UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ELIZABETH A. HOLMES,

Defendant.

Case No. 5:18-cr-00258-EJD-1

ORDER RE: HOLMES' MOTION TO EXCLUDE EXPERT OPINION TESTIMONY OF DR. STEPHEN MASTER UNDER RULES 401-403 AND 702

Defendants Elizabeth Holmes ("Holmes") and Ramesh "Sunny" Balwani ("Balwani") are charged with wire fraud, in violation of 18 U.S.C. § 1343, and conspiracy to commit wire fraud, in violation of 18 U.S.C. § 1349. The charges stem from Defendants' allegedly deceptive representations about their company, Theranos, and its technology. Pending before the Court is Holmes' motion to exclude expert opinion testimony of Dr. Stephen Master under Federal Rules of Evidence 401-403 and 701. ("Mot."), Dkt. No. 560. Having had the benefit of oral argument and having considered the parties' papers, the Court **DENIES IN PART** and **DEFERS IN PART** Holmes' motion to exclude Dr. Master's expert opinion testimony. Specifically, the Court will not exclude Dr. Master's opinions regarding industry standards and the Vitamin D assay, and will defer ruling on the balance of Holmes' motion to exclude pending a *Daubert* hearing.

I. BACKGROUND

A. DR. STEPHEN MASTER

In support of its case, the Government offers Dr. Stephen Master as an expert in clinical

pathology and chemistry. Specifically, Dr. Master was retained to provide opinions on whether Theranos was market ready and able to produce accurate and reliable fingerstick results for tests such as Vitamin D, chloride, potassium, bicarbonate, HIV, HbA1c, hCG, cholesterol, calcium, and sodium. *See* Declaration. of Amy Mason Saharia In Support Of Ms. Holmes' Motions In Limine And Daubert Motions To Exclude Expert Testimony ("Saharia Decl.") Ex. 6 (Expert Report of Stephen Master, MD, PhD, FCAP, FAACC ("Master Report")), Dkt. No. 580-5 at 2-3.

Dr. Master is the Chief of Clinical Chemistry Laboratory Services at Weil Cornell Medicine and New York Presbyterian Hospital. Master Report at 1. He also currently serves as Chief of the Division of Laboratory Medicine and Medical Director of the Michael Palmieri Laboratory for Metabolic and Advanced Diagnostics at the Children's Hospital of Philadelphia, and as an Associate Professor of Pathology and Laboratory Medicine at the Perelman School of Medicine, University of Pennsylvania. *Id*. He is a Fellow of the College of American Pathologists and President-Elect of the Board of Directors of the American Association for Clinical Chemistry. Dr. Master holds both an MD and a PhD (in cell and molecular biology) from the University of Pennsylvania School of Medicine.

B. THE MASTER REPORT

Dr. Master's twenty-page report sets forth two primary opinions regarding (1) Theranos' adherence to industry standards and (2) the accuracy and reliability of specific Theranos blood tests.

i. Industry Standards

First, Dr. Master sets forth general background principles regarding how blood tests are performed, how the performance of a laboratory test is measured, and the regulatory framework in which laboratories operate. Master Report at 3-11. Specifically, Dr. Master explains that there are two basic concepts that characterize the performance of a laboratory test: accuracy and precision. Accuracy refers to "how close the result comes to the 'true' amount of the analyte"—*i.e.*, the substance being tested— "in a blood sample." *Id*. at 6. Precision, according to Dr. Master, refers

to the degree to which a test produces the same result when it measures the same sample multiple times. *Id*. at 6-7. In other words, "in order to produce accurate and reliable results, a clinical assay must typically agree with the accepted results from a gold standard (accuracy), and it also must be able to do this reproducibly (reliab[ility])." *Id*. at 12. Because Dr. Master was retained to opine only on Theranos' fingerstick tests, he expressly disclaims offering any opinions on the many tests that Theranos performed on "traditional venous samples on FDA-approved or cleared instruments from third-party vendors." *Id*. at 11.

Dr. Master then gives an overview of the regulatory framework that applies to clinical laboratories. *Id*. at 8-11. He explains that "clinical testing is regulated by the Clinical Laboratory Improvements Amendments ("CLIA"), which specifies the legal requirements for engaging in medical testing and is broadly administered under the Center for Medicare and Medicaid Services ("CMS"). He notes that CLIA requires laboratories to perform certain experiments to ensure their tests are suitable for clinical use, including proficiency testing, quality control checks, establishing and verifying reference ranges, and other validations of accuracy and precision. *Id*. at 8-10.

