No. 21-

IN THE

Supreme Court of the United States

FLOYD CALHOUN DENT, III,

Petitioner,

v.

UNITED STATES, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), makes it a felony to "knowingly and willfully" offer, solicit, pay, or receive "any remuneration (including any kickback, bribe, or rebate)" in exchange for referring an individual for, or arranging or recommending, any item or service paid for by a federal healthcare program. The AKS is intended to promote cost savings and "protect patients from doctors whose medical judgments might be clouded by improper financial considerations." *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015).

In this case, independent contractors made sales presentations to physicians regarding specialized blood testing. Contractors provided general information and marketing materials but had no input or direct influence in a physician's decision to refer a patient for testing. Nevertheless, the Fourth Circuit held that such routine marketing activities constituted "referring" patients for testing or "arranging or recommending" a referral, such that sales commissions paid to the contractors constituted prohibited "remuneration" under the AKS, even though *exactly the same conduct* would be legal if engaged in by employees and even though the Fifth Circuit reached a directly contrary conclusion on indistinguishable facts. *See United States v. Miles*, 360 F.3d 472 (5th Cir. 2004).

The question presented is:

> Whether the AKS prohibits the payment of sales commissions to independent contractors who make marketing presentations to physicians but who are not medical professionals, have no

contact with patients, and are not even present when a physician decides to refer a patient for services?

PARTIES TO THE PROCEEDING

The following list identifies all parties appearing here and in the United States Court of Appeals for the Fourth Circuit. *See* Supreme Court Rule 14.1(b).

Petitioner here, and Defendant-Appellant below, is Floyd Calhoun Dent, III. Respondents here, and Plaintiffs-Appellees below, are the United States of America and *qui tam* relators Scarlett Lutz, Chris Reidel, Kayla Webster, and Dr. Michael Mayes.

Additional Appellants in the Fourth Circuit, who are not Petitioners here, are Defendants-Appellants Robert Bradford Johnson, Bluewave Healthcare Consultants, Inc., and Latonya Mallory; and Parties-in-Interest-Appellants Christina M. Dent; Lakelin Pines, LLC; Trini "D" Island, LLC; AROC Enterprises, LLC; Blue Eagle Farming, LLC; CAE Properties, LLC; War-Horse Properties, LLLP; Eagle Ray Investments, LLC; Forse Investments, LLC; Royal Blue Medical, Inc.; and Cobalt Healthcare Consultants, Inc.

Additional Defendants in the United States District Court for the District of South Carolina, who were not Appellants in the Fourth Circuit and are not Petitioners here, are Health Diagnostic Laboratory Inc.; Singulex Inc.; Laboratory Corporation of America Holdings; Philippe J. Goix, PhD; Berkeley Heartlab, Inc.; and Quest Diagnostics, Inc.

CORPORATE DISCLOSURE STATEMENT

Petitioner Floyd Calhoun Dent, III is a natural person for whom no corporate disclosure statement is required by Supreme Court Rule 29.6.

RELATED PROCEEDINGS

In the United States District Court for the District of South Carolina:

United States of America ex rel. Mayes v. Berkeley Heartlab Inc., et al., No. 9:11-cv-1593-RMG. Judgment entered: June 5, 2015 (administratively closed due to consolidation with No. 9:14-cv-230-RMG).

United States of America, et al. v. BlueWave Healthcare Consultants Inc., et al., No. 9:14-cv-230-RMG. Judgment entered: May 23, 2018.

United States of America, et al., ex rel. Lutz v. Laboratory Corporation of America Holdings, No. 9:14-cv-3699-RMG. Judgment entered: None (case is currently pending).

United States of America ex rel. Reidel v. Heart Diagnostics Laboratory Inc., et al., No. 9:15-cv-2485-RMG. Judgment entered: July 24, 2015 (administratively closed due to consolidation with No. 9:14-cv-230-RMG).

United States of America v. AROC Enterprises, LLC, et al., No. 9:19-cv-234-RMG. Judgment entered: None (case is currently pending).

In the United States Court of Appeals for the Fourth Circuit:

BlueWave Healthcare Consultants Inc., et al., Defendants-Appellants v. United States of America,

Intervenor-Appellee, No. 16-1597(L). Judgment entered: March 23, 2017 (dismissed).

Blue Eagle Farming, LLC, et al., Parties-in-Interest-Appellants v. United States of America, Intervenor-Appellee, No. 16-1600. Judgment entered: March 23, 2017 (dismissed).

Christina M. Dent, et al., Parties-in-Interest-Appellants v. United States of America, Intervenor-Appellee, No. 16-1601. Judgment entered: March 23, 2017 (dismissed).

United States of America ex rel. Lutz, Plaintiffs-Appellees v. Mallory, Defendant-Appellant, No. 18-1811(L). Judgment entered: February 22, 2021.

United States of America ex rel. Lutz, Plaintiffs-Appellees v. Christina M. Dent, et al., Parties-in-Interest-Appellants, No. 18-1812. Judgment entered: February 22, 2021.

United States of America of ex rel. Lutz, Plaintiffs-Appellees v. Robert Bradford Johnson, et al., Defendants-Appellants, No. 18-1813. Judgment entered: February 22, 2021.

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OPINIONS BELOW

The opinion of the court of appeals (App. 1a-23a) is reported at 988 F.3d 730. The order of the district court granting the motion of the United States (the Government) for entry of judgment pursuant to Federal Rule of Civil Procedure 54(b) (App. 24a-44a) is unreported.

JURISDICTION

The Fourth Circuit issued its opinion on February 22, 2021. Petitioner filed a timely petition for rehearing or rehearing *en banc*, which was denied on April 21, 2021. (App. 45a-48a) Pursuant to this Court's order of July 19, 2021, the deadline for filing a petition for a writ of certiorari was extended to 150 days after the denial of rehearing, *i.e.*, September 20, 2021. The jurisdiction of this Court is invoked under 28 U.S.C § 1254(1).

STATUTORY PROVISIONS INVOLVED

The AKS provides in relevant part:

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

> (B) in return for … 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 and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
>
> …
>
> [A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [31 U.S.C. § 3720].

42 U.S.C. § 1320a-7b(b), (g).

The False Claims Act provides in relevant part:

> [A]ny person who … knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval … is liable to the United States Government for a civil penalty … plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

STATEMENT OF THE CASE

A. Petitioner's Business Operations

Petitioner Floyd Calhoun Dent, III (Dent) and his business partner, Robert Bradford Johnson (Johnson) met in 2005, when both worked for Berkeley HeartLab (Berkeley). Dent and Johnson marketed advanced lipid testing, which detects and enables early treatment of cardiovascular disease. Latonya Mallory (Mallory) was also employed by Berkeley, as a lab operations manager. Although all three worked for Berkeley at the same time, Dent and Johnson did not know Mallory.

Mallory left Berkeley in 2008 and formed Health Diagnostic Laboratory (HDL), of which she was CEO. HDL, like Berkeley, offered advanced blood testing related to cardiovascular disease and diabetes. Her partners in HDL were Russ Warnick, a pioneer in advanced lipid testing, and Dr. Joe McConnell, former director of the cardiovascular laboratory at the Mayo Clinic. Additionally, Mallory retained Dennis Ryan, co-founder of the LeClairRyan law firm, as HDL's counsel. Ryan and other LeClairRyan attorneys advised Mallory on virtually every aspect of HDL's formation and operation. Among other things, LeClairRyan advised that HDL should contract with another entity for marketing services.

In 2009, Petitioner and Johnson were considering leaving Berkeley to start their own business. Mallory reached out to them about forming a company to market HDL's tests. Petitioner and Johnson left Berkeley and formed BlueWave, of which each owned 50 percent. HDL's and BlueWave's attorneys then negotiated and drafted a

contract establishing the terms on which BlueWave would provide marketing services to HDL. Under the contract, BlueWave marketed HDL's tests in a nine-state region ranging from Texas to North Carolina. In exchange for these services, HDL agreed to pay BlueWave a base amount plus a set percentage of whatever revenues HDL earned from tests ordered by physicians in BlueWave's territory. In 2010, BlueWave entered into a similar contract with Singulex, another specialty lab.

BlueWave hired individuals to market HDL and Singulex tests. On the advice of BlueWave's counsel, who concluded that BlueWave did not have the organizational resources to comply with the employment tax laws of multiple states, BlueWave hired marketers as independent-contractors rather than as employees.

B. The Government's Investigation

Specialized labs like Berkeley, HDL, Singulex, and many others face the challenge of getting a blood sample from the patient's location to where the lab is—possibly across the country—while preserving the sample's viability for testing. Someone must draw the patient's blood, process each vial (HDL's tests required four vials of blood), and pack the processed vials for shipping to Virginia (for HDL) or California (for Singulex). Because of the specialized nature of their testing, it was not cost-effective for HDL or Singulex to embed an employee in the office of every physician who might order blood drawn for testing.

One option available to specialty labs was to pay a larger lab, such as LabCorp or Quest Diagnostics, to draw,

process, and ship blood samples. This was not a complete solution, however. Some labs charged high fees of at least $25 per specimen, while others simply refused to perform these services for other labs.

By the time HDL began operating, the standard industry-wide practice among specialized labs was to compensate a medical practice for the time its staff spent collecting, processing, and shipping blood samples for testing. The amounts paid for such work were known as process and handling fees ("P&H fees").

In the early 2010s, the Government began investigating the payment of P&H fees by specialty labs. As part of that investigation, in January 2013 the Government issued subpoenas to HDL, BlueWave, and Singulex. The contracts between HDL and BlueWave and between Singulex and BlueWave, as well as BlueWave's contracts with marketers, were all produced in response to the subpoenas.

Throughout the Government's investigation, HDL and BlueWave were completely open regarding their business practices, including the payment of sales commissions. Above all, Petitioner and Johnson believed, and had been advised by counsel, that their conduct complied with all applicable laws, including the AKS. During the course of the investigation, counsel engaged in numerous discussions with the Government about the legality of paying P&H fees, but the Government never identified sales commissions as an area of concern.

C. District Court Proceedings

The proceedings below arose from three actions, subsequently consolidated, filed by four *qui tam* relators.

The Government intervened and filed its complaint in intervention on August 7, 2015, naming as defendants former HDL CEO Latonya Mallory, BlueWave, Petitioner, and Johnson.[1] The Government alleged, in relevant part, that the named defendants submitted claims to Medicare, or caused claims to be submitted, that were false because they were tainted by violations of the AKS, specifically: (1) P&H fees, which the Government alleged were remuneration intended to induce physicians to refer patients for testing by HDL or Singulex; and (2) commissions paid by HDL or Singulex to BlueWave, and by BlueWave to its independent contractors, which the Government contended were remuneration intended to induce contractors to "recommend" or "arrange for" physicians' referrals or patients to HDL or Singulex.

The case was tried to a jury over two weeks in January 2018. The Government's trial presentation focused almost exclusively on its assertion that payment of P&H fees violated the AKS. Payment of commissions was clearly a secondary concern. For example, of the 60 transcript pages occupied by the Government's closing argument, commissions are mentioned on only eight.

Petitioner and his co-defendants requested an advice-of-counsel instruction, arguing that such an instruction was required in light of extensive trial evidence that they had acted in reliance on the advice of numerous attorneys who advised HDL, Singulex, and BlueWave.

1. The Government also named Berkeley as a defendant. Berkeley reached a settlement with the Government and was dismissed from the action in 2017. HDL, Singulex, and Singulex's CEO Philippe Goix were all named as defendants in *qui tam* suits filed by individual relators but settled the claims against them before the Government intervened.

