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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. CR-18-00258-EJD **DEFENDANT'S MOTION TO EXCLUDE EXPERT OPINION TESTIMONY OF DR. STEPHEN MASTER UNDER RULES 401-403 AND 702** Date: January 22, 2021 Time: 10:00 AM CTRM: 4, 5th Floor Hon. Edward J. Davila

NOTICE OF DAUBERT MOTION

PLEASE TAKE NOTICE that on January 22, 2021 at 10:00 a.m., or on such other date and time as the Court may order, in Courtroom 4 of the above-captioned Court, 280 South 1st Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Elizabeth Holmes will and hereby does respectfully move the Court pursuant to Rules 401-403 and 702 of the Federal Rules of Evidence for an Order excluding certain expert testimony of Dr. Stephen Master. The Motion is based on the below Memorandum of Points and Authorities and Exhibits, the Declaration of Amy Mason Saharia, the record in this case, and any other matters that the Court deems appropriate.

DATED: November 20, 2020

/s/ Amy Mason Saharia
KEVIN DOWNEY
LANCE WADE
AMY MASON SAHARIA
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MEMORANDUM OF POINTS AND AUTHORITIES

The government's fraud case rests in large part on its allegations that Ms. Holmes represented Theranos' blood tests to be accurate and reliable but knew they were not consistently accurate and reliable. To support the proposition that Theranos' tests were not consistently accurate and reliable, the government has proffered the expert opinion of Dr. Stephen Master, a clinical pathologist. But nearly all of Dr. Master's opinions lack the relevancy, rigor, and reliability that the Federal Rules of Evidence require. They should be excluded.

Experts must ground their analysis in sufficient facts and data and apply a reliable methodology. Dr. Master describes in detail the scientific data analysis that experts in his field use to determine the accuracy and reliability of blood tests. *He did not, however, conduct that analysis for any of Theranos' tests.* Instead, he purports to reach opinions about the accuracy and reliability of Theranos' tests based on customer complaints, e-mails, and isolated snippets of data from limited time periods. His opinions rest on unsound extrapolation and speculation. Notably, Dr. Master himself concedes that he lacks sufficient information to render an opinion on accuracy and reliability for four of the tests for which the government requested an opinion. As for those tests, again based on anecdotes, he asserts only that the tests had "problems" of unknown origin. This unreliable non-opinion will not help the jury answer any question before it in this case.

Dr. Master also opines that Theranos' lab did not comply with his view of applicable "industry standards," and that this supposed noncompliance had the "potential" to jeopardize the accuracy and reliability of Theranos' test results. But he rests his opinion on "industry standards" on his interpretation of federal law and its application to Theranos. Those opinions on complicated questions of law—which Dr. Master is not qualified to give—are squarely impermissible under Rule 702. They will also confuse and mislead the jury. Ms. Holmes is not charged with negligent laboratory practices. Because Dr. Master opines only that the supposed noncompliance had the "potential" to affect the accuracy and reliability of Theranos' test results, his opinion does not fit this case and will not help the jury.

Dr. Master's opinions violate Rule 702 in every way. This Court should exercise its gatekeeping duty and exclude them.

BACKGROUND

The government offers Dr. Master as an expert in clinical pathology and chemistry. *See* Ex. 6 (Master Report) at 3. It retained Dr. Master to opine on two sets of issues. *First*, it asked him to opine about the accuracy and reliability of tests "such as" a list of ten enumerated Theranos tests. *Id.* at 2-3. It is unclear how these ten tests were selected; the government claims in the Indictment that Theranos was unable to produce accurate or reliable results for 23 tests. *See* TSI ¶ 16, ECF 469. *Second*, it asked Dr. Master to opine about Theranos' lab practices—specifically (i) whether Theranos adhered to normal industry standards for clinical laboratory testing from 2013-2015, and (ii) whether any lack of adherence to normal industry standards had the potential to impact adversely test accuracy and reliability. Ex. 6 at 2-3. Dr. Master purports to base his opinions on his "training in clinical pathology and chemistry, [his] experience as a laboratory medical director and [his] knowledge of standards and best practices as established by federal regulations and by the College of American Pathologists." *Id.* at 3.

The government retained Dr. Master on February 19, 2020, less than 2 ½ weeks before its expert disclosure deadline. Ex. 7 (USAO-006872). On February 28, the government sent Dr. Master an outline of its desired opinions. Ex. 8 (USAO-007115-7116). Dr. Master responded on March 1 that he had received the outline but had not received other documents he had discussed with the government. *Id.* He received those documents later that day. *Id.* On March 5, Dr. Master reported that to "fully render the opinion" the government wanted with respect to four tests (HIV, HbA1C, hCG, and Calcium," he would need more documents. Ex. 9 (USAO-006916). Dr. Master sent the government the first draft of his report on March 5. *Id.* He sent the government the final report on March 7. Ex. 10 (USAO-007057). Dr. Master thus appears to have formulated his opinions about the reliability and accuracy of a set of ten distinct blood tests in the course of one week.

