United States of America et al v. Bluewave Healthcare Consultants Inc et al Doc. 550

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

United States of America, *et al.*, Plaintiffs, *ex rel.* Scarlett Lutz, *et al.*, Plaintiffs-Relators, v. Berkeley Heartlab, Inc., *et al.*, Defendants.	Civil Action No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2458-RMG) **ORDER and OPINION**

This matter is before the Court on the United States' motion to exclude Jennifer Bolen's expert testimony proffered by BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson (collectively, "the BlueWave Defendants"). (Dkt. No. 444.) For the reasons set forth below, the motion to exclude is granted.

I. Background

The Government has filed a complaint in intervention against the BlueWave Defendants and Latonya Mallory alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the False Claims Act ("FCA"), 42 U.S.C. § 3729(a). (Dkt. No. 75.) The alleged FCA violations arise from BlueWave's marketing of laboratory tests for two laboratory companies, Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"), between 2010 and 2014. The Government has alleged that Defendants violated the FCA when they engaged in multiple kickback schemes to induce physicians to refer blood samples to HDL and Singulex for large panels of blood tests, many of which were medically unnecessary. For example, the Government alleges that Defendants offered and facilitated the payment of

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processing and handling ("P&H") fees to physicians to induce referrals, in violation of the AKS and FCA. The P&H fees – which purportedly covered physicians' processing, handling and shipping of blood specimens for laboratory diagnostic testing – were paid pursuant to written P&H fee agreements between HDL and Singulex and the physicians or their practices. BlueWave marketed HDL and Singulex lab testing services to physicians pursuant to written sales agreements with the two laboratories.

The United States has proffered Kathy McNamara to provide an expert opinion about the commercial reasonableness of Defendants' offering P&H fees to physicians and about the FMV of those P&H fees. The BlueWave Defendants have proffered Jennifer Bolen's expert testimony in response to McNamara's report. Bolen's report includes opinions about (1) the commercial reasonableness of the P&H fees (Dkt. No. 477 at 2); (2) the clinical utility of HDL and Singulex's lab tests; and (3) the zero-balance billing allegations in the complaint. (Dkt. No. 444-1.) The parties disagree about whether Bolen has the requisite qualifications to provide these opinions. (Dkt. Nos. 477 at 3-9; 444 at 3-6.) All of Ms. Bolen's opinions fail to meet the Rule 702 requirements for admissible expert testimony, so the Court has not considered the particulars of Bolen's various professional affiliations and her prosecutorial misconduct.

II. Legal Standard – *Daubert*

Under Rules 104(a) and 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 Pharm., Inc.*, 509 U.S. 579, 589 (1993). The trial court must ensure that: (1) "the testimony is the product of reliable principles and methods"; (2) "the expert has reliably applied the principles and methods to the facts of the case"; and (3) the "testimony is based on sufficient facts or data." Fed. R. Evid. 702(b) - (d). "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid," *Daubert*, 509 U.S. at 592-93, and

whether the expert has "faithfully appl[ied] the methodology to facts," *Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 602 (4th Cir. 2006). To make this determination, courts consider several factors including: (1) "whether a theory or technique . . . can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the theory or technique has garnered "general acceptance." *Daubert*, 509 U.S. at 593-94; *accord United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014). However, these factors are neither definitive nor exhaustive, *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015) (quoting *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003)), and "merely illustrate[] the types of factors that will bear on the inquiry," *Hassan*, 742 F.3d at 130 (quoting *Crisp*, 324 F.3d at 266).

Courts have also considered whether the "expert developed his opinions expressly for the purposes of testifying," *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998), or through "research they have conducted independent of the litigation," *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand), and whether experts have "failed to meaningfully account for . . . literature at odds with their testimony." *McEwen v. Balt. Wash. Med. Ctr. Inc.*, 404 F. App'x 789, 791 (4th Cir. 2010).

Rule 702 also requires courts "to verify that expert testimony is 'based on sufficient facts or data.'" *EEOC v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (quoting Fed. R. Evid. 702(b)). Thus, "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Id.* The court may exclude an opinion if "there is simply too great an analytical gap between the data and the opinion offered." *Id.* "The proponent of the [expert] testimony must establish its

admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The Court is mindful that the *Daubert* inquiry involves "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). "On the one hand, . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence," *id.*, and "the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013), (citing Fed. R. Evid. 702 advisory committee's note), *cert. denied*, 134 S. Ct. 1002 (2014). On the other hand, "[b]ecause expert witnesses have the potential to be both powerful and quite misleading,' it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *Fultz*, 591 F. App'x at 227 (quoting *Cooper*, 259 F.3d at 199).