The Government also proposed an advice-of-counsel instruction. Experienced health care lawyers drafted the HDL-BlueWave and Singulex-BlueWave contracts, including the provisions for sales commission payments. HDL's lawyers specifically advised Mallory to have an independent contractor relationship with BlueWave. Separately, BlueWave's attorney advised Petitioner and Johnson that marketers hired by BlueWave should be independent contractors. *None of these attorneys* ever told Petitioner that paying commissions to marketers might violate the AKS. No issues regarding the contracts—including the payment of commissions—were ever raised during external compliance audits commissioned by HDL and Singulex. And throughout its lengthy and intensive investigation of HDL and BlueWave, the Government *never* suggested that paying commissions to independent-contractor marketers might violate the AKS.

In its verdict, the jury inexplicably exonerated BlueWave while finding Petitioner and Johnson liable. The jury held Petitioner and Johnson responsible for 35,074 false claims submitted by HDL, with a total value of $16,601,591.00, and for 3,813 false claims submitted by Singulex, with a total value of $467,935.00.[2] *Id.* After trebling of damages and imposition of civil penalties of $5,000 *per claim*, the district court entered judgment against Petitioner, jointly and severally, for over $114 million.

Petitioner, Johnson, and Mallory timely filed notices of appeal on July 13, 2018.

2. The jury also found Mallory liable for the 35,074 false claims submitted by HDL.

D. The Decision Below

After focusing its investigation, complaint, and trial presentation almost exclusively on P&H fees, the Government abruptly switched gears on appeal. Tacitly acknowledging its failure to establish liability based on HDL's and Singulex's payment of P&H fees, the Government's appellate brief focused primarily on payment of commissions. The Government began emphasizing commissions only after Petitioner's opening brief demonstrated that the Government had failed to prove Petitioner willfully violated the AKS by paying P&H fees. *Accord Reynolds v. Behrman Capital IV LP*, 2020 WL 4335847, *6 (N.D. Ala. July 28, 2020) (because legality of P&H fees was unclear prior to 2014, the Mintz Levin law firm did not commit malpractice by advising a competitor of HDL that P&H fees were "risky" rather than that they were illegal).

The Fourth Circuit affirmed in a published *per curiam* opinion issued on February 22, 2021. (App. 1a-23a) The court rested affirmance on its uncritical acceptance of the Government's theory that payment of commissions to independent contractors who make marketing presentations is "remuneration" for "arranging for or recommending" referrals, and thus is a *per se* violation of the AKS. The court likened commissions paid to BlueWave sales contractors to clandestine kickbacks to individuals who (1) controlled the selection of a pacemaker-monitoring service, *United States v. Polin*, 194 F.3d 863 (7th Cir. 1999); (2) recruited patients for orders of unprescribed medical equipment, *United States v. St. Junius*, 739 F.3d 193 (5th Cir. 2013); or (3) decided which specialty pharmacy would fill a patient's expensive prescription, *United States v. Vernon*, 723 F.3d 1234 (11th Cir. 2013).

REASONS FOR GRANTING THE PETITION

This case starkly illustrates the devastating consequences of imposing quasi-criminal liability under the False Claims Act. It is a case where concerns about fair notice and disproportionate liability have not been addressed at all, let alone through "strict enforcement of the Act's materiality and scienter requirements," as required by this Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar,* 136 S. Ct. 1989, 2002 (2016). BlueWave's contracts with its marketers, as well as the HDL-BlueWave and the Singulex-BlueWave contracts, were structured in accordance with the advice of numerous, highly qualified counsel from large, nationally known healthcare law firms like LeClairRyan (representing HDL) and Ballard Spahr (representing Singulex). No prior agency guidance suggested to these lawyers that sales commissions would be deemed illegal kickbacks. Petitioner continued to seek, and to follow, counsel's advice throughout the time relevant to this case. When the Government began its investigation, Petitioner was open and forthright about BlueWave's business arrangements, which were set forth in written contracts drafted by numerous attorneys and reviewed by outside auditors. Despite all of this, an honest businessmen has been ruined because he was found to have crossed an invisible, moving line set by Government attorneys and administrators, not by Congress or duly empowered regulators.[3]

3. The Government could not bring this case today. A Department of Justice policy *adopted during the midst of the trial of this case* now prohibits "use [of] its enforcement authority to effectively convert agency guidance documents into binding rules." Rachel Brand, U. S. Dep't of Justice, *Limiting Use of Agency*

The Petition should be granted. First, the Fourth Circuit's decision creates a clearly defined circuit split and, in so doing, unjustifiably expands the reach of the AKS, a criminal statute. Second, this is a matter of exceptional importance. In *Safeco Insurance Company v. Burr*, 551 U.S. 47 (2007), this Court reiterated the important Due Process principle that imposition of criminal or quasi-criminal liability is only permitted where there has been fair notice of what conduct is prohibited. The Fourth Circuit's decision purports to adhere to *Safeco* but in fact disregards *Safeco's* plain holding in favor of a ruling that exacerbates the due process problem identified in *Safeco*: the imposition of liability based not on the law but on the subjective (and possibly biased) views of individuals with no policy-making authority.

A. The Decision Below Creates a Circuit Split

In affirming the judgment, the Fourth Circuit held that it is a felony under the AKS to pay commissions to independent contractors who make routine marketing presentations to physicians, while the same commissions paid to employees making the same marketing presentations are legal. As explained *infra*, this holding expands the reach of the AKS in a manner wholly unjustified by either its text or the purpose for which it was enacted. Additionally, the Fourth Circuit's holding conflicts with the Fifth Circuit's decision in *United States v. Miles*, 360 F.3d 472 (5th Cir. 2004), which recognized that the AKS does not prohibit the payment of commissions to

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Guidance Documents In Affirmative Civil Enforcement Cases, at 2 (Jan. 25, 2018), *available at* https://bit.ly/2u9k1cu. That is exactly what has been done to Petitioner.

non-employee marketers who neither *participate in* nor *make* referrals for medical services.

In *Miles*, home health care provider APRO contracted with Premier to market APRO's services. Premier distributed literature, business cards, and plates of cookies to physicians' offices. "When a physician determined that home health care services were needed for a patient, the physician's office might contact [Premier], who would then furnish APRO with the patient's name and Medicare number for billing purposes." *Id.* at 479. APRO paid Premier $300 for each patient referred by a physician as a result of Premier's efforts. *See id.*

The Fifth Circuit reversed the AKS convictions of Premier's owners, agreeing with them that the AKS "was designed to ensure that a doctor's independent judgment regarding patient care is not compromised by promises of payment from Medicare service providers." *Id.* at 480. Premier's activities posed no such threat:

> Premier supplied promotional materials to Houston-area doctors describing APRO's home health care services. *After* a doctor had decided to send a patient to APRO, the doctor's office contacted Premier, which then supplied the necessary billing information to APRO and collected payment. There was no evidence that Premier had any authority to act on behalf of a physician in *selecting* the particular home health care provider. … The payments from APRO to Premier were not made to the *relevant decisionmaker* as an inducement or kickback for sending patients to APRO.

Id. (second emphasis added). The Fifth Circuit noted that its use of the term "relevant decisionmaker" rather than "physician" recognized that "[t]here are … certain situations where payments to non-doctors would fall within the scope of the [AKS]." *Id.* The court pointed to *Polin* as such a case, explaining that because the defendant in *Polin* decided which monitoring service to use, he "was the relevant decisionmaker and his judgment was shown to have been improperly influenced by the payments he received from the monitoring service." *Id.*

Miles is on all fours with the facts of this case. Just as APRO contracted with Premier for marketing services, HDL and Singulex contracted with BlueWave for marketing services. BlueWave hired independent contractors who engaged in marketing activities much like those engaged in by Premier. Just like Premier in *Miles*, BlueWave contractors merely informed physicians about the testing offered by HDL and Singulex. There was no evidence that any BlueWave contractor had authority to act on behalf of a physician in referring a particular patient for testing. To the contrary, BlueWave contractors had no contact with patients and were not present when a physician decided to make a referral.

Despite the clear parallels between this case and *Miles*, the Fourth Circuit failed to address the Fifth Circuit's decision in that case. Moreover, the Fourth Circuit ignored the qualitative differences between Petitioner's conduct and the conduct of the defendants in *Miles*, on one hand, and the conduct at issue in *Polin*, *St. Junius*, and *Vernon*, on the other. The latter three cases involved quid-pro-quo payments to individuals who influenced or outright controlled referrals of specific patients.

B. This Dispute Presents a Matter of Exceptional Importance

Certiorari is also warranted because the decision below vastly expands the reach of the AKS to reach a broad range of completely innocent conduct.

1. Congress Could Not Have Intended That Ordinary Marketing Activity Would Violate the AKS

Two purposes of the AKS are to promote cost savings and "protect patients from doctors whose medical judgments might be clouded by improper financial considerations." *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). Neither of these goals is advanced by construing the AKS, as the Government urges and the Fourth Circuit holds, to bar commissions to independent sales contractors who do not arrange and are not in any way involved in making referrals of patients.

The Government contends that sales commissions paid by HDL and Singulex to BlueWave, and by BlueWave to its marketers, violated the AKS because they constituted remuneration for "arranging for or recommending" referrals to the labs. 42 U.S.C. § 1320a-7b(b)(1)(B), (b)(2)(B). This theory stretches the text and purpose of the statute beyond recognition. To constitute an illegal kickback, remuneration: (1) must be directed at an individual or entity in a position to refer "Federal health care program patients," and (2) reasonably induce the person or entity to refer such patients. *See Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 401 (6th Cir. 2015). As a matter of simple logic, no amount of

money can induce someone to make or control a referral when that person is not in a position to do so. A payment made to a person who is not "in a position to generate Federal health care program business" cannot be an inducement for a referral. *See* OIG Guidance, 70 Fed. Reg. at 4864; *accord Jones-McNamara*, 630 F. App'x at 406.

Payment of commissions to BlueWave contractors cannot violate the AKS because the sales contractors were never in a position to make referrals or to exercise control over any physician's decision to refer a patient for testing—in the parlance of the Fifth Circuit, they were never the "relevant decisionmaker." BlueWave marketers made generalized sales presentations *solely* to physicians. They *never* met with patients, never conferred with physicians regarding any patient, and *never* posed any threat to any physician's exercise of independent medical judgment in deciding to refer a patient for testing by HDL or Singulex.

Moreover, the Government presented *no* evidence that commissions paid to BlueWave contractors subverted the AKS by increasing amounts paid by Medicare or, more importantly, by enabling contractors to unduly or improperly influence physicians' exercise of professional judgment. The Government presented *no* evidence that *any* physician ordered *any* test from HDL or Singulex based on pressure from a marketer or on *any* consideration other than the physician's determination that testing was medically necessary. To the contrary, physicians who referred or arranged HDL or Singulex testing for their patients testified that the tests were valuable diagnostic tools that aided in preventing potentially life-threatening cardiac events.

As numerous courts have correctly held, the AKS prohibits arrangements that masquerade as ordinary marketing but which actually involve payment of remuneration as a quid pro quo for corrupt referrals. *See, e.g.*, *Polin*, 194 F.3d at 866 (AKS violated where CVS, a cardiac monitoring service, paid a per-patient fee to a pacemaker salesperson in exchange for his recommendation of CVS as a monitoring service; salesperson's recommendations were never rejected and in fact he personally arranged CVS's monitoring of the patient); *St. Junius*, 739 F.3d at 199 (affirming AKS conviction where home health care employee surreptitiously provided patient information to durable medical equipment supplier, who ordered unnecessary equipment for such patients and paid the employee a percentage of Medicare reimbursements); *Vernon*, 723 F.3d at 1254 (affirming conviction under AKS where a "patient advocate" for hemophiliacs "was effectively responsible for deciding which specialty pharmacy to use for filling … patients' prescriptions"). The activities of BlueWave marketers bears no resemblance to the corrupt activities in *Polin*, *St. Junius*, and *Vernon*.

