STATES coimt{!VHJ CLERK'S OFFICE OF SOUTH

DIVISION ZOil JUL lt 1

g: United States

Plaintiffs,

(Consolidated with

OPINION

United States'

"the Defendants").

Statute ("AKS"), U.S.C. ("FCA"), U.S.C.

("HDL") ("Singulex"), 2010 2014.

IN THE UNITED DISTRICT

DISTRICT CAROLINA

CHARLESTON 2 A 3 b of America, et al.,

ex rel. Scarlett Lutz, et al.,

Plaintiffs-Relators, v. Berkeley Heartlab, Inc., et al.,

Defendants.

Civil No, . and 9:15-cv-2458-RMG) ORDER and

United States of America et al v. BlueWave Healthcare Consultants Inc et al

2017 | Cited 0 times | D. South Carolina | July 24, 2017

This matter is before the Court on the motion to exclude Jennifer Bolen's expert testimony proffered by Blue Wave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson (collectively, BlueWave (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 Blue Wave Defendants and Latonya Mallory alleging violations of the Anti-Kickback 42 § 1320a-7b(b), and the False Claims Act 42 § 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. and Singulex, Inc. between and 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

-1- 9:14-cv-00230-RMG Date Filed 07/24/17 Entry Number 550 Page 1 of 9

("P&H") AKS P&H

P&H

United States

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702

Under 104(a) 702, "the

reliable." Pharm., 509 U.S. "the

methods"; "the case"; "testimony data." 702(b) "This

valid," 509 U.S. processing and handling fees to physicians to induce referrals, in violation of the and FCA. The fees - which purportedly covered physicians' processing, handling and shipping of blood specimens for laboratory diagnostic testing - were paid pursuant to written

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 has proffered Kathy McNamara to provide an expert opinion about the commercial reasonableness of Defendants' offering fees to physicians and about the FMV of those fees. The Blue Wave 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 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

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

Rules and trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but Daubert v. Merrell Dow

Inc., 579, 589 (1993). The trial court must ensure that: (1) testimony is the product of reliable principles and (2) expert has reliably applied the principles and methods to the facts of the and (3) the is based on sufficient facts or Fed. R. Evid. - (d). entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically Daubert, at 592-93, and

-2- 9:14-cv-00230-RMG Date Filed 07/24/17 Entry Number 550 Page 2 of 9

"faithfully facts," 602 2006). "whether tested"; "whether publication"; "known error"; "existence

operation"; "general acceptance." 509 U.S. 104, 130

2003)), "merely inquiry,"

130

"expert testifying," "research litigation,"

"failed testimony." 404 2010). 702 "to data."'

"trial

reliable."

offered." "The whether the expert has appl[ied] the methodology to Roche v. Lincoln Prop. Co., 175 F. App'x 597, (4th Cir. To make this determination, courts consider several factors including: (1) a theory or technique ... can be (and has been) (2)

the theory or technique has been subjected to peer review and (3) the or potential rate of (4) the and maintenance of standards controlling the technique's and (5) whether the theory or technique has garnered

Daubert, at 593-94; accord United States v. Hassan, 742 F.3d (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. and illustrate[] the types of factors that will bear on the Hassan, 742 F.3d at (quoting Crisp, 324 F.3d at 266).

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

Rule also requires courts verify that expert testimony is 'based on sufficient facts or EEOC v. Freeman, 778 F.3d 463, 472 (4th Cir. 2015) (quoting Fed. R. Evid. 702(b)). Thus, 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 Id. The court may exclude an opinion if ''there is simply too great an analytical gap between the data and the opinion Id. proponent of the [expert] testimony must establish its

-3- 9:14-cv-00230-RMG Date Filed 07/24/17 Entry Number 550 Page 3 of 9

proof." Smith 2001).

"two principles." "On 702 evidence," "the

system." United States 2013),

702 S. 1002 (2014). On "[b

opinion."

Opinion

"included analysis" "referenced

opinion." 10.)

"HDL Analysis." admissibility by a preponderance of Cooper v. & Nephew, Inc., 259 F.3d 194, 199 (4th Cir.

The Court is mindful that the Daubert inquiry involves guiding, and sometimes competing, Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999).

the one hand, . . . Rule was intended to liberalize the introduction of relevant expert

id., and trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary v. Stanley, 533 F. App'x 325, 327 (4th Cir. (citing Fed. R. Evid. advisory committee's note), cert. denied, 134 Ct. the other hand,]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 Fultz, 591 F. App'x at 227 (quoting Cooper, 259 F.3d at 199). III. Discussion

a. Bolen's Commercial Reasonableness 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 an FMV (Dkt. No. 477 at 2), and she

and relied in part on a charge methodology as a component of her [commercial reasonableness] analysis and (Dkt. No. 477 at

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

-4- 9:14-cv-00230-RMG Date Filed 07/24/17 Entry Number 550 Page 4 of 9

"Map-a-Code"

"the Singulex."

"what paid."

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Opinion

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"Map-a-Code" "in cases"

"justify" "the framework" "especially 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 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 average charges are all within the fee spread paid by HDL and/or (Dkt. No. 444-1at8.) 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 [physicians] have been

(Dkt. No. 444-3 at 46.) For the reasons outlined in this Court's order granting the motion to exclude Curtis 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 that Do Not

Rely on a Charge-Based Analysis are Inadmissible a few lines of Bolen's commercial reasonableness opinion suggest that she considered data outside of the average charges from the tool. For example, she noted that some HDL or Singulex purchased time and services from business competitors, which she says would a higher P&H fee. Bolen also writes that regulatory for specimen collection, for advanced cardiac/metabolic

panels" "further framework."

9-10.)

Singulex

"test methodologies"

"different methodologies." She

"Profile") "served demonstrate[s] the commercial reasonableness of the payment (Dkt. No. 444-1 at 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

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 and clinical utility oftest 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 laboratory test

(Dkt. No. 444-1 at 12.) 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 relevant to this case a clinical

purpose."

Profile

Profile

"not physician"

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Profile,

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P&H Profile

Profile "likely"

"clinical efficacy." 20, (Dkt. No. 444-1 at 12.) Bolen is unqualified to provide an expert opinion about the clinical utility of the 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 (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 a and indicated that she would need to consult a physician to answer any questions about the tests included in the

(Id.) Even if Bolen were qualified to offer an opinion on the clinical utility of the 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 fees to the 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

likely had significant clinical utility to ordering physicians separate and apart from the value of the fees. In my opinion, and based on the items I have reviewed to date, HDL and Singulex encouraged healthcare providers to request the when necessary for the care of their patients. The healthcare provider was free to modify his/her decision at any time. The fees were commercially reasonable and appropriate, separate and apart from the value of the referrals. HDL and Singulex structured the 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

has clinical utility. 1

(Dkt No. 444-1 at 1.) Bolen' s opinion about the clinical

1 The Blue Wave defendants have also asked the Court to take judicial notice that the lab tests at issue have utility and (Dkt. No. 477 at n.5.) The BlueWave defendants

Profile

"address terms."

"Application HDL/Singulex"

"industry practice" utility of the 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 the issues of patient responsibility in general (Id. at 5.) Bolen's actual opinion on this issue appears in the section titled to

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 for notification about patient responsibility in the context of a

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.)

-8- 9:14-cv-00230-RMG Date Filed 07/24/17 Entry Number 550 Page 8 of 9

IV.

IS SO ORDERED.

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United States 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.

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

July Charleston, Carolina

-9-

District Court Judge 9:14-cv-00230-RMG Date Filed 07/24/17 Entry Number 550 Page 9 of 9