Based on "publicly available information, scholarly research, and materials produced in discovery in this case," Dr. Master concludes that "Theranos did not adhere to normal industry standards for clinical laboratory testing from 2013-2015." *Id*. at 17. He stated that "[r]unning patient samples when QC is giving values out of the acceptable range directly impacts the accuracy and reliability of the results that are returned to the patient or clinician." *Id*. He opined further that "Theranos did not appropriately engage in proficiency testing," and that this had the potential to adversely affect the accuracy of its results. *Id*. at 18.

ii. Theranos Blood Tests

Second, Dr. Master opines about Theranos blood tests. To form his opinions, he reviewed materials provided in discovery in this case, including the Center for Medicare and Medicaid Services survey report ("CMS Report"), which included data from three Theranos devices, covering quality control data for approximately 30 days in 2014, the Icahn School of Medicine

Report ("Icahn Report"), "frequent complaints from customers according to internal Theranos emails," and other internal Theranos emails and documents. *Id*. at 15-16.

Based on those documents, Dr. Master concludes "Theranos was not market ready and able to produce accurate and reliable fingerstick results for tests such as Vitamin D, chloride, potassium, bicarbonate, cholesterol, and sodium." Master Report at 12. He opines further "there are substantial questions about the ability of their laboratory to provide patient-appropriate results for calcium, HIV, HbA1c, and hCG," but notes that "there are insufficient additional details in the material I have reviewed to determine the cause of these issues, the relationship to either the sample type or Theranos technology, or the resolution of the problems." *Id*. at 12, 15.

II. LEGAL STANDARD

Under Rule 702, expert testimony is admissible only when it (1) "will help the trier of fact to understand the evidence or to determine a fact in issue"; (2) "is based on sufficient facts or data"; (3) "is the product of reliable principles and methods"; and (4) the expert has "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *see Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589-90 (1993). An expert witness may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. To be considered reliable, scientific opinions must be based on scientifically valid principles. *Daubert*, 509 U.S. at 589. The proponent of expert testimony has the burden of proving admissibility in accordance with Rule 702.

Under *Daubert*, the Court exercises a gatekeeping function to ensure an expert's proffered testimony is relevant and reliable. *United States v. Valencia-Lopez*, 971 F.3d 891, 897-98 (9th Cir. 2020). "[T]he case law—particularly Ninth Circuit case law—emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it's shaky, or because he thinks the jury will have cause to question the expert's credibility. So long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge." *Optronic Techs., Inc. v. Ningbo Sunny Elec. Co.*, No. 5:16-CV-06370-EJD, 2019 WL 4780183, at *1 (N.D. Cal. Sept. 30,

2019) (citing *In re Roundup Prods. Liab. Litig.*, 2018 WL 3368534 (N.D. Cal. July 20, 2018). "Rule 702 and *Daubert* are not 'guarantees of correctness;' rather, they are safeguards against unreliable or irrelevant expert opinions." *NetFuel, Inc. v. Cisco Sys. Inc.*, No. 5:18-CV-02352-EJD, 2020 WL 1274985, at *2 (N.D. Cal. Mar. 17, 2020) (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 855 (Fed. Cir. 2010)).

III. DISCUSSION

Holmes argues that Dr. Master's opinions about the reliability and accuracy of Theranos blood tests, as well as his opinions about Theranos' compliance with industry standards, should be excluded. Holmes also argues that Dr. Master is unqualified to opine on fingerstick technology.

A. QUALIFICATIONS

The parties agree that Dr. Master is qualified to opine about laboratory practices and clinical pathology generally, and the Court agrees. Holmes argues, however, that Dr. Master is not qualified to provide opinions on "the accuracy or reliability of fingerstick testing on Theranos devices" specifically. Mot. at 24. While Holmes acknowledges Dr. Master's significant training and experience in clinical pathology and chemistry, she argues that he "does not identify any relevant experience with fingerstick blood testing" and "does not claim to have any knowledge of Theranos' proprietary technology." Mot. at 24.