At the very least, the jury should have been allowed to consider Petitioner's advice-of-counsel defense. The commission payment structure appears on the face of the HDL-BlueWave, Singulex-BlueWave, and BlueWave-marketer contracts. These contracts were negotiated and drafted by counsel. The uncontradicted evidence shows that HDL's counsel recommended an independent contractor relationship with BlueWave. Further, BlueWave's counsel recommended the independent contractor relationship with marketers for reasons that had nothing to do with the AKS. BlueWave's counsel

was concerned that an employment relationship with marketers in different states would create tax-reporting obligations that BlueWave was not administratively equipped to handle. Petitioner followed counsel's advice and created independent-contractor relationships with BlueWave's marketers. "A client often comes to his lawyer with a plan and asks him to find a way to implement it in a legal manner." *United States v. DeFries*, 129 F.3d 1293, 1309 (D.C. Cir. 1997). That is precisely what Petitioner did. *See id.* at 1308 ("The district court is required to give [an advice-of-counsel] instruction if there is any foundation in the evidence sufficient to bring the issue into the case, even if that evidence is weak, insufficient, inconsistent, or of doubtful credibility." (internal quotation marks omitted)).[4]

The "good faith" instruction given by the district court was no substitute for a formal advice-of-counsel instruction. The Fourth Circuit's conclusion that the good faith instruction "captured the essence" of a formal advice-of-counsel instruction (App. 15a), cannot be correct. On this reasoning, a district court could *never* err by refusing

4. The prejudice caused by the district court's refusal to give an advice-of-counsel instruction becomes even more clear when it is considered that the district court allowed the Government to discover Petitioner's attorneys' entire files, including attorney work product, on the grounds that Petitioner had implicitly waived privilege by invoking advice of counsel in his defense. Notably, the Government produced no communications between Petitioner and counsel suggesting that any material information was withheld. Moreover, the evidence is clear that every attorney was aware how HDL and BlueWave operated, entitling Petitioner to an advice-of-counsel instruction. *See DeFries*, 129 F.3d at 1309 ("So long as the primary facts which a lawyer would think pertinent are disclosed, or the client knows the lawyer is aware of them, the predicate for an advice-of-counsel defense is laid.").

to give a formal advice-of-counsel instruction, so long as a "good faith" instruction is provided. But a mere "good faith" instruction omits "one critical piece of the puzzle: good-faith reliance on advice of counsel [is] a valid defense that, if proved, require[s] acquittal." *DeFries*, 129 F.3d at 1309; *see United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 391-92 (4th Cir. 2015) (Wynn, Circuit Judge, concurring) (the advice-of-counsel defense provides "a vehicle for absolving [the defendant] of [FCA] liability").[5]

The "good faith" instruction given by the district court was no substitute for the advice-of-counsel instruction, especially considering that the district court also told the jury "[g]ood faith has no precise definition." Petitioner was entitled to an instruction explaining the legal significance of his defense. *See DeFries*, 129 F.3d at 1309.

2. The Decision Below Nullifies the Flexibility Congress Built Into the AKS

Commissions paid to employees fall into one of the AKS's statutory safe harbors. *See* 42 U.S.C. § 1320a-7b(b)(3)(B). The Government's theory—which was barely an afterthought at trial but became the centerpiece of its argument on appeal—is that because commission compensation paid to independent contractors does not

5. The Fourth Circuit cited *Tuomey* in its discussion of whether Petitioner should have been "warned away" from hid reasonable interpretation of the AKS. (App. 8a) But *Tuomey* involved conflicting opinions from retained counsel, not unsolicited comments from third parties. Moreover, the conflicting advice did not preclude giving a formal advice-of-counsel instruction. *Tuomey*, 792 F.3d at 380-81. Rather, it precluded the district court from granting Tuomey's judgment as a matter of law. *Id.*

fall within the employee safe harbor, it is a *per se* violation of the AKS. In affirming, the Fourth Circuit adopted the Government's binary view of the AKS, holding that because BlueWave marketers were contractors rather than employees, payment of commissions necessarily violated the AKS.

Certiorari review is warranted because the Fourth Circuit's decision effectively rewrites the AKS, expanding the scope of criminal liability under the AKS in a way that cannot be squared with congressional intent as expressed in the statutory language. The necessary consequence of the Fourth Circuit's flawed reasoning is that *any* compensation arrangement that does not meet the criteria for a safe harbor *must be* a violation of the AKS. But that is not the law.

To ameliorate the breadth of the AKS, Congress enacted statutory safe harbors and has authorized the OIG to create other safe harbors via regulation. 42 U.S.C. § 1320a-7b(b)(3); 42 U.S.C. § 1320a-7d; *see MedPricer.com, Inc. v. Becton, Dixon & Co.*, 240 F. Supp. 3d 263, 269 (D. Conn. 2017). The Government's binary view of the AKS—payments that meet safe harbor criteria are legal, all others are illegal— reflects a fundamental misunderstanding of the AKS. The OIG long ago made clear that a payment practice does not violate the AKS simply because it does not fall into a safe harbor. "Whether a particular payment practice violates the statute is a question that can only be resolved by an analysis of the elements of the statute as applied to that set of facts," including the parties' intent. *Clarification of OIG Safe Harbor Anti-Kickback Provisions*, 59 Fed. Reg. 37202, 37203, 1994 WL 377320 (July 21, 1994).

In fact, the OIG has indicated approval of at least one commission-based payment practice involving an independent contractor. See OIG Advisory Op. 99-3, 1999 WL 24984727, at *7 (Mar. 23, 1999). In Advisory Opinion 99-3, the inquirer proposed to pay a contract sales agent a commission of 20 percent of sales of specialized mattresses. Because this practice did not qualify for a safe harbor, the OIG considered its particular characteristics. *Id.* The OIG concluded the practice posed a low risk of overutilization and thus did not run afoul of the AKS.[6] *Id.* The OIG concluded, "Of course, in all cases the statute is not violated unless the parties have the requisite intent to induce referrals." *Id.*

3. The Decision Below Violates the Due Process Standard Established in *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007)

To establish an AKS violation, the Government had to prove Petitioner acted willfully, *i.e.*, that he "either knew or showed reckless disregard for … whether [his] conduct was prohibited by" the AKS. *Trans World Airlines, Inc. v. Thurston*, 469 U.S. 111, 127 (1985). The decision below does not deny that Petitioner, advised by counsel, reasonably interpreted the AKS to permit commission payments to marketers of HDL and Singulex testing. The Fourth Circuit held, however, that Petitioner was "warned" by unofficial, non-authoritative sources—such as statements in a demand letter written by an attorney representing

6. Among other things, the OIG noted that the commission was a fixed percentage, *i.e.*, the percentage did not change as the volume or value of referrals increased. *Id.* The agreements at issue here, likewise, set a fixed percentage that did not change with the volume or value of sales.

a former BlueWave contractor, even though that same lawyer and his client subsequently cashed a check paying the very sales commissions the lawyer claimed violated the AKS—that paying commissions "might well" violate the AKS. (App. 8a) This reasoning conflicts with *Safeco*, which clearly holds that only authoritative guidance can warn a defendant away from an objectively reasonable interpretation. *See Safeco*, 551 U.S. at 70.

In *Safeco*, this Court held that the defendants' reliance on an objectively reasonable interpretation of the Fair Credit Reporting Act precluded a finding that they recklessly disregarded their obligations under the Act. *Id.* at 69-70. The Court reasoned that establishing reckless disregard required proof that the defendants' interpretation created a "substantially greater" risk of a violation than a "merely careless" interpretation. *Id.* at 69. This standard cannot be met when the defendant relies on an objectively reasonable interpretation of the law—especially when the interpretation is based on the advice of counsel—at least in the absence of authoritative guidance to the contrary:

> This is not a case in which the business subject to the Act had the benefit of guidance from the courts of appeals or the Federal Trade Commission (FTC) that might have warned it away from the view it took. Before these cases, no court of appeals had spoken on the issue, and no authoritative guidance has yet come from the FTC[.]

Id. at 70.

In *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015), the court applied *Safeco* to an FCA case. To obtain loans from the Export-Import Bank, MWI certified that it paid only "regular commissions" to agents, based on its reasonable interpretation of "regular commissions" to mean amounts consistent with past commissions paid to that agent. MWI was found liable under the FCA based on the government's interpretation of "regular commissions" to mean amounts consistent with industry benchmarks. *Id.* at 284-85.

Relying on *Safeco*, the D.C. Circuit reversed. The court held that MWI's interpretation of "regular commissions" was objectively reasonable and there was no official agency guidance that could have "warned away" MWI. *Id.* at 289-90. Notably, the court rejected evidence that the Bank had informally advised MWI that "regular commissions" should be about five percent, holding that "this suggestion hardly amounts to the necessary 'authoritative guidance'" required by *Safeco*. *Id.* at 289. Similarly, the court held that MWI was not warned away by concerns some employees expressed about the correctness of MWI's interpretation. *Id.*

The Fourth Circuit's assertion that Petitioner was "repeatedly 'warned away from [his] interpretation'" of the AKS (App. 10a), contradicts both *Safeco* (which the court did not cite) and *Purcell* (which it attempted, unconvincingly, to distinguish as involving contractual rather than statutory language). *Safeco* clearly holds that a defendant relying on an objectively reasonable interpretation of a statute can only be "warned away" from that interpretation by "authoritative guidance" from the enforcing agency or an appellate court. *Safeco*, 551 U.S. at 70. Under *Safeco*, the concerns expressed by HDL's

in-house counsel (which were unknown to Petitioner) or agenda-driven positions taken by outsiders like Brian Dickerson cannot establish willfulness in the face of Petitioner's objectively reasonable interpretation of the AKS.[7]

The Fourth Circuit opinion ignores that Petitioner's objectively reasonable interpretation of the AKS was based on the advice of the many lawyers with substantial experience in healthcare law who advised HDL, Singulex, and BlueWave. Experienced health care lawyers drafted the HDL/BlueWave and Singulex/BlueWave contracts, including the commission payments. HDL's lawyers advised Mallory to have an independent contractor relationship with BlueWave. Separately, BlueWave's attorney advised Petitioner and Johnson that marketers should be independent contractors.[8] None of these attorneys ever so much as suggested to Petitioner that paying commissions to marketers might violate the AKS.[9]

7. There is, however, authoritative guidance supporting Petitioner's interpretation of the AKS. *See Miles*, 360 F.3d at 480-81, discussed *supra*.

8. The Fourth Circuit faulted Petitioner for relying on BlueWave's counsel, Sellers, who is not a health care specialist. But Petitioner's reliance on Sellers is not evidence that he *willfully* violated the AKS.

The opinion also unfairly criticizes Petitioner for not obtaining a legal opinion approving commission payments to marketers, even though he had no reason to do so. HDL, not BlueWave, submitted claims to Medicare, and it was acting pursuant to advice given by numerous well-qualified health care lawyers.

9. Petitioner was paid commissions as an employee of Berkeley Heartlab. He was never advised that employees can earn commissions but independent contractors cannot.

No issues were raised in external compliance audits commissioned by HDL and Singulex. Throughout its lengthy and intensive investigation of HDL and BlueWave the government *never* suggested that commission payments were at issue.

CONCLUSION

Justice Oliver Wendell Holmes wrote that "[m]en must turn square corners when they deal with the Government." *See Rock Island A. & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). "That advice cuts both ways: those who deal with the government have a right to expect fair treatment in return." *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 26 (1st Cir. 2003). Nowhere is the Government's obligation to deal fairly with its citizens more critical than under the FCA and AKS. Serious due process concerns are raised when individuals are subjected to ruinous FCA liability for an incorrect, but reasonable, interpretation of an ambiguous statute, arrived at in reliance on the advice of qualified counsel. *See Purcell*, 807 F.3d at 287-88. This Court has acted, in *Escobar*, *Safeco*, and other cases, to rein in Government overreach that results in punitive, confiscatory judgments imposed on individuals like Petitioner.

Petitioner respectfully requests that the Petition be granted.

Respectfully Submitted by,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT, FILED FEBRUARY 22, 2021

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 18-1811

UNITED STATES OF AMERICA, AND THE STATE OF NORTH CAROLINA, CALIFORNIA AND ILLINOIS, ex rel., SCARLETT LUTZ, RELATOR; CHRIS REIDEL; KAYLA WEBSTER, RELATOR; DR. MICHAEL MAYES, RELATOR,

Plaintiffs - Appellees,

v.

