

and Singulex for large panels of blood tests, many of which were medically unnecessary. The Government alleges that the kickback schemes violated the Anti-Kickback Statute, resulted in false claims submitted to the Medicare and TRICARE programs, and caused the Government to pay HDL more than \$330 million.

The BlueWave Defendants have proffered Daniel Mulholland, III, as an expert witness. Mulholland is an attorney who “has advised clients for over 30 years whether the relevant federal healthcare programs allow or disallow certain practices.” (Dkt. No. 474 at 1.) The BlueWave Defendants say Mulholland will “apply an accepted methodology in his field—review of relevant executive guidance documents—to opine whether such documents would have put [the BlueWave Defendants] and/or their attorneys on notice that the relevant federal healthcare authorities considered a specific practice—process and handling fees paid by a laboratory—implicated or violated the Anti-Kickback statute.” (Dkt. No. 474 at 1.) Mulholland will opine that the BlueWave Defendants had “no reason to know that” their conduct violated the AKS which they claim is a “factual issue” relevant to whether they had the necessary scienter to violate the FCA. (Dkt. No. 474 at 5-6.)

The Government seeks to exclude Mulholland’s testimony based on Federal Rules of Evidence 104(a), 401, 402, 403, 702, and 703, arguing that Mulholland’s testimony would “usurp the role of the Court to instruct on the law and the jury’s role to apply the facts to the law,” and is based on unreliable methods and insufficient facts. The Government further argues that Mulholland’s opinion, “that the BlueWave Defendants would have no reason to know that paying compensation to physicians for laboratory process and handling fees would violate the Anti-Kickback Statute until 2014,” is based on unreliable methodology because Mulholland limited the evidence he reviewed to reach his opinion to a limited class of documents rather than

the full range of information available to the BlueWave Defendants. (Dkt. Nos. 442 at 5-10; 442-1 at 2.)

II. Legal Standard

A. 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), (c), (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 “whether a theory or technique . . . can be (and has been) tested,” “whether the theory or technique has been subjected to peer review and publication,” the “known or potential rate of error,” the “existence and maintenance of standards controlling the technique’s operation,” and 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), and “merely illustrate[] the types of factors that will bear on the inquiry.” *Hassan*, 742 F.3d at 130. 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, 791-92 (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) 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.” *United States v. Fultz*, 591 F. App’x 226, 227 (4th Cir. 2015).

B. False Claims Act Liability

The test for False Claims Act liability is (1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that involved a “claim,” because it caused the government to pay out money or

to forfeit moneys due. 31 U.S.C.A. § 3729 *et seq.*; *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir. 1999). Claims that include items or services resulting from a violation of the AKS are false or fraudulent under the FCA. 42 U.S.C. §1320a-7b(g). The Government bears the burden of showing that Defendant acted with the requisite scienter which, under the FCA, is “knowingly,” meaning with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(a).

III. Discussion

A. **The proposed Mulholland testimony improperly infringes upon the province of the Court to define the meaning of the controlling law and the jury’s duty to apply the facts to the law.**

The proposed Mulholland testimony is nothing more than a poorly disguised effort to tell the jury what the law is and how the jury’s verdict should read in this case. It is, of course, well settled, that it is the duty of the Court, and not a party’s expert, to state the meaning of the law. *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002). “Opinion testimony that states a legal standard or draws legal conclusion by applying law to facts is generally inadmissible.” *United States v. McIver*, 470 F.3d 550, 561-562 (4th Cir. 2006). “It is the Court’s duty to instruct the jury on Defendant’s obligations and duties under the law, and the jury’s role to determine whether Defendant has violated a legal duty.” *Shoemake v. Rental Serv. Corp.*, 2008 WL 215824 at *1 (S.D. Miss. 2008).

The proposed Mulholland testimony presumes to offer an opinion about “whether or not the BlueWave Defendants would have had reason to know what the legal obligations were during a particular period of time.” (Dkt. No. 442-2 at 24). This necessarily requires drawing a legal standard and applying the law to the facts. As the Fourth Circuit once observed, such “testimony supplies the jury with no information other than the witness’s view of how the verdict

should read.” *United States v. Barile*, 286 F. 3d at 760. Such testimony is not helpful to the jury and invades the well-settled roles of the Court and the jury.

B. Mulholland’s proposed opinion testimony is based upon unreliable methodology and would mislead the jury.

A critical element of the Court’s gatekeeping role regarding the admission of expert testimony is to determine whether the presumed expert’s methods are reliable and are based on sufficient data. Fed. R. Evid. 702(b), (c). The proposed Mulholland opinion seeks to offer the general opinion that “the BlueWave Defendants would have no reason to know that a laboratory paying compensation to physicians for laboratory process and handling fees would violate or implicate the Anti-Kickback Statute until July 2014.” (Dkt. No. 442-1 at 2.) However, Mulholland admitted under cross-examination in his deposition that this opinion was based upon a limited universe of documents potentially accessible to the BlueWave Defendants, and he failed to consider many other sources of information which had the potential to inform them that their practices were unlawful. (Dkt. No. 442-2 at 10-11.)

As the Government noted in its memorandum in support of the motion to exclude Mulholland’s testimony, this “expert” failed to review complaints received by Defendants from physicians or physician practices, including a specific complaint that the BlueWave Defendants’ process and handling fee of “\$17 that the laboratory is paying would be considered a kickback.” (Dkt. Nos. 442 at 8; 442-4 at 7). Mulholland did not review communications the BlueWave Defendants received from attorneys, including a December 2011 statement that the process and handling fees of the Defendants was “as blatantly illegal as anything that I have seen for a long time. It would be a criminal violation of the federal and state kickback laws . . . and could form the basis for liability under the false claims act.” (Dkt. No. 442-5 at 3). Mulholland also did not review complaints the BlueWave Defendants received from competitors, including a March 2012

letter in which the competitor warned a physician that BlueWave's processing and handling fees "potentially place the laboratory and the physician in violation of the Federal Anti-Kickback Statute and the False Claims Act." (Dkt. No. 442-6 at 5.) He also did not consider an August 2012 warning in the National Lipid Association newsletter for its members not to enter into processing and handling agreements or the March 2014 warning letter to the Defendants from the Department of Justice. (Dkt. Nos. 442-7 at 2; 442-8 at 4-5.)

The failure of Mulholland to review highly material information indicating that the practices of the BlueWave Defendants may be violative of federal law before presuming to offer a general opinion that they had "no reason to know" they were violating the law raises profound questions in the Court's mind about Mulholland's methodology and the adequacy of his data. This Court would be in serious dereliction of its duty as a gatekeeper of expert testimony to allow the offering of an opinion based on such inadequate data. Furthermore, such opinion testimony is clearly excludable under Rule 403 of the Federal Rule of Evidence because any probative value of the testimony would be substantially outweighed by the risk of misleading the jury.

IV. Conclusion

For the reasons set forth above, the Government's motion to exclude the expert testimony of Daniel Mulholland, III, (Dkt. No. 442) is GRANTED.

AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

June 26, 2017
Charleston, South Carolina