"Experts are not required to have previous experience with the product at issue." *In Re: Macbook Keyboard Litigation*, No. 5:18-CV-02813-EJD, 2021 WL 1250378, at *6 (N.D. Cal. Apr. 5, 2021) (quoting *Czuchaj v. Conair Corp.*, No. 313CV01901BENRBB, 2016 WL 4414673, at *3 (S.D. Cal. Aug. 19, 2016)); *see also Abaxis, Inc. v. Cepheid*, No. 10-CV-02840-LHK, 2012 WL 2979019, at *3 (N.D. Cal. July 19, 2012) ("Rule 702 imposes no requirement that experts have personal experience in an area to offer admissible testimony relating to that area"). Dr. Master is board certified in Clinical Pathology by the American Board of Pathology, and fingerstick blood testing falls within the discipline of Clinical Pathology. His responsibilities as Laboratory Director and Chief of Clinical Laboratory Services at multiple hospitals over more

than a decade undoubtedly included oversight of fingerstick testing. The Court finds that Dr. Master need not have extensive personal knowledge in fingerstick testing, nor in Theranos' technology specifically, to offer a helpful and reliable opinion about the accuracy and reliability of such testing.

B. INDUSTRY STANDARDS

Holmes seeks to exclude Dr. Master's testimony and opinions about Theranos' laboratory practices. Specifically, Dr. Master opines "Theranos did not adhere to normal industry standards for clinical laboratory testing from 2013-2015," and that "this lack of adherence had the potential to adversely impact test accuracy and reliability." Master Report at 17. Holmes argues that these opinions should be excluded because they constitute impermissible legal opinions and because they will not be helpful to the jury.

First, Holmes argues that Dr. Master's opinions about Theranos' compliance with industry standards rest on his interpretation of federal law and its application to Theranos. Dr. Master indeed explains the "legal requirements" for clinical testing under CLIA and relevant U.S. Food and Drug Administration ("FDA") regulations as part of the background necessary to understand how and why laboratories operate the way they do. He concludes that Theranos did not adhere to normal industry standards for laboratory testing because (1) it did not prevent patient samples from being run on devices where the quality control indicated that the device was operating improperly, (2) it did not appropriately engage in any proficiency testing, and (3) it did not add a disclaimer to its laboratory developed tests—a designation that encompasses all Theranos tests—indicating that the test was not FDA approved or cleared.

Holmes argues that Dr. Master's "subjective, non-lawyer interpretation of what federal law requires and how it applies to Theranos are 'inappropriate subjects for expert testimony.'" Mot. at 19 (quoting *Aguilar v. Int'l Longshoremen's Union Local No. 10*, 966 F.2d 443, 447 (9th Cir. 1992)). Holmes maintains that, because Dr. Master is not a lawyer, he is not qualified to provide a legal opinion about what Theranos was or was not legally obligated to do under CLIA and FDA

regulations. And even if he was so qualified, Holmes argues that it is not permissible for expert testimony to "prescribe legal standards to apply to the facts of the case" or to opine on "legal compliance in the language of 'industry practice.'" Mot. at 20 (citing *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d at 558 ("testimony encompassing an ultimate legal conclusion based upon the facts of the case is not [admissible] and may not be made so simply because it is presented in terms of industry practice")).

The Government argues that Dr. Master is not prohibited from testifying about industry standards, of which he has extensive knowledge, merely because federal regulations form part of those standards. The Ninth Circuit has permitted experts to testify about industry standards even where the testimony "relie[s] in part on [the expert's] understanding of the requirements of . . . law." *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1017 (9th Cir. 2004) ("'[A] witness may refer to the law in expressing an opinion without that reference rendering the testimony inadmissible. Indeed, a witness may properly be called upon to aid the jury in understanding the facts in evidence even though reference to those facts is couched in legal terms'") (quoting *Specht v. Jensen*, 853 F.2d 805, 809 (10th Cir. 1988)); *see also King v. GEICO Indem. Co.*, 712 Fed. Appx. 649 (9th Cir. 2017) ("Although it is well established that experts may not give opinions as to legal conclusions, experts may testify about industry standards").