LATONYA MALLORY,

Defendant - Appellant,

and

HEALTH DIAGNOSTIC LABORATORY INC.; SINGULEX INC.; LABORATORY CORPORATION OF AMERICA HOLDINGS; BLUEWAVE HEALTHCARE CONSULTANTS, INC.; PHILIPPE J. GOIX, PHD; FLOYD CALHOUN DENT, III; ROBERT BRADFORD JOHNSON; BERKELEY HEARTLAB, INC.; QUEST DIAGNOSTICS, INCORPORATED,

Defendants.

No. 18-1812

UNITED STATES OF AMERICA, AND THE STATES OF NORTH CAROLINA, CALIFORNIA AND ILLINOIS, ex rel., SCARLETT LUTZ, RELATOR; DR. MICHAEL MAYES, RELATOR; CHRIS RIEDEL; KAYLA WEBSTER, RELATOR,

Plaintiffs - Appellees,

v.

CHRISTINA M. DENT; LAKELIN PINES, LLC; TRINI "D" ISLAND, LLC,

Parties-in-Interest - Defendants,

and

LATONYA MALLORY; HEALTH DIAGNOSTIC LABORATORY INC.; LABORATORY CORPORATION OF AMERICA HOLDINGS; PHILIPPE J. GOIX, PHD; BERKELEY HEARTLAB, INC.; QUEST DIAGNOSTICS, INCORPORATED; SINGULEX INC.; BLUEWAVE HEALTHCARE CONSULTANTS, INC.; FLOYD CALHOUN DENT, III; ROBERT BRADFORD JOHNSON,

Defendants.

No. 18-1813

UNITED STATES OF AMERICA, AND THE STATE OF NORTH CAROLINA, CALIFORNIA AND ILLINOIS, ex rel., SCARLETT LUTZ; KAYLA WEBSTER; CHRIS RIEDEL; DR. MICHAEL MAYES,

Plaintiffs - Appellees,

v.

ROBERT BRADFORD JOHNSON; FLOYD CALHOUN DENT, III; BLUEWAVE HEALTHCARE CONSULTANTS, INC.,

Defendants - Appellants,

AROC ENTERPRISES, LLC; BLUE EAGLE FARMING, LLC; CAE PROPERTIES, LLC; WAR-HORSE PROPERTIES, LLLP; EAGLE RAY INVESTMENTS, LLC; FORSE INVESTMENTS, LLC; ROYAL BLUE MEDICAL INCORPORATED; COBALT HEALTHCARE CONSULTANTS, INC.,

Parties-in-Interest - Appellants,

and

BERKELEY HEARTLAB, INC.; LATONYA MALLORY,

Defendants.

Appeals from the United States District Court for the District of South Carolina, at Beaufort. Richard Mark Gergel, District Judge. (9:11-cv-01593-RMG; 9:14-cv-00230-RMG; 9:15-cv-02485-RMG).

December 8, 2020, Argued
February 22, 2021, Decided

Before MOTZ, WYNN, and FLOYD, Circuit Judges.

Affirmed by published opinion. Judge Motz wrote the opinion, in which Judge Wynn and Judge Floyd joined

DIANA GRIBBON MOTZ, Circuit Judge:

LaTonya Mallory, the owner of a blood testing laboratory, and the two men who led its sales operation, Floyd Calhoun Dent III and Robert Bradford Johnson (collectively, "Defendants"), appeal a jury verdict finding them liable for multiple violations of the False Claims Act, 31 U.S.C. § 3729. During a twelve-day trial, the Government presented evidence that Defendants violated the Act in several ways, including by paying physicians for drawing patients' blood and processing the blood samples in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Notwithstanding their vigorous protestations of innocence, the jury found that Defendants had indeed violated the False Claims Act and assessed actual damages in excess of $16 million. In a series of careful opinions, the district court denied their post-trial motions for judgment as a matter of law and for a new trial. After trebling the actual damages and adding civil

penalties, as required by the False Claims Act, the district court entered judgment against all three Defendants for $111,109,655.30 and against Dent and Johnson for an additional $3,039,006.56. For the reasons that follow, we affirm the judgment of the district court in all respects.

I.

In 2008, Mallory founded Health Diagnostic Laboratory ("HDL"), which provided blood testing for cardiovascular disease and diabetes. One year later, Dent and Johnson formed BlueWave Healthcare Consultants, Inc., which entered into an exclusive contract with HDL to market and sell HDL's tests. In addition to a base fee, HDL agreed to pay BlueWave a percentage of its revenue based on the number of HDL blood tests that physicians ordered. In 2010, BlueWave entered into a similar agreement with another lab, Singulex, which also provided blood testing for cardiovascular disease. This contract, too, permitted BlueWave to collect a base amount plus a sales commission based on the number of tests sold.

HDL agreed to pay BlueWave between 13.8 and 19.8 percent of the revenue it generated for HDL. Singulex agreed to pay BlueWave 24 percent of the revenue it generated for HDL. To fill out its sales force, BlueWave then contracted with other independent salespeople. Under these agreements, the salespeople also obtained commissions based on the volume of sales made.

HDL and Singulex used the same business model: in exchange for ordering one of their blood tests, the labs

paid physicians a "process and handling fee" ("P&H fee"). According to Defendants, the P&H fee covered the costs physicians incurred when preserving a blood sample and shipping it to either HDL or Singulex. HDL paid physicians a $3 "draw fee" (compensation for drawing blood) plus a $17 P&H fee (compensation for handling and shipping the blood samples), for a total of $20. Singulex paid physicians $13 for drawing and processing the blood.

Between 2010 and June 2014, Medicare and TRICARE (the federal health care plan for members of the military) paid HDL approximately $538 million and HDL paid BlueWave approximately $220 million. Medicare and TRICARE paid Singulex approximately $47 million, and Singulex paid BlueWave approximately $24 million.

At trial, the Government contended that the volume-based commissions paid by HDL and Singulex to BlueWave and its sales contractors violated the Anti-Kickback Statute because these commissions constituted "remuneration" intended to induce sales representatives to sell as many tests as possible. The Anti-Kickback Statute prohibits "knowingly and willfully" soliciting or receiving remuneration in exchange for "arranging for the furnishing" of a healthcare service and "recommending purchasing" a healthcare service. 42 U.S.C. § 1320a-7b(b)(1). It also prohibits "knowingly and willfully" paying remuneration to "induce" someone to take such actions. *Id.* § 1320a-7b(b)(2). The Government maintained that the statute thus prohibited HDL and Singulex from paying BlueWave for inducing others to arrange the tests. Similarly, the Government contended that the statute

prohibited BlueWave from paying its salespeople for recommending purchase of the tests. The Government argued that since Defendants knowingly entered into agreements to pay independent contractors based on volume, they violated the Anti-Kickback Statute. Because that statute provides that a claim that violates its terms also "constitutes a false or fraudulent claim" under the False Claims Act, *id.* § 1320a-7b(g), the Government contended that this Anti-Kickback Statute violation also gave rise to liability under the False Claims Act. The jury agreed.

II.

Defendants assert that the district court fundamentally erred in denying them judgment as a matter of law. *See* Fed. R. Civ. P. 50(b). We review the denial of a judgment as a matter of law *de novo*, but reverse only if substantial evidence does not support the jury's findings. *Konkel v. Bob Evans Farms Inc.*, 165 F.3d 275, 279 (4th Cir. 1999). We can set aside the verdict only if "no rational trier of fact could have agreed with the jury." *Cavazos v. Smith*, 565 U.S. 1, 2, 132 S. Ct. 2, 181 L. Ed. 2d 311 (2011) (per curiam).

A.

Defendants initially and principally contend that the Government failed to prove that they "knowingly and willfully" violated the Anti-Kickback Statute, *see* 42 U.S.C. § 1320a-7b(b)(1), and so they cannot have "knowingly" run afoul of the False Claims Act. This argument rings

hollow. The Government provided abundant evidence as to Defendants' knowledge and intent.

Attorneys from within both HDL and BlueWave warned Defendants that paying commissions to independent contractors might well violate the Anti-Kickback Statute.[1] For example, in August 2012, HDL's general counsel, Derek Kung, wrote a memo to HDL board members — including Mallory — explaining that its BlueWave contract posed a "high degree of risk" of violating the Anti-Kickback Statute. Kung explained that the U.S. Department of Health and Human Services's Office of the Inspector General "has provided commentary regarding its concern over independent contractor sales agreements with compensation based on a percentage of sales." He urged the Board to change to an "employee based sales system."

Similarly, HDL employee Nicholas Pace, a lawyer who oversaw HDL's compliance efforts, testified that he recognized that the Anti-Kickback Statute prohibited arrangements like the commission-based one with BlueWave, and that he discussed these concerns in meetings with board members, including Mallory. He told the Board that HDL's arrangement with BlueWave was concerning because HDL "rel[ied] on a third party that owned the customer relationship, paying them tens of millions of dollars under that arrangement." And in

1. Because we conclude that the Government provided sufficient evidence to show that the commissions violated the Anti-Kickback Statute and accordingly the False Claims Act, we do not address the Government's other theories of liability.

November 2013, an attorney working for BlueWave sent Johnson the opinion in *United States v. Vernon*, 723 F.3d 1234 (11th Cir. 2013), which upheld a conviction under the Anti-Kickback Statute based on the payment of commissions to a third party.

The Government also offered evidence that outside lawyers warned all three Defendants about the illegality of the commissions. Brian E. Dickerson, an attorney for BlueWave salesperson Emily Barron, testified that he cautioned BlueWave about problems with the commissions in September 2013. He recalled that Barron came to him with a legal opinion from another lawyer stating that both the P&H fees and the volume-based commission structure violated the Anti-Kickback Statute, so she asked him to review her contract with BlueWave. Dickerson agreed that the scheme was not legal and advised Barron to terminate her relationship with BlueWave.

Dickerson also attempted to reach someone at BlueWave who could offer a legal opinion as to its business practices. At one point, Mallory forwarded an email from Dickerson to her colleagues, including Dent and Johnson. In her email, Mallory stated that Dickerson "communicated to Derek [Kung] yesterday and again today that he has issues with the [BlueWave] contract."

Dickerson testified that he told three BlueWave attorneys directly that the commissions violated the Anti-Kickback Statute. He never received a legal opinion from BlueWave in response. Shortly thereafter, BlueWave fired Barron. From these clear warnings about the commissions

scheme's potential illegality, a reasonable jury could certainly infer that Defendants "knowingly and willfully" offered or accepted remunerations in violation of the Anti-Kickback Statute.

Moreover, Defendants' justifications for their continued blind eye to illegal activity in no way undermines the jury's conclusion as to their knowledge. Defendants claim that because the Anti-Kickback Statute is ambiguous, they could have reasonably concluded that the statute did not prohibit volume-based commissions, and so they cannot have knowingly violated the False Claims Act. They rely on *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 420 U.S. App. D.C. 176 (D.C. Cir. 2015), but that case involved a dispute over duties based on ambiguous contractual language, not a claim based on assertedly ambiguous statutory language. In any event, contentions "like these — that a defendant cannot be held liable for failing to comply with an ambiguous term — go to whether the government proved knowledge." *Id.* at 287. Here, unlike in *Purcell*, Defendants were repeatedly "warned away from [their] interpretation" of purportedly ambiguous terms, including by legal practitioners. *Id.* at 288. Ample evidence permitted the jury to conclude that Defendants willfully violated the Anti-Kickback Statute, and so knowingly violated the False Claims Act.

