's argument (at 40-43) that the free POCT cups it provided to physicians were not "remuneration" under the AKS fails for essentially the same reasons discussed above. Like the Stark Law, the AKS broadly defines the term "remuneration" to include "transfers of items or services for free or for other than fair market value," 42 U.S.C. 1320a-7a(i)(6), but it contains no exception for laboratory supplies. Because the AKS is a criminal statute, it applies only to the "knowing and willful" payment of remuneration to induce a referral for an item or service reimbursable under a federal health care program. 42 U.S.C. 1320a-7b.

As with its Stark Law argument, Millennium makes no attempt to ground its position in the text of the statute. Instead, Millennium relies exclusively on snippets culled from various OIG advisory opinions and guidance to suggest that the provision of free POCT cups is not "remuneration" under the AKS. OIG is the entity principally charged with issuing interpretive guidance concerning the AKS, but the cited OIG guidance and opinions do not support Millennium's argument. Instead, both the advisory opinions Millennium relies upon and other OIG guidance make clear that free POCT cups are different from those laboratory supplies that are not treated as "remuneration," because the test strips in the cups serve a wholly independent purpose unrelated to any function performed by Millennium, because they are valuable to physicians, and because they create a financial arrangement tying

physicians to laboratory referrals, including a notable financial penalty for *not* referring specimens to Millennium for additional testing.

Millennium first argues that the OIG "has consistently made clear that 'free items and services that are integrally related to the offering provider's or supplier's services' are not considered 'remuneration.'" Millen. Br. at 40 (quoting OIG Advisory Op. 12-10). But this argument misconstrues OIG's use of the word "integrally." As other advisory opinions make clear, OIG has only found items or services to be "integrally related" to the provider's services when they "can be used *only* as part of the underlying service being provided" and they thus "have no independent value apart from the underlying service." OIG Advisory Opinion 12-19, at 11 (citing 56 Fed. Reg. 35952, 35978 (July 29, 1991)). *See also* OIG Advisory Op. 12-20 (free computer interfaces were used only to transmit laboratory test results); OIG Advisory Op. 10-20 (provider of imaging services obtained pre-authorizations from insurers for the requestor's own services); OIG Advisory Op. 12-19 (pharmacy provided community homes with access to a software program that enabled homes to communicate with the pharmacy regarding pharmacy orders).

In short, OIG's advisory opinions recognize that some incidental benefits to physicians may be permissible so long as they are directly related to the provider's services and do not extend beyond those services. As explained above, Millennium's free POCT cups fail that test because they confer significant benefits on physicians

wholly apart from, and unrelated to, Millennium's laboratory testing services, which do not depend in any way on POC testing.

Millennium also contends that a footnote in OIG's June 25, 2014 Special Fraud Alert on specimen collection fees supports its argument that free test cups constitute remuneration only if they are billed. Millen. Br. at 42. In that opinion, OIG noted that the provision of "free or below-market point of care urine testing cups to health care providers who use the cups to perform billable in-office testing" might violate the AKS. *See OIG Special Fraud Alert: Laboratory Payments to Referring Physicians*, at 3 n.5 (Jun. 25, 2014). But OIG's fleeting reference to billable services in that footnote does not in any way purport to limit the AKS's definition of "remuneration" to situations where physicians can independently bill for the service provided. On the contrary, the document as a whole strongly reaffirms a much broader presumption in this context: that "whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." *Id.* at 2 (quoting *OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services* (Oct. 1994), *reprinted at* 59 Fed Reg. 65,372, 65,377 (Dec. 19, 1994)). In sum, OIG guidance confirms, rather than refutes, that Millennium's provision of free POCT cups satisfies the broad definition of "remuneration" under the AKS.

III. The District Court Properly Instructed the Jury that Civil Claims Alleging Violations of the Anti-Kickback Statute Must Be Proved by a Preponderance of the Evidence.

Millennium also briefly argues that the district court erred in instructing the jury that it could find an AKS violation based upon a "preponderance of the evidence," because the AKS is a criminal statute and the proper burden of proof is "beyond a reasonable doubt." Millen. Br. at 46. That is incorrect, and if this Court reaches this issue, it should clarify that the relevant standard of proof in a civil suit predicated upon an AKS violation is preponderance of the evidence.

Millennium's argument is flatly contrary to Supreme Court precedent. In *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479 (1985), the Court considered the burden of proof in a civil action involving an alleged RICO violation and observed the "general principle" that "conduct that can be punished as criminal only upon proof beyond a reasonable doubt will support civil sanctions under a preponderance standard." *Id.* at 491. *See also United States v. One Assortment of 89 Firearms*, 465 U.S. 354, 361 (1984) (acknowledging that civil and criminal actions based upon the same conduct may entail different burdens of proof). Likewise, some courts of appeals have applied a preponderance standard in civil cases based on predicate criminal offenses. *See Liquid Air Corp. v. Rogers*, 834 F.2d 1297, 1301 (7th Cir. 1987).

In the context of civil litigation under the False Claims Act, some district courts have similarly held that the proper burden of proof for claims predicated on violations

of the AKS is a preponderance of the evidence. For example, in *United States v. Rogan*, 459 F. Supp. 2d 692, 716 n. 12 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008), the court specifically rejected the argument that the United States had to establish the elements of the predicate AKS violations beyond a reasonable doubt in a False Claims Act suit.[3] Relying on *Sedima,* the court held that "[t]he criminality of predicate offenses in an underlying civil statute . . . does not mandate application of a higher burden of proof in a civil case." *Id.* at 716 n.2. Other district courts have reached similar conclusions in this context. *See, e.g., United States ex rel. Health Dimensions Rehab., Inc. v. Rehab Care Group*, 2013 WL 534 0910, at *4 (E.D. Mo. 2013); *United States v. Campbell*, 2011 WL 43013, at *5 (D.N.J. Jan. 4, 2011).

None of the cases cited by Millennium compels a contrary result. For example, in *United States ex rel. Jamison v. McKesson Corp.,* 900 F. Supp. 2d 683, 698 (N.D. Miss. 2012), the district court actually applied a "preponderance of the evidence" standard while commenting in a footnote that if the government had met the preponderance standard, then the court would have been forced to decide if the higher "beyond a reasonable doubt" standard applied. *Id.* at 698, n.7. Likewise, Millennium's reliance on *United States ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 748 F. Supp. 2d 95, 113

[3] Notably, the False Claims Act specifies that "the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence." 31 U.S.C. § 3731(d). This standard thus applies where a violation under the AKS or another criminal statute forms the basis for a False Claims Act action.

(W.D. Tex. 2010), and *United States ex rel. Sharp v. Consol. Med. Transp., Inc.*, 2001 WL 1035720, *10 (N.D. Ill. Sept. 4, 2001), is entirely misplaced. Neither case addressed the burden of proof at all; rather, the cited pages in both cases concern the AKS *scienter* standard, which the courts simply described as a "criminal" standard.

CONCLUSION

For the foregoing reasons, this Court should reject Millennium's arguments that the district court misapplied the Stark Law and the AKS and affirm the judgment below with respect to the issues addressed in this brief.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced typeface. I further certify that this brief complies with Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7)(B) because it contains 6,647 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ Charles W. Scarborough
CHARLES W. SCARBOROUGH

CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2015, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the appellate CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Charles W. Scarborough
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