The Court agrees with the Government that Dr. Master should not be precluded from testifying about industry standards in clinical laboratories simply because that industry happens to be heavily regulated. Cases where courts have excluded expert witness testimony on these grounds have generally focused on preventing the expert from opining on an "ultimate legal conclusion" in the case. *See e.g.*, *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d at 558 ("expert testimony must be circumscribed carefully to ensure that 'the expert does not usurp either the role of the trial judge in instructing the jury as to the applicable law and the role of the jury in applying that law to the facts before it.'"); *Aguilar v. Int'l Longshoremen's Union Loc. No. 10*, 966 F.2d at 447 (affirming the exclusion of expert testimony as to the reasonableness and foreseeability of

plaintiffs' reliance on an employer's promise in a promissory estoppel claim). The applicable law in this case will not include the CLIA and FDA regulations about which Dr. Master testifies. Nor will the jury be asked to decide whether Theranos or Holmes violated any such regulation. Thus, there is little risk in this case that Dr. Master's testimony about applicable regulations will unduly influence the jury as to any ultimate legal issue in the case.

Moreover, Dr. Master's focus will be on whether Theranos adhered to industry standards, not whether Theranos violated applicable regulations. While certain conduct may implicate regulations, the Court anticipates that any confusion or unfair prejudice resulting from testimony about regulatory violations can be mitigated by careful examination and thoughtful language. For example, while Dr. Master may be precluded from testifying that Theranos violated CLIA regulations by failing to perform sufficient proficiency testing, he may testify that it is typical to perform proficiency testing in the industry and that Theranos did not do so. *See, e.g.*, *Sands v. Integon Nat'l Ins. Co.*, 2020 WL 7027442, at *4 (D. Colo. Nov. 30, 2020) ("[The expert] may not opine whether defendants met their duties under applicable caselaw or violated various statutes, but may testify whether, in his opinion, defendants' conduct conformed with specific insurance industry standards, including ones identified in those statutes").

Finally, Holmes argues that Dr. Master's opinions about industry standards will be unhelpful to and mislead the jury. Dr. Master opines that Theranos' lack of adherence to industry standards "had the potential to adversely impact test accuracy and reliability." Master Report at 17. According to Holmes, "[t]o be helpful to [the] jury's assessment of accuracy and reliability, Dr. Master's testimony would need to show that Theranos' supposed deviations from industry practice affected the integrity of its tests to such a degree that it would be materially false for someone with knowledge of the deviations to represent that Theranos' tests were accurate and reliable." Mot. at 22-23.

The Government argues that the Master Report adequately ties Theranos' practices to the accuracy and reliability of their blood tests, such that Dr. Master's testimony will be helpful to the

jury. For example, Dr. Master explains that the failure to abide by industry-wide quality control standards can impact testing: "[r]unning patient samples when QC is giving values out of the acceptable range [as the CMS report described] directly impacts the accuracy and reliability of the results that are returned to the patient or clinician." Master Report at 17. The Government also points out that the Holmes herself recognized the connection between laboratory compliance practices and accuracy, touting Theranos' 100% proficiency testing score in investor PowerPoints as an indicator of accuracy. Gov't Mots. in Limine, Ex. A, Dkt. No. 588-2 at ECF pg. 8.

The Court disagrees with Holmes' characterization of what evidence may be helpful to the jury. Dr. Master's testimony need not provide complete or even direct evidence of Holmes' guilt to be helpful to the jury. *United States v. Christian*, 749 F.3d 806, 811 (9th Cir. 2014) ("a district court deciding whether to admit expert testimony should evaluate whether that *testimony* 'will assist the trier of fact in drawing its own conclusion as to a fact in issue' and should not limit its consideration to 'the existence or strength of an expert's *opinion*'"), *overruled on other grounds by United States v. Bacon*, 979 F.3d 766 (9th Cir. 2020) (emphasis in original). Although Dr. Master does not specifically conclude that Theranos' failure to abide by industry standards actually affected test results, his testimony about the purpose and effect of industry standards is nonetheless helpful.

Thus, the Court finds Dr. Master's opinions about industry standards relevant to determining whether Theranos tests were consistently accurate and reliable, and helpful to the jury in assessing whether Holmes' statements were misleading. Accordingly, Holmes' motion is **DENIED** as to these opinions.

C. THERANOS BLOOD TESTS

Holmes challenges Dr. Master's opinions about the reliability and accuracy of particular Theranos blood tests on three grounds.

First, for four of the assays Dr. Master was asked to consider (HIV, HbA1c, hCG, and Calcium), he concluded that "there are substantial questions about the ability of [the] laboratory to provide patient-appropriate results" but that he lacks sufficient data to reach a more definitive

opinion. Master Report at 12, 15. Holmes argues "[t]hat nonopinion will not help the jury" and is unreliable. Mot. at 8.