Nor do we find any more persuasive Defendants' contention that they could not have known about the commissions' illegality because attorneys helped draft the contracts providing for commission payments. Defendants point to no legal opinion on which they relied in concluding

that the Anti-Kickback Statute permitted commission payments to independent contractors. Moreover, the jury could have reasonably concluded that Defendants should have given more consideration to the many subsequent warnings about the commissions. *See U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 381 (4th Cir. 2015) ("In determining whether [defendants] reasonably relied on" the advice of counsel, the jury "was entitled to consider all the advice given to it by any source." (internal citation omitted)).

Similarly, Defendants cannot rely on outside audits as a justification for questioning the legality of the commission scheme. These audits did not require the jury to find that Defendants acted legally. In fact, one auditor specifically explained that its services were "not designed, nor should they be relied upon, to disclose . . . illegal acts."

In sum, Defendants offer no argument or evidence that required the district court to grant them judgment as a matter of law. Rather, based on all of the evidence presented at trial, a reasonable jury could conclude that Defendants willfully paid commissions to independent contractors and, accordingly, that they knowingly violated the Anti-Kickback Statute. Of course, the jury did not have to reach this conclusion — but certainly the evidence offered by the Government permitted it to do so.

B.

Defendants also contend that they are entitled to judgment as a matter of law because, assertedly,

commissions to salespeople can never constitute kickbacks under the Anti-Kickback Statute. But no language in the statute so provides. Moreover, federal appellate courts have frequently, and indeed invariably, upheld Anti-Kickback Statute violations based on commission payments to third parties. *See, e.g., United States v. St. Junius*, 739 F.3d 193, 209-10 (5th Cir. 2013); *United States v. Vernon*, 723 F.3d 1234, 1256-58 (11th Cir. 2013); *United States v. Polin*, 194 F.3d 863, 864-66 (7th Cir. 1999).

The Anti-Kickback Statute does include a statutory safe harbor for commissions paid to salespeople who are "employee[s]" that have a "bona fide employment relationship" with their employer. 42 U.S.C. § 1320a-7b(b)(3)(B). But the Department of Health and Human Services has expressly recognized that this safe harbor does not cover independent contractors. In 1989, when considering regulatory safe harbors, the agency noted that "many commenters" wanted to expand the safe harbor "to apply to independent contractors paid on a commission basis," but it "declined to adopt this approach." 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989). The agency explained that it refused to do so because of the "many examples of abusive practices by sales personnel who are paid as independent contractors." *Id.* The Department then noted that if employers "desire to pay [] salesperson[s] on the basis of the amount of business they generate," they "should make these salespersons employees" to avoid "civil or criminal prosecution." *Id.* Two years later, in 1991, when the Department finalized its safe harbor rules, it again refused to apply the commissions safe harbor to independent contractors "because of the existence of

widespread abusive practices by salespersons who are independent contractors." 56 Fed. Reg. 35,952 (July 29, 1991).

Defendants also argue that, because BlueWave sales representatives did not directly refer HDL or Singulex tests to patients, Defendants cannot be liable under the Anti-Kickback Statute. But they misread the plain text of the statute. The statute expressly prohibits individuals from receiving remuneration in exchange for "arranging for or recommending purchasing" healthcare services. 42 U.S.C. §§ 1320a-7b(b)(1)(B), (b)(2)(B). This includes sales representatives who are compensated for recommending a healthcare service, like the HDL or Singulex tests, to physicians. *See Vernon*, 723 F.3d at 1254 (explaining that no provision of the Anti-Kickback Statute is "limited to payments to physicians"); *Polin*, 194 F.3d at 866 (noting that § 1320a-7b(b)(2)(B) penalizes the recommendation of healthcare services, regardless of who recommends them). Again, Defendants' argument does not provide a basis for judgment as a matter of law.

III.

In addition to their claim of entitlement to judgment as a matter of law, Defendants offer a litany of reasons why the district court assertedly erred in denying them a new trial. We review denials of a new trial for abuse of discretion, and a new trial is warranted only if the verdict is against the clear weight of the evidence, based upon false evidence, or will result in a miscarriage of justice. *Minter v. Wells Fargo Bank, N.A.*, 762 F.3d 339, 346 (4th Cir. 2014).

A.

First, Defendants contend that they are entitled to a new trial based on a variety of purported legal errors in the district court's jury instructions.

i.

Defendants argue that the district court erred in refusing to give a stand-alone advice-of-counsel instruction. To establish the advice-of-counsel defense, a "defendant must show the (a) full disclosure of all pertinent facts to [counsel], and (b) good faith reliance on [counsel's] advice." *Drakeford*, 792 F.3d at 381 (alterations in original) (quoting *United States v. Butler*, 211 F.3d 826, 833 (4th Cir. 2000)).

Defendants requested an instruction stating that they "have asserted an affirmative defense of advice of counsel to the Government's allegations that they violated the False Claims Act" and that the affirmative defense, "if true, will completely defeat the Government's allegations under the False Claims Act." The district court refused to give this instruction because it concluded that the instruction did not fit the facts of the case.

This was so, the court explained, because Defendants did not produce evidence that they made full disclosure of all pertinent facts to counsel, nor did they identify any specific legal opinion, written or otherwise, that they relied upon from HDL and BlueWave's formation until at least 2012. In response, Defendants point to an email

sent by an attorney from the law firm LeClairRyan to his colleague in 2009. However, Defendants offered no evidence that they ever read this email. And in the email, the lawyer simply says that in his "recollection, P&H fees do[] not run afoul of Anti-[K]ickback," but he "want[ed] to confirm that no recent OIG [o]pinions have slipped past [him]." This is hardly a clear endorsement of the P&H fee structure.

Furthermore, although the district court did not give the advice-of-counsel affirmative defense instruction proposed by Defendants, it did instruct the jury to consider Defendants' "good faith" reliance on legal advice. The court explained:

> A defendant who acts with a good-faith belief that his or her conduct is lawful does not willfully violate the Anti-Kickback Statute even if that belief is mistaken . . . . In determining whether a defendant acted in good faith, you must consider the totality of the evidence presented. This includes all of the legal opinions and advice received by or known to the defendant, regardless of the source, to determine whether the defendant acted in good faith.

This charge captured the essence of Defendants' proposed instruction — if the jury found that Defendants, relying on the advice of counsel, had a good-faith belief that their conduct was legal, then they did not violate the Anti-Kickback Statute. Thus, the district court's refusal to give the stand-alone advice-of-counsel instruction that

Defendants requested provides no basis for reversal. *See Noel v. Artson*, 641 F.3d 580, 586 (4th Cir. 2011) (only when a requested instruction is "not substantially covered by the court's charge to the jury" does an appellate court reverse).

ii.

Defendants' next challenge to the jury instructions arises from former BlueWave sales contractor Kyle Martel's invocation of the Fifth Amendment. The district court instructed the jury that:

> [I]f you find that [a] witness was a member of a conspiracy to violate the False Claims Act, you may but are not required to infer [from their] refusal [to testify] that the witness's answer would have been unfavorable to the interests of any co-conspirator.

At trial, the Government questioned Martel for 25 minutes, and he invoked the Fifth Amendment in response to nearly every question. The Government presented Martel with a number of exhibits, including emails he sent marketing HDL's tests as a profit source. Defendants contend that the district court improperly instructed the jury that it could infer guilt from his silence.[2]

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2. Defendants do not renew on appeal their trial challenge to the admission of Martel's invocation of his Fifth Amendment rights as violative of the Federal Rules of Evidence.

The Supreme Court has long recognized that there exists a "prevailing rule that the Fifth Amendment does not forbid adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence offered against them." *Baxter v. Palmigiano*, 425 U.S. 308, 318, 96 S. Ct. 1551, 47 L. Ed. 2d 810 (1976). And a "non-party's silence in a civil proceeding implicates Fifth Amendment concerns to an even lesser degree" than a party's invocation of the privilege. *LiButti v. United States*, 107 F.3d 110, 121 (2d Cir. 1997) (quoting *RAD Servs., Inc. v. Aetna Cas. & Sur. Co.*, 808 F.2d 271, 275 (3d Cir. 1986)) (internal quotation marks omitted).

In determining whether a district court may permit adverse inferences, we engage in a case-specific analysis. *See Cerro Gordo Charity v. Fireman's Fund Am. Life Ins. Co.*, 819 F.2d 1471, 1481 (8th Cir. 1987). Courts generally follow the factors set forth by the Second Circuit in *LiButti*: (1) the nature of the relevant relationships; (2) the degree of control of the party over the non-party witness; (3) the compatibility of interests of the party and non-party witness in the outcome of the litigation; and (4) the role of the non-party witness in the litigation. *LiButti*, 107 F.3d at 123-24.

As a BlueWave contractor, Martel played a substantial role in Defendants' scheme. *See RAD Servs.*, 808 F.2d at 277 (permitting the jury to draw an adverse inference when the record was "replete with circumstantial evidence of" the witnesses' "involvement with the alleged plan"). The Government introduced evidence that BlueWave paid Martel nearly $6 million in commissions in exchange for

selling HDL's tests. Evidence also showed that Martel emphasized physicians' ability to profit from P&H fees, a key component of the Government's case. And by requiring that the jury first find that Martel was a co-conspirator, the district court cabined its instruction, ensuring that the jury would only consider Martel's invocation of the Fifth Amendment to the extent it was relevant to their assessment of Defendants' liability.

It is immaterial that Martel no longer worked for BlueWave or HDL at the time of trial. Courts have often permitted invocation of the Fifth Amendment by a former employee of a company that is a party to the litigation. *See, e.g.*, *Cerro Gordo Charity*, 819 F.2d at 1481; *RAD Servs.*, 808 F.2d at 276; *Brink's Inc. v. City of New York*, 717 F.2d 700, 710 (2d Cir. 1983). Accordingly, we see no error in the jury instructions permitting the jury to make adverse inferences based on Martel's testimony.

iii.

Defendants raise two additional challenges to the jury instructions. Both are meritless.

Defendants first contend that the district court erred by failing to instruct the jury that it must find that a false claim be "material." Instead, the court instructed the jury that if it found that a claim violated the Anti-Kickback Statute, the second element of the False Claims Act — that "[t]he claim was false or fraudulent" — was necessarily satisfied. The instruction was proper. The Anti-Kickback Statute expressly states that "a claim that includes items

or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the False Claims Act. 42 U.S.C. § 1320a-7b(g). A violation of the Anti-Kickback Statute thus automatically constitutes a false claim under the False Claims Act. *See United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017) ("An [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act]."); *see also Guilfoile v. Shields*, 913 F.3d 178, 190-91 (1st Cir. 2019).[3]

Defendants also argue that the district court erred when it told the jury that the Government must prove "that at least one purpose of the remuneration" was to induce the referral of services, rather than the "primary purpose of the remuneration." This instruction, too, was proper, as every circuit to address the issue has held. *See, e.g., United States v. Borrasi*, 639 F.3d 774, 781-82 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985).

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3. Defendants appear to argue that the district court should have also instructed the jury on the False Claims Act's "false statement" provision, which prohibits knowingly making or causing to be made "a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). But the theory of liability propounded by the Government — on which we base our holding — implicates only the "presentment" provision of that statute, which prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." *Id.* § 3729(a)(1)(A). The district court properly instructed the jury on the elements of a "presentment" claim, so Defendants' argument is not relevant here.

B.

In addition to their jury-instruction arguments, Defendants contend that the district court abused its discretion by excluding three defense experts: Daniel Mulholland, a healthcare attorney; Jessica Schmor, a nurse; and Curtis Udell, a purported expert on the fair-market value of P&H fees.

Under Federal Rule of Evidence 702, the trial judge "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). In determining whether an expert's reasoning or methodology is scientifically valid, a court considers a host of *Daubert* factors, including whether the theory can be (and has been) tested; whether the technique is subject to peer review; the rate of error; the existence of standards controlling the technique's operation; and whether the technique has garnered general acceptance. *Id.* at 593-94.