III. Discussion

a. Bolen's Commercial Reasonableness Opinion is Inadmissible Because it Relies on an Average Charge Analysis

Bolen's opinion about the commercial reasonableness of the P&H fees that the laboratories paid to physicians appears to be the focus of her report. The Government argues that Bolen's commercial reasonableness opinion is inadmissible because it inappropriately relies on a charge-based methodology. According to the BlueWave defendants, Bolen's commercial reasonableness opinion merely "included an FMV analysis" (Dkt. No. 477 at 2), and she "referenced and relied in part on a charge methodology as a component of her [commercial reasonableness] analysis and opinion." (Dkt. No. 477 at 10.)

The commercial reasonableness section of Bolen's report is titled "HDL and Singulex's P&H Fees were Commercially Reasonable Based on an Average Charge Analysis." (Dkt. No. 444-1 at 7.) In that section, Bolen outlines what she believes are the commercially reasonable fee

ranges for each of the three methods available to HDL and Singulex for specimen collection: (1) collection by physician office personnel; (2) free-standing specimen collection stations; and (3) utilization of an internal framework for specimen handling. (Dkt. No. 444-1 at 8-10.)

Bolen relies on national average charges from Find-a-Code's "Map-a-Code" tool, a commercial website that purports to provide physicians' average Medicare charge amounts by code and by year. (Dkt. No. 444-1 at 8.) Relying on this charge data, Bolen concludes that the P&H fees HDL and Singulex paid for collection by physician office personnel were commercially reasonable because "the average charges are all within the fee spread paid by HDL and/or Singulex." (Dkt. No. 444-1 at 8.) Relying on the average charge data, she reached the same conclusion for the fees HDL and Singulex paid for free standing specimen collection stations. Bolen's commercial reasonableness opinion relies almost entirely on an average charge analysis. Bolen acknowledged that she did not consider "what [physicians] have been paid." (Dkt. No. 444-3 at 46.) For the reasons outlined in this Court's order granting the motion to exclude Curtis Udell's expert testimony (Dkt. No. 527), a charge-based analysis is not a reliable methodology for determining the fair market value of physician services. A commercial reasonableness opinion that relies primarily on a charge-based fair market value analysis is likewise inadmissible.

b. The Portions of Bolen's Commercial Reasonableness Opinion that Do Not Rely on a Charge-Based Analysis are Inadmissible

Only a few lines of Bolen's commercial reasonableness opinion suggest that she considered data outside of the average charges from the "Map-a-Code" tool. For example, she noted that "in some cases" HDL or Singulex purchased time and services from business competitors, which she says would "justify" a higher P&H fee. Bolen also writes that "the regulatory framework" for specimen collection, "especially for advanced cardiac/metabolic

panels" "further demonstrate[s] the commercial reasonableness of the payment framework." (Dkt. No. 444-1 at 9-10.) It is not clear whether Bolen is asserting that these circumstances (a) justify fees that are consistent with the average charges she identified or (b) justify fees that are higher than the average charges she identified. If she intended to assert the latter, she failed to explain how she determined that these practices were not already accounted for by the average charge analysis. Bolen's opinion is inadmissible because it is not based on sufficient facts or data, and it appears to use the fatally-flawed average-charge data as a baseline.

i. Laboratory Test Methodologies

Bolen also challenges McNamara's opinion that the P&H fee framework HDL and Singulex used to pay physicians was not commercially reasonable because the laboratories only paid P&H fees when physicians ordered panels of tests, not when physicians ordered single tests. Bolen claims that McNamara's analysis failed to consider the "test methodologies" and clinical utility of test panels. (Dkt. No. 444-1 at 11.)

Bolen asserts that it would be commercially reasonable for a lab to pay physicians P&H fees for a panel of several tests because the various tests require "different laboratory test methodologies." (Dkt. No. 444-1 at 12.) She provides no explanation as to how the testing methodologies used by the laboratories have any impact on a physician's P&H costs for collecting and transporting specimens to the laboratories. Although the Court might surmise that P&H costs for a panel may be higher due to the need for more tubes or labels, Bolen has not provided sufficient facts or data to support the conclusion that it is commercially reasonable to charge a P&H fee for a panel and not a single test.