To assess whether proffered expert testimony would help the jury in a given case, courts "must look to the governing substantive standard." *Daubert II*, 43 F.3d at 1320. In this case, the substantive charge is wire fraud. The Government argues that "[g]iven the certitude and breadth with which Defendant spoke – the highest levels of accuracy for virtually every test – Dr. Master's opinion will assist the jury in assessing if that was true" for these four tests. Opp'n, Dkt. No. 668 at 8. The Court agrees, in principle, that Dr. Master's testimony about these four tests and his conclusion that there are "substantial questions" about their accuracy could be helpful to the jury *if* that conclusion is based on sufficient facts or data to be reliable. The Court has concerns, however, about Dr. Master's representations that the materials he had access to were insufficient. *See, e.g.*, Master Report at 15 ("there are insufficient additional details in the material I have reviewed to determine the cause of these issues, the relationship to either the sample type or Theranos technology, or the resolution of the problems"); *id.* at 16 ("in many cases I have not been able to identify a clear paper trail demonstrating the root of these inaccuracies").

Second, Holmes argues Dr. Master's testimony about all ten tests is unreliable because he does not apply the scientific methodology that he himself outlines for determining whether a given test is suitable for clinical practice; rather, he bases his opinions on "anecdotes or snippets of data, none of which reliably support his opinions." Mot. at 8. More specifically, Dr. Master reported that he relied on the CMS Report for his opinion as to Vitamin D, the Icahn Report for his opinion as to cholesterol, and "frequent complaints from customers" derived from internal Theranos emails or "Theranos internal investigations" for his opinions as to all other tests. The Government maintains that these bases are sufficiently reliable, and that Holmes' objection goes to the weight of the testimony rather than its admissibility. Opp'n at 7-8.

In determining admissibility under Rule 702, the Court must "assess whether 'the reasoning or methodology underlying the testimony is scientifically valid' and 'properly can be applied to the facts in issue,' with the goal of ensuring that the expert 'employs in the courtroom

the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188 (9th Cir. 2019) (quoting *Daubert*, 509 U.S. at 592-93 and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

The Court is satisfied that Dr. Master's reliance on the CMS Report is scientifically sound. The CMS Report contains a significant amount of quality control data from Theranos assays, which is precisely the type of data that Dr. Master asserts is necessary to assess the accuracy of a given blood test. Thus, the Court finds Dr. Master's testimony and opinion as to the Vitamin D assay to be reliable.

As to Dr. Master's testimony and opinions about all other assays, Dr. Master does not provide sufficient information—about his underlying reasoning or methodology—in his report for the Court to assess the reliability of his opinion. Where a party "raises a material dispute as to the admissibility of expert scientific evidence, the district court must hold an *in limine* hearing (a so-called *Daubert* hearing) to consider the conflicting evidence and make findings about the soundness and reliability of the methodology employed by the scientific experts." *Daubert II*, 43 F.3d at 1319 n.10 (citing Fed. R. Evid. 104(a)). The Court concludes that a Daubert hearing is appropriate to assess the reliability of Dr. Master's methodology, which he employed to provide testimony and opinions about chloride, potassium, bicarbonate, HIV, HbA1c, hCG, cholesterol, calcium, and sodium.

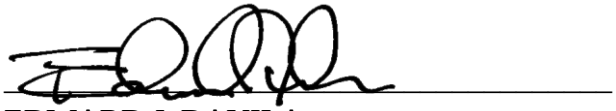
IV. CONCLUSION

For the reasons stated, the Court **DENIES** the motion to exclude Dr. Master's opinions regarding industry standards and the Vitamin D assay. The Court will defer ruling on the balance of Holmes' motion to exclude pending a *Daubert* hearing. The Government shall determine Dr. Master's availability for a *Daubert* hearing, meet and confer with Holmes' counsel regarding scheduling, and shall notify the deputy clerk of the parties' proposed date for a *Daubert* hearing. Any supplemental material the Government plans to rely on at the hearing shall be filed no later than ten business days before the hearing. Holmes may file a responsive brief no later than five

business days before the hearing.

IT IS SO ORDERED.

Dated: May 21, 2021



EDWARD J. DAVILA
United States District Judge