The district court excluded Mulholland's testimony as to whether Defendants "would have reason to know what the legal obligations were." The court explained that this testimony presents a legal conclusion informing the jury about how it should apply the law, which is prohibited. *See United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002). The district court excluded Schmor's testimony because her opinion did not rest on sufficient facts or data. Schmor, a nurse, sought to testify as to Medicare's reimbursement code calculations, but she lacked personal knowledge about

Medicare's precise methodology. Similarly, the district court excluded Udell's testimony because the Court found his methodology for calculating the fair market value of P&H fees unreliable. Udell based his calculation on the amount physicians charge for various services. Because physicians consistently inflate charges to ensure they receive full reimbursement from Medicare, the court concluded that Udell's proposed figures did not represent the actual value of the processing and handling services. In excluding the testimony of these experts, the district court did not abuse its discretion.[4]

IV.

Finally, Dent challenges the district court's grant of prejudgment writs of attachment. At issue are three properties that Dent transferred to his wife and to two corporations that she controlled.

Pursuant to the Federal Debt Collection Procedures Act, the Government may obtain a prejudgment remedy

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4. We summarily reject two additional, meritless contentions from Defendants. First, they argue that the jury rendered a fatally inconsistent verdict by imposing personal liability on Dent and Johnson but not BlueWave. The jury rendered a general verdict in this case, which in civil cases "must be accepted" notwithstanding any possible inconsistencies. *Hines v. IBG Int'l, Inc.*, 813 F.2d 1331, 1334 (4th Cir. 1987). Second, using cherry-picked data, Mallory argues that the $16,601,591 damages award against her improperly included certain false claims attributed to Singulex. Given the dearth of support for her argument and our "general reluctance to inquire into the workings of the jury," *United States v. Powell*, 469 U.S. 57, 69, 105 S. Ct. 471, 83 L. Ed. 2d 461 (1984), this challenge cannot succeed.

in connection with a "claim for a debt." 28 U.S.C. § 3001. Under Subchapter D of the Act, the Government must first establish that a transfer is fraudulent. *Id.* § 3304. Then, the Government can rely on "applicable principles of equity" to void the transfer, use a remedy against "the asset transferred or other property of the transferee," or seek "any other relief the circumstances may require." *Id.* § 3306(a).

The district court found that Dent's property transfers were fraudulent. A transfer is fraudulent if the debtor makes the transfer "with actual intent to hinder, delay, or defraud a creditor." *Id.* § 3304(b)(1)(A). The statute outlines certain factors courts should look to in determining intent in this context, including whether the transfer was to an insider, whether the debtor retained control of the property after the transfer, whether the debtor had been threatened with suit before the transfer, whether the value of the consideration was roughly equivalent to the value of the asset, and whether the debtor was insolvent. *Id.* § 3304(b)(2).

Many of these factors are present here. The timing of the transfers, as well as the nominal amount of consideration, cuts in favor of the Government. Dent made the transfers several months after he knew he was under federal investigation. He received a subpoena from the Department of Health and Human Services in January 2013. On May 1, 2013, he purchased a real property for $1.6 million, and sold it to his wife for $5 that same day — consideration far less than the value of the property. In August 2013, he sold a parcel of land that he had purchased

for $2.75 million to his wife, again for $5. In February 2014, Dent sold six more properties to his wife for $5, and an island to one of his wife's corporate entities for $5.

Moreover, Dent transferred the properties to an insider — either to his wife or to corporations controlled by his wife. He retained possession and control of the properties, acknowledging that one of the properties at issue remains his "family home" and that his parents reside in another. Dent's actions meet the standard for a fraudulent transfer. *See id.* § 3304(b)(2). Accordingly, the district court did not err in granting the prejudgment writ of attachment.

V.

For the foregoing reasons, the judgment of the district court is in all respects

AFFIRMED.

APPENDIX B — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA, BEAUFORT DIVISION, DATED MAY 23, 2018

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

Civil Action No. 9:14-cv-00230-RMG
(Consolidated with 9:11-cv-1593-RMG
and 9:15-cv-2458-RMG)

UNITED STATES OF AMERICA, *et al.*,

Plaintiffs,

ex rel. SCARLETT LUTZ, *et al.*,

Plaintiffs-Relators,

v.

BLUE WAVE HEALTHCARE CONSULTANTS, INC., FLOYD CALHOUN DENT, III, ROBERT BRADFORD JOHNSON, AND LATONYA MALLORY,

Defendants.

This matter is before the Court on the United States' Motion for Entry of Judgment under Rule 54(b) of the Federal Rules of Civil Procedure asking this Court to (a)

enter judgment for the United States on Counts I–III of its Complaint in the amount of $111,872,273 against Defendants Floyd Calhoun Dent, III, Robert Bradford Johnson, and Latonya Mallory, and in the additional amount of $3,136,305 against Defendants Dent and Johnson.[1] The motion is granted in part subject to findings below regarding treble damages, set-offs, and statutory penalties.

I. Background

On January 31, 2018, a twelve-member jury returned a unanimous verdict, finding that defendants violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33. (Dkt. No. 870.) The jury found Johnson, Dent, and Mallory responsible for 35,074 false claims for services by Health Diagnostics Laboratories ("HDL"), for which Medicare and TRICARE paid $16,601,591. (*Id.* at 1-2.) The jury also found Dent and Johnson responsible for 3,813 false claims for services by Singulex, for which Medicare and TRICARE paid $467,935. (*Id.* at 2-3.)

II. Discussion

A. Sufficiency of the Evidence — Damages

Dent and Johnson argue that there was not sufficient evidence in the record for the jury to find them liable for any damages all:

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1. This Order also addresses the parties' arguments about the sufficiency of the evidence with respect to damages. Several of these issues were first raised in the parties' briefings on Defendants' motions for judgment as a matter of law and/or for a new trial. (Dkt. Nos. 878, 880, 887, 891, 899.)

> In this case, there has never been a determination that the United States (or anyone else for that matter) sustained any actual harm because of Defendants Dent's or Johnson's alleged violations of the False Claims Act or Anti-Kickback Statute. To the contrary, the jury only determined the total number and value of claims as to which Defendants Dent and Johnson violated those statutes. The government did not show (and the jury did not determine) whether the government (or patients on whose behalf it was paying) received what it paid for with regard to the identified claims . . . . The United States has not shown that the laboratories did not perform the work for which they were paid. The United States has not shown that any of the tests involved in the 38,887 claims were not medically necessary.

(Dkt. No. 888 at 14.) The Court has already ruled several times on Defendants' theory, which is essentially a re-packaged version of their argument that the Government was not damaged if the tests that were ordered were actually performed. Defendants ignore the substantial evidence in the record that their actions caused unnecessary tests to be ordered and reimbursed by Medicare, discussed at length in this Court's May 14, 2018 Order. (Dkt. No. 906 at 11-12.) Defendants' argument also ignores this Court's prior order on materiality, finding that whether a test is medically unnecessary or violates the Anti-Kickback Statute ("AKS") is, as a matter of law, material to the Government's decision to

reimburse a claim. (Dkt. No. 795 at 35); *see United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386-87 (4th Cir. 2015) ("By reimbursing [defendant] for services that it was legally prohibited from paying [under the Stark Law], the government has suffered injury equivalent to the full amount of the payments."). It bears repeating here that AKS violations are not technical violations of unnecessarily strict regulatory requirements, like the oft-discussed example of a Medicare requirement that a contractor use only American-made staplers. Claims that were induced by violations of the Anti-Kickback Statute are serious, so serious that the Government often punishes them criminally, as discussed at length in this Court's December 4, 2017 Order. (Dkt. No. 795 at 4-5.) The Court will not further explain why patients, the Medicare program, and, in turn, American taxpayers, are damaged by the performance of (and reimbursement of claims for) medically unnecessary testing.

Defendant Mallory argues that there was not sufficient evidence in the record to support the jury's verdict finding her liable for 35,074 false claims valued at $16,601,591. (Dkt. No. 878-1 at 1-7.) Mallory argues (1) that the jury's verdict cannot be accurate because it was based on aggregate damages figures for HDL and Singulex, and (2) that the jury incorrectly began measuring damages from a date on which Johnson received a communication from attorney Lauren DeMoss, a date Mallory argues is not relevant to her liability because she did not receive the communication. (Dkt. N. 878-1.)

Pursuant to Federal Rule of Civil Procedure 50(b), a party is entitled to judgment as a matter of law

notwithstanding a jury verdict if the Court "determines, without weighing the evidence or considering the credibility of the witnesses, that substantial evidence does not support the jury's findings." *Konkel v. Bob Evans Farms, Inc.*, 165 F.3d 275, 279 (4th Cir. 1999); *see also Wilhelm v. Blue Bell, Inc.*, 773 F.2d 1429, 1433 (4th Cir. 1985) (judgment in favor of movant is appropriate where there is not "substantial evidence in the record to support the jury's findings."). The evidence must be viewed in the light most favorable to the non-moving party, but a mere "scintilla" of evidence is not enough; the plaintiff must "adduce substantial evidence in support of [its] claim." *Demaine v. Bank One, Akron*, 904 F.2d 219, 220 (4th Cir. 1990).

While a jury "may not render a verdict based on speculation or guesswork," a jury is "allowed to act upon probable and inferential, as well as direct and positive proof" and "may make a just and reasonable estimate of the damage based on relevant data." *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264-66, 66 S. Ct. 574, 90 L. Ed. 652 (1946); *accord Bresler v. Wilmington Trust Co.*, 855 F.3d 178, 201 (4th Cir. 2017) ("[E]stimates that lack mathematical certainty are permissible so long as the [factfinder] has a basis to make a responsible estimate of damages."). "A district court abuses its discretion by upholding an award of damages only when the jury's verdict is against the weight of the evidence or based on evidence which is false." *Gregg v. Ham*, 678 F.3d 333, 343 (4th Cir. 2012). "A jury's award of damages stands unless it is grossly excessive or shocking to the conscience." *Fox v. Gen. Motors Corp.*, 247 F.3d 169, 180 (4th Cir. 2001).

Here, the jury had sufficient evidence to support its verdict that Mallory was liable for 35,074 false claims valued at $16,601,591. The Government's forensic accounting expert, Eric Hines, gave thorough testimony about the following damages calculations: (1) quarterly figures for the number and value of the claims HDL and Singulex submitted during the relevant period that were induced by kickbacks (Dkt. No. 836 at 166:1-170:12; 198:10-15; Dkt. No. 859 at 2674:15-2675:4); (2) the number and value of the claims submitted by HDL and Singulex on a quarterly basis from 2010 and 2014 that were connected to the process and handling ("P&H") and commission kickback schemes (Dkt. No. 836 at 193:13-197:13, 197:14-198:9, 198:16-23; Dkt. No. 859 at 2675:5-2676:2); (3) the percentage of false claims related to the P&H kickback scheme broken down between HDL and Singulex (Dkt. No. 859 at 2674:8-2677:7) and related to both the P&H and commission kickback schemes (*id.*); (4) specific tests on test panels offered by Singulex and HDL that were not medically necessary (Dkt. No. 857 at 1957-1971); (5) testimony that between 15 and 20 percent of all physician orders of HDL tests were for the "standard panel" (Dkt. No. 857 at 2049:2-20 and (6) several data points of the observed decline in HDL and Singulex test orders from physicians after the P&H fee practice ceased (Dkt. No. 836 at 178 (testimony from Eric Hines that test orders dropped "approximately 40 percent"); Dkt. No. 837 at 402:12-15 (testimony from BlueWave sales representative Jeffrey Cornwell that sales in Texas declined 15 to 20 percent after the P&H practice was terminated); Dkt. No. 838 at 612:4-14 (testimony from sales representative Larry Paul Mincey, Jr. that sales dropped by about 10 percent); Dkt.

No. 855 at 1636 (testimony from Defendant Dent that sales dropped by (at "the highest") 11 percent)).