ii. Clinical Utility of the Profile

Bolen's expert report includes a brief discussion outlining her opinion that the Advanced Cardiovascular/Metabolic Test Profile (the "Profile") relevant to this case "served a clinical

purpose." (Dkt. No. 444-1 at 12.) Bolen is unqualified to provide an expert opinion about the clinical utility of the Profile because she possesses absolutely no knowledge about the Profile, including under what circumstances a doctor might order any of the individual tests included in the Profile (e.g., a patient's symptoms or medical history). (Dkt. No. 444-3 at 66-68.) During her deposition, Bolen reminded the deposing attorney that she was "not a physician" and indicated that she would need to consult a physician to answer any questions about the tests included in the Panel. (*Id.*)

Even if Bolen were qualified to offer an opinion on the clinical utility of the Profile, the opinion she has provided is a complete non-sequitur. Her opinion is brief, so the Court has excerpted it here in full:

> McNamara's suggestion that HDL/Singulex tied the P&H fees to the Profile so that physicians would order pre-bundled test panels instead of a single test is misplaced. In my years of experience auditing clinical laboratory claims, I know that physicians typically order pre-bundled laboratory test profiles (multiple tests) instead of a single laboratory test because the profile or bundle combines tests necessary to give the physician a complete clinical picture of the patient's medical condition. Thus, laboratory test profiles are commonly used in the clinical laboratory industry to meet the clinical needs of their physician clients. The Profile likely had significant clinical utility to ordering physicians separate and apart from the value of the P&H fees. In my opinion, and based on the items I have reviewed to date, HDL and Singulex encouraged healthcare providers to request the Profile when necessary for the care of their patients. The healthcare provider was free to modify his/her decision at any time. The P&H fees were commercially reasonable and appropriate, separate and apart from the value of the referrals. HDL and Singulex structured the Profile to serve a clinical purpose for its customers; [t]his is what laboratories do.

(Dkt. No. 444-1 at 12.) Bolen's assertion that test panels can be clinically useful because they may provide full picture of a patient's medical status does not support her conclusion that *this* Profile "likely" has clinical utility.[1] (Dkt No. 444-1 at 1.) Bolen's opinion about the clinical

[1] The BlueWave defendants have also asked the Court to take judicial notice that the lab tests at issue have "clinical utility and efficacy." (Dkt. No. 477 at 20, n.5.) The BlueWave defendants

utility of the Profile is not admissible because she is not qualified to give the opinion, her opinion is not based on sufficient facts or data, and there is too great an analytical gap between the data and the opinion provided.

For the reasons above, the Court concludes that Bolen's commercial reasonableness opinion is overwhelmingly based on a fair market value analysis that relies on physician charges. The portions of her report that do not rely on an average charge analysis are inadmissible because they are not based on sufficient facts or data.

c. Zero-Balance Billing

Bolen's report also includes her opinion about the allegations in the complaint that Defendants improperly waived Tricare's copayments and deductibles. (Dkt. No. 444-1 at 5-7.) Bolen says she attempts only to "address the issues of patient responsibility in general terms." (*Id.* at 5.) Bolen's actual opinion on this issue appears in the section titled "Application to HDL/Singulex" in which she concludes that HDL's requisition form, which contains language advising patients of their financial responsibilities with regard to copayments and deductibles, is consistent with industry standards for notification of patient responsibility for these payments. (Dkt. No. 444-1 at 7.) It is not clear whether Bolen's opinion is the product of any particular methodology, that she reliably applied that methodology to the facts of this case, or that she relied on sufficient facts or data. As she was unable to speak to the laboratories' actual payment policies and practices during her deposition, she does not appear to have applied any methodology to the facts of this case. Bolen cannot provide expert testimony about what constitutes "industry practice" for notification about patient responsibility in the context of a

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did not identify which specific tests they were referring to with regard to this request. The Court declines to take judicial notice of the clinical utility or efficacy of any tests relevant to this lawsuit because, for the reasons explained by the Government in its brief, the Court does not have enough information to make this determination. (Dkt. No. 486 at 2-3.)

particular payment policy when she has no knowledge about the payment policy at issue. For this and the other reasons outlined in the Government's brief, Bolen's opinion on patient notification practices is inadmissible because it is not based on sufficient facts or data and there is too great an analytical gap between the data relied on and the conclusion reached. (Dkt. No. 444 at 16-17.) Her opinion provides so little supporting data and context that it is likely to confuse a jury.

IV. Conclusion

For the reasons set forth above, the Government's motion to exclude the expert testimony of Jennifer Bolen (Dkt. No. 444) is GRANTED.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

July 21, 2017
Charleston, South Carolina