Mallory argues that the jury did not have sufficient evidence to render an accurate verdict as to her liability because the United States' damages expert, Eric Hines, provided aggregate figures for damages caused by HDL and Singulex claims. (Dkt. No. 878-1 at 1-7.) Mallory takes issue primarily with Mr. Hines's testimony on the first day of trial that he was not asked to apportion liability directly to any Defendant. (Dkt. No. 836 at 223.) Mallory argues in her briefs that this statement is proof that Mr. Hines attributed Singulex false claims to her and that the jury, in turn, miscalculated her liability. (Dkt. No. 878-1 at 4.) This argument has no merit. Mr. Hines testified explicitly on the first day of trial that he provided schedules breaking down the false claims between HDL and Singulex. (Dkt. No. 836 at 223.) On Day Ten of the trial, Mr. Hines broke down the total number and value of HDL claims and Singulex claims associated with the process and handling payments and the commission payments. (Dkt. No. 859 at 244-250.) He also provided an overall ratio of HDL to Singulex claims (*Id.* at 250.) Mr. Hines testified that those ratios were generally consistent and would be accurate if applied to the quarterly figures he gave for damages on the first day of the trial. (*Id.*) It is undisputed that Mallory's role rendered her liable for false claims submitted by HDL but not Singulex. The jury had sufficient information to find Mallory liable for the HDL claims that Hines determined were made during the relevant time period and in violation of the False Claims Act. The jury's verdict as to Mallory is therefore not against the weight of the evidence.

Mallory also argues that the jury's verdict must be incorrect as to her liability because the "jury's calculation is based on a triggering date of November 14, 2013" (Dkt. No. 878-1 at 6), the same date that Defendant Johnson received in an email from attorney DeMoss. Mallory argues that the jury incorrectly used the same date to determine when she became liable for false claims, even though she did not receive or otherwise have knowledge of this email. (See Dkt. No. 878-1 at 6-7.) Mallory's argument is rife with speculation about how the jury ultimately determined the total number and value of claims for which each Defendant was or was not liable. She states that the jury "seemingly added one-half of the fourth quarter of 2013 claims (or 9,498) to the claims from the first and second quarters of 2014, to obtain the total number of claims that were found in violation of the FCA." (Dkt. No. 878-1 at 3.) Mallory's theory may well be a correct assessment of the jury's analysis, but this Court will not engage in an in-depth inquiry into the jury's deliberations because doing so "would be replete with dangerous consequences." *McDonald v. Pless*, 238 U.S. 264, 266-67, 269, 35 S. Ct. 783, 59 L. Ed. 1300 (1915) (affirming judgment despite allegation that jury "adopted an arbitrary and unjust method" in arriving at "quotient verdict"). For reasons stated in this Court's May 14, 2017 Orders (Dkt. Nos. 907, 907), there is sufficient evidence in the record to support the jury's verdict finding Mallory liable for certain claims submitted by HDL. Additionally, there is sufficient evidence in the record (discussed just above) to allow the jury to "make a just and reasonable estimate of the damage," *Bigelow*, 327 U.S. at 264, caused by those claims. For these reasons, the jury's award "was

not reached against the clear weight of the evidence, and would not result in a miscarriage of justice." *Bresler v. Wilmington Trust Co.*, 855 F.3d 178, 201 (4th Cir. 2017).

III. Treble Damages

The Government has asked the Court to treble the total value of the false claims for which the jury found Defendants liable as required under Title 31, United States Code, Section 3729(a)(1). *See Fresenius Med. Care Holdings, Inc. v. United States*, Civ. A. No. 08-12118-DPW, 2013 U.S. Dist. LEXIS 66234, 2013 WL 1946216, at *6 (D. Mass. May 9, 2013) ("[T]he government need only prove its single damages, after which multiple damages are applied as a matter of course."). In accordance with the False Claims Act, the Court hereby trebles the single damages as determined by the jury: Dent, Johnson, and Mallory are jointly and severally liable for treble damages of $49,804,773 for the false claims submitted by HDL. Additionally, Dent and Johnson are jointly and severally liable for treble damages of $1,403,805 for the false claims submitted by Singulex.[2]

2. Dent, Johnson, and Mallory are jointly and severally liable for the treble damages and penalties for the HDL claims, and Dent and Johnson are jointly and severally liable for the treble damages and penalties for the Singulex claims. *See Mortgages, Inc. v. U.S. Dist. Ct. for the Dist. of Nev.*, 934 F.2d 209, 212 (9th Cir. 1991) ("Where one or more persons have committed a fraud upon the government in violation of the FCA, each is joint and severally liable for the treble damages and statutory penalty."); *accord United States ex rel. Abbott-Burdick v. Univ. Med. Assocs.*, No. 2:96-1676-12, 2002 U.S. Dist. LEXIS 26986, 2002 WL 34236885, at *4 (D.S.C. May 23, 2002) (collecting cases).

IV. Set-Offs

"[W]hen a plaintiff receives a settlement from one defendant, a nonsettling defendant is entitled to a credit of the settlement amount against any judgment obtained by the plaintiff against the nonsettling defendant as long as both the settlement and judgment represent common damages." *See Singer v. Olympia Brewing Co.*, 878 F.2d 596, 600 (2d Cir. 1989); *Peterson v. Air Line Pilots Ass'n*, 622 F. Supp. 232, 237 (M.D.N.C. 1985); *accord Rutland v. South Carolina Dep't of Transp.*, 400 S.C. 209, 734 S.E.2d 142, 145 (2012) ("[I]t is almost universally held that there can be only one satisfaction for an injury or wrong.") (quotation marks and citation omitted).

The parties do not dispute that all three Defendants are entitled to a set-off for the amounts the United States has received from its settlements with HDL and Singulex. However, Defendants are only entitled to a set-off for those amounts "previously received" by the United States that are attributable to common damages. *See United States v. Bornstein*, 423 U.S. 303, 316, 96 S. Ct. 523, 46 L. Ed. 2d 514 (1976); *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 501 F. Supp. 2d 51, 53 (D.D.C. 2007).

As of the parties' briefings on these issues, the United States had received $6,355,147.48 from HDL and $972,984.41 from Singulex pursuant to their settlements of FCA allegations. (Dkt. No. 887-2.) The United States argues that because neither HDL nor Singulex was a Defendant in this case, and because HDL and Singulex

both settled allegations of broader misconduct[3] than the United States alleged against Dent, Johnson, and Mallory, only a portion of these settlements can be regarded as "common" to the damages Dent, Johnson, and Mallory are liable for here. While HDL settled with the United States to resolve allegations concerning 289,818 allegedly false claims, Mallory, Dent, and Johnson were found liable for only 35,074 (12%). Likewise, while Singulex settled with the United States to resolve allegations about 38,138 allegedly false claims, Dent and Johnson were found liable here for only 3,813 (10%). The United States therefore argues that Dent, Johnson, and Mallory are entitled to apply 12% of HDL's settlement payments as a set-off to the verdict against them and that Dent and Johnson are entitled to apply 10% of Singulex's settlement payments as a set-off to the verdict against them. The Court agrees and finds that Dent, Johnson, and Mallory are entitled to a set-off of 12% of the amount the United States has already received from HDL (*i.e.*, $762,617.70) for the HDL claims. Dent and Johnson are entitled to a set-off of 10% of the amount the United States has already received from Singulex (*i.e.*, $97,298.44) for the Singulex claims. This set-off is applied to the already trebled damages discussed above. *See Bornstein*, 423 U.S. at 316-17 ("in computing the [multiple] damages authorized by the [FCA], the

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3. FIDL settled allegations including offering and paying kickbacks in "speaker programs; advisory boards; consulting arrangements; goods and services; and gifts" and submitting claims for payment for tests "that were not appropriately coded." (Dkt. No. 588-1 ¶¶ (D)(1),(3).) Singulex settled allegations in connection with offering and paying kickbacks in "speaker and other consulting fees." (Dkt. No. 588-2 ¶ (D)(1).)

Government's actual damages are to be [multiplied] before any subtractions are made for compensatory payments previously received by the Government from any source."); *see also Bill Harbert*, 501 F. Supp. 2d at 54 n.4 (approving this approach even under the new treble damages provision).

Defendants argue that they are entitled to additional set-offs. (Dkt. No. 880-1 at 50; 878-1 at 21.) For example, they argue that because HDL's trustee waived the attorney-client privilege as to certain documents demanded by the government in exchange for the Government's release of $53,500,000.02 in claims against the estate, they are entitled to a damages set-off of that amount. Defendants' assertion that the Government somehow received the value of $53,500,000.02 when it released future claims against the bankruptcy estate valued at that amount in exchange for a limited privilege waiver is not compelling. In any event, neither this agreement nor the pre-petition claim cited by Defendants (Dkt. Nos. 880-9; 878-2) represents payment received by the United States in connection with common damages because the agreements did not settle FCA claims.

Defendants also claim that they are entitled to a set-offs for any amounts the United States has received from physician practices, but they cite no physician or physician practice who settled FCA claims related to the receipt of P&H fees from HDL or Singulex. Defendants have also not identified any settlement reached between the United States and HDL's former owners that could form the basis for an additional set-off.

Defendants claim that they are entitled to an equitable lien on future payments made by HDL that represent common damages. *See Mills v. GAF Corp.*, 20 F.3d 678, 682 (6th Cir. 1994) (holding that the non-settling defendant is entitled to an equitable lien on any future payments to the plaintiff from a settling defendant). The Sixth Circuit stated in *Mills*, however, that "Carey Canada must pay the full amount of the verdict and will receive a lien on any future payments to the plaintiffs under the settlement agreements." *Id.* at 682. For this reason, the judgment in this action is not presently reduced by any liens. As already stated, the Government cannot recover twice for common damages among HDL, Singulex, and these Defendants.

V. Civil Statutory Penalties

FCA liability "triggers the imposition of civil penalties." *United States v. Karron*, 750 F. Supp. 2d 480, 493 (S.D.N.Y. 2011). Individuals found liable for claims submitted between 2010 and 2014 are subject to "civil penalties amounting to a minimum of $5,500 and a maximum of $11,000." *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 401 n.10 (4th Cir. 2013); *see also Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 123 n.1, 123 S. Ct. 1239, 155 L. Ed. 2d 247 (2003) ("The [FCA] penalty is currently $5,500 to $11,000.") (citing Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, § 5; 28 U.S.C. § 2461 note); 64 Fed. Reg. 47099, 47103-04 (1999).

The United States seeks to impose the minimum FCA penalty ($5,000) for each of 11,285 HDL claims and

315 Singulex claims for which the jury found Defendants liable, resulting in total civil penalties of $62,067,500 for the HDL claims and $1,732,500 for the Singulex claims.[4] Imposing the requested civil penalties would result in the following judgment:

	Treble Damages	**Less Set-Off**
Singulex Claims (Dent and Johnson)	$1,403,805	($97,298.44)
HDL Claims (Dent, Johnson, and Mallory)	$49,804,773	($762,617.70)

	Civil Penalties	**Total**
Singulex Claims (Dent and Johnson)	$1,732,500	$3,039,006.56
HDL Claims (Dent, Johnson, and Mallory)	$62,067,500	$111,109,655.3

4. The United States could seek penalties for 38,887 false claims for a total of between $213,878,500 and $427,757,000 but has discretion under the FCA "to accept reduced penalties." *Bunk*, 741 F.3d at 408; *see also United States v. Mackby*, 339 F.3d 1013, 1015 (9th Cir. 2003) (upholding penalties sought by United States on 111 of 1459 false claims).

Defendants argue that imposition of these judgments against them would violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth Amendment. Many courts have rejected the notion that the Eighth Amendment limits the potential recovery in False Claims Act cases. See *Hudson v. United States*, 522 U.S. 93, 104, 118 S. Ct. 488, 139 L. Ed. 2d 450 (1997) ("money penalties" have not "historically been viewed as punishment"); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) ("It is far from clear that the Excessive Fines Clause applies to civil actions under the False Claims Act."); *Karron*, 750 F. Supp. 2d at 493 n.12 ("It is well-settled that punitive damages do not constitute 'fines' for the purpose of an Eighth Amendment analysis"). Even if the Excessive Fines Clause is applicable to civil FCA judgments, the judgment here passes Constitutional muster. Under the Eighth Amendment, "judgments about the appropriate punishment for an offense belong in the first instance to the legislature," to which "substantial deference" is accorded. *United States v. Bajakajian*, 524 U.S. 321, 336, 118 S. Ct. 2028, 141 L. Ed. 2d 314, (1998). As the Fourth Circuit recently reiterated:

> No proof is required to convince one that to the Government a false claim, successful or not, is always costly. Just as surely, against this loss the Government may protect itself, though the damage be not explicitly or nicely ascertainable. The FCA seeks to reimburse the Government for just such losses. For a single false claim, the civil penalty would not seem exorbitant. Furthermore, even when multiplied

> by a plurality of impostures, it still would not appear unreasonable when balanced against the expense of the constant Treasury vigil they necessitate.

Bunk, 741 F.3d at 409 (quoting *Toepleman v. United States*, 263 F.2d 697, 699 (4th Cir. 1959) (brackets omitted)). For reasons discussed in this Court's order on materiality (Dkt. No. 795 at 4-5) and earlier in this order, the jury found Defendants liable for serious violations of the law. In light of the seriousness of these alleged violations, the fact that there is a "substantial difference" between the civil penalties the jury verdict would support and the damages the United States actually seeks "weighs against a finding of gross disproportionality." *Mackby*, 339 F.3d at 1018. The Fourth Circuit has determined that the "instances in which the penalty prescribed under the FCA is unconstitutionally excessive will be 'infrequent'" *Tuomey*, 792 F.3d at 387 (quoting *Bunk*, 741 F.3d at 408).

Defendants have also raised Fifth Amendment objections to the Government's requested judgment. "[T]he Due Process Clause imposes limits on 'grossly excessive' monetary penalties that go beyond what is necessary to vindicate the government's 'legitimate interests in punishment and deterrence.'" *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 562, 116 S. Ct. 1589, 134 L. Ed. 2d 809 (1996)). The Fourth Circuit has stated that it has "no reason to believe" that the "approach to punitive damages under the Fifth Amendment would differ dramatically from analysis under the Excessive Fines Clause." *Tuomey*, 792 F.3d at 388.

"The Supreme Court has instructed courts to consider three guideposts when reviewing punitive damages awards under the Due Process Clause: '(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.'" *Tuomey*, 792 F.3d 364, 388 (4th Cir. 2015) (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416, 123 S. Ct. 1513, 155 L. Ed. 2d 585, (2003)).[5]

In *Tuomey*, the Fourth Circuit indicated that the Stark Law "expresses Congress's judgment of the reprehensibility of the conduct at issue by deeming services provided in violation of the law worthless." *Tuomey*, 792 F.3d at 388. The same is true of Anti-Kickback Statute violations. In addition, Defendants' conduct "involved repeated actions" and was not the result of a "mere accident," two factors that inform the reprehensibility of Defendants' conduct and support substantial punitive damages. *See State Farm*, 538 U.S. at 419; *Saunders v. Branch Banking & Tr. Co. of Va.*, 526 F.3d 142, 153 (4th Cir. 2008) (finding the presence of only a single *State Farm* factor sufficient to "provide justification for a substantial award of punitive damages").

The ratio of punitive to compensatory damages in this verdict is constitutionally sound. The Due Process

5. The jury did not have discretion to award punitive damages in this case, so this factor is not dispositive here.

clause "does not apply to compensatory damages because compensatory damages are intended to directly redress Plaintiff's injury and that injury is factual determination already made by the jury. *Id.* at 387. The Supreme Court has noted that because "some amount of money beyond actual damages is 'necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims'" there is a compensatory aspect to treble damages. *Tuomey*, 792 F.3d at 388 (quoting *Cook Cnty.*, 538 U.S. at 130. The treble damages provision also allows the Government to be compensated for the award it must pay to compensate relators in qui tam actions, *id.*, between 15 percent and 25 percent "of the proceeds of the action or settlement of the claim." 31 U.S.C. § 3730(d). The civil penalties imposed in FCA cases are entirely punitive. *See Mackby*, 261 F.3d at 830. The Supreme Court indicated in *State Farm* that a 4-to-1 ratio of punitive to compensatory damages "might be close to the line of constitutional impropriety." *State Farm*, 538 U.S. at 425.

This Court has applied the same analysis the Fourth Circuit used in *Tuomey* and determined that the compensatory damages in this case is comprised of a 15% relators' share of the total recovery and one-third of the trebled damages (i.e., single damages). The remainder of the damages (two-thirds of the treble damages and all of the civil penalties) are punitive. *See Tuomey*, 792 F.3d at 389 (applying this calculation and determining that the ratio of punitive to compensatory damage, was about 3.6-to-1, was constitutional).

For the Singulex claims, Dent and Johnson are each liable for $938,380.75 in compensatory damages comprised of single damages ($467,935) combined with the relator's share (15%) of the total recovery ($470,445.75).[6] The remainder of the total recovery, $2,197,924.25, is punitive damages. The ratio of punitive to compensatory damages for the Singulex claims is 2.3-to-1. For the HDL claims, Dent, Johnson, and Mallory are each liable for $33,382,431.95 in compensatory damages comprised of single damages ($16,601,591.) combined with the relators' share (15%) of the total recovery ($16,780,840.95). The remainder of the total recovery, $78,489,841.05, is punitive. The ratio of punitive to compensatory damages for the HDL claims is 2.35-to-1. The ratio of punitive to compensatory damages for the HDL and Singulex claims in this judgment is therefore well below the 4-to-1 ratio that raises constitutional concerns under the Due Process clause.

VI. COMMON LAW CLAIMS

The United States also asks the Court to sever the remaining causes of action, including the common law causes of action in Counts IV (payment by mistake of fact) and V (unjust enrichment) of the United States' Complaint. (Dkt. No. 75). The Government argues that because there is a higher scienter requirement for AKS/FCA claims than there is for the common law causes of

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6. The set-offs discussed earlier in this order are not relevant to whether the punitive damages in the judgment are constitutional. For this reason, the Court has not incorporated any set-off into the calculation of the total recovery.

action, the jury's finding that defendants were only liable for a subset of the allegedly false claims has no binding or preclusive effect on the litigation of the common law causes of action. *See* 31 U.S.C. 3729(b)(1) (defining "knowingly" for purposes of FCA). "[C]ommon law actions are available to the government to supplement those remedies found in federal statutes, as long as the statute does not expressly abrogate those rights." *United States v. Moffitt, Zwerling & Kemler, P.C.*, 83 F.3d 660, 667 (4th Cir. 1996). While the Government may not recover twice for the same claims, it may pursue "consistent remedies, even to final adjudication." *See, e.g., Pennsylvania Nat'l Mut. Cas. Ins. Co. v. Pine Bluff*, 354 F.3d 945, 950-51 (8th Cir. 2004).

With this Order, the Court is entering Rule 54(b) judgment on the Government's FCA causes of action. The common law causes of action are severed and held in abeyance. If this judgment is affirmed on appeal, or otherwise becomes final, then the common law causes of action could be dismissed. *See U.S. ex. rel. Drakeford v. Tuomey*, 976 F. Supp. 2d 776, 791-92, 794 (D.S.C. 2013) (denying without prejudice Tuomey's motion to require election of remedies after the Government prevailed on its FCA claims).

VII. Waiver of Copayments and Deductibles

All Defendants have moved for judgment as a matter of law on the Government's FCA claims based on the waiver of copayments and deductibles. The Government has not objected to that judgment and indeed did not present any evidence at trial from which the jury could

assess damages that resulted from this practice (or even find that the practice violated the FCA). For this reason, Defendants are entitled to judgment as a matter of law with respect to the Government's claims based on the waiver of co-payments and deductibles.

VIII. Conclusion

For the reasons set forth above, the Court hereby enters judgment against Defendants Mallory, Dent and Johnson for $111,109,655.30 for the HDL claims and against Dent and Johnson for $3,039,006.56 for the Singulex claims.

AND IT IS SO ORDERED.

/s/ Richard Mark Gergel
Richard Mark Gergel
United States District, Judge

May 23, 2018
Charleston, South Carolina

APPENDIX C — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT, FILED APRIL 21, 2021

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

April 21, 2021, Filed

No. 18-1811 (L)
(9:14-cv-00230-RMG)
(9:11-cv-01593-RMG)
(9:15-cv-02485-RMG)

UNITED STATES OF AMERICA, AND THE STATE OF NORTH CAROLINA, CALIFORNIA AND ILLINOIS, EX REL, SCARLETT LUTZ, RELATOR; CHRIS REIDEL; KAYLA WEBSTER, RELATOR; DR. MICHAEL MAYES, RELATOR,

Plaintiffs-Appellees,

v.

LATONYA MALLORY,

Defendant-Appellant,

and

HEALTH DIAGNOSTIC LABORATORY INC.; SINGULEX INC.; LABORATORY CORPORATION OF AMERICA HOLDINGS; BLUEWAVE

HEALTHCARE CONSULTANTS, INC.; PHILIPPE J. GOIX, PhD; FLOYD CALHOUN DENT, III; ROBERT BRADFORD JOHNSON; BERKELEY HEARTLAB, INC.; QUEST DIAGNOSTICS, INCORPORATED,

Defendants.

No. 18-1812
(9:14-cv-00230-RMG)
(9:11-cv-01593-RMG)
(9:15-cv-02485-RMG)

UNITED STATES OF AMERICA, AND THE STATES OF NORTH CAROLINA, CALIFORNIA AND ILLINOIS, EX REL, SCARLETT LUTZ, RELATOR; DR. MICHAEL MAYES, RELATOR; CHRIS RIEDEL; KAYLA WEBSTER, RELATOR,

Plaintiffs-Appellees,

v.

CHRISTINA M. DENT; LAKELIN PINES, LLC; TRINI “D” ISLAND, LLC,

Parties-in-Interest-Appellants,

and

LATONYA MALLORY; HEALTH DIAGNOSTIC LABORATORY INC.; LABORATORY

CORPORATION OF AMERICA HOLDINGS; PHILIPPE J. GOIX, PhD; BERKELEY HEARTLAB, INC.; QUEST DIAGNOSTICS, INCORPORATED; SINGULEX INC.; BLUEWAVE HEALTHCARE CONSULTANTS, INC.; FLOYD CALHOUN DENT, III; ROBERT BRADFORD JOHNSON,

Defendants.

No. 18-1813
(9:14-cv-00230-RMG)
(9:11-cv-01593-RMG)
(9:15-cv-02485-RMG)

UNITED STATES OF AMERICA, AND THE STATE OF NORTH CAROLINA, CALIFORNIA AND ILLINOIS, EX REL, SCARLETT LUTZ; KAYLA WEBSTER; CHRIS RIEDEL; DR. MICHAEL MAYES,

Plaintiffs-Appellees,

v.

ROBERT BRADFORD JOHNSON; FLOYD CALHOUN DENT, III; BLUEWAVE HEALTHCARE CONSULTANTS, INC.,

Defendants - Appellants,

AROC ENTERPRISES, LLC; BLUE EAGLE FARMING, LLC; CAE PROPERTIES, LLC;

Appendix C

WAR-HORSE PROPERTIES, LLLP; EAGLE RAY INVESTMENTS, LLC; FORSE INVESTMENTS, LLC; ROYAL BLUE MEDICAL INCORPORATED; COBALT HEALTHCARE CONSULTANTS, INC.,

Parties-in-Interest-Appellants,

and

BERKELEY HEARTLAB, INC.; LATONYA MALLORY,

Defendants.

ORDER

The court denies the petition for rehearing and rehearing en banc. No judge requested a poll under Fed. R. App. P. 35 on the petition for rehearing en banc.

Entered at the direction of the panel: Judge Motz, Judge Wynn, and Judge Floyd.

For the Court

/s/ Patricia S. Connor, Clerk