A. The Accuracy and Reliability of Specified Theranos Tests

Dr. Master's first sets of opinions concern whether Theranos was "able to produce accurate and reliable fingerstick results" for ten specified blood tests.[1] Ex. 6 at 2-3. Dr. Master expressly disclaims

[1] Dr. Master identifies only nine tests in the "scope of assignment" portion of his report, but his

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. The government has proffered no expert to opine about those tests.

Dr. Master first explains the general methodology by which a professional in the field of hematology determines whether a laboratory test is accurate and reliable. *Id.* at 6-7. According to Dr. Master, professionals make that determination by combining an assessment of two metrics—accuracy and precision. *Id.*

Accuracy, Dr. Master explains, 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. If a "gold-standard reference" test measures a certain amount of an analyte in a patient's blood, then an accurate test would exhibit the same result. *Id.* Although any deviation from the gold standard is referred to as exhibiting "bias," Dr. Master notes that "[a] certain amount of bias is a normal and expected feature of [all] laboratory tests." *Id.* In other words, there is a certain amount of expected error in laboratory testing. In fact, one study concluded that "the total [lab] testing process error rate ranges widely from 0.1% to 3.0%." *See* J. Hammerling, A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today, 43 LabMedicine 41 (2012).[2]

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. Ex. 6 at 6-7. A test's precision is assessed using a measure known as the percent coefficient variation (%CV), which expresses how close a test will be to its expected value. *Id.* at 6-7. For example, if a test has a 10%CV, then most of the time the measured value of the test will be within 10% of its expected value. Thus, if a test has an expected value of 100, most of the time the measured value will be between 90 and 110. The higher the %CV, the higher the

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report actually discusses ten tests: Vitamin D, chloride, potassium, bicarbonate, calcium, HIV, HbA1c, hCG, cholesterol, and sodium.

[2] Moreover, under federal lab regulations (CLIA), there can be substantial variations between labs on tests performed on the same sample, without any of the results considered to be inaccurate. For example, under CLIA, tests conducted at two different labs for cholesterol, high density lipoprotein (HDL) can produce results that vary by as much as 60 percent (+/- 30 percent of the target value), and both results are deemed accurate. 42 C.F.R. § 493.931(c).

variation, and the less precise the test.

Dr. Master next explains that the concept of total allowable error (TEa) helps determine "whether a lab test can accurately guide patient care" by accounting for both accuracy and precision. Specifically, to fit within the TEa, "the more bias an assay has, the more precise it has to be [and] the more imprecise it is, the less bias it can tolerate." *Id.* If a test result does not fit within the TEa, according to Dr. Master, it is not suitable for clinical use. *Id.*

After setting out the methodology by which professionals in his field accuracy and reliability, Dr. Master discusses ten specific Theranos tests. Notwithstanding his lengthy discussion of this methodology, he does not apply that methodology to Theranos' tests. He does not review a comprehensive set of Theranos data to attempt to calculate the accuracy, precision, or TEa for any test. He does not draw a representative sample of data to attempt to make such calculations. He applies no methodology to determine whether his opinions could hold across the three-year period of the charged conspiracy—*i.e.*, to determine whether Theranos was "consistently" able to produce accurate and reliable results. TSI ¶ 16, ECF 469. In fact, he does not engage in any data analysis at all.

Dr. Master divides his opinions regarding these ten tests into two categories. *First*, for six tests—Vitamin D, chloride, potassium, bicarbonate, cholesterol, and sodium—he opines that "Theranos was not market ready and able to produce accurate and reliable fingerstick results." Ex. 6 at 12.

Based on his review of a subset of tests in this first category, Dr. Master further opines there was a widespread issue with Theranos' "Edison" blood-testing device. *Id.* at 13-14. He acknowledges that "[i]t is not possible to be certain whether [any bias in the instrument] was due to inherent issues with the technology, or with poor lab operational practice." *Id.* at 13. He nonetheless finds it "reasonable to conclude that the instrument problems were not merely a result of poor operational practice, but were related to the quality of the instruments and [tests] themselves." *Id.* at 14.

Second, for the remaining four tests—calcium, HIV, HbA1c, and hCG—Dr. Master offers what amounts to a non-opinion. He states that "there are substantial questions about the ability of [Theranos'] 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. He does *not* opine that Theranos was unable to produce accurate and reliable fingerstick results for these four tests.

B. Adherence to Industry Standards by Theranos

Dr. Master also assessed the "[r]egulation" of "[b]lood [t]esting" and Theranos' clinical laboratory's adherence to those regulations. Although he does not cite any actual provision of law or agency guidance, Dr. Master purports to describe:

(1) the FDA approval and clearance process;
(2) how the Clinical Laboratory Improvement Amendments ("CLIA") regulate labs running FDA-approved tests;
(3) how CLIA regulates in-house tests known as "laboratory-developed tests," including how such tests must be verified;
(4) how CLIA applies to alterations to FDA-approved tests;
(5) CLIA's regulation of the position of designated laboratory director; and
(6) CLIA's regulation of proficiency testing and quality control.

Ex. 6 at 8-11.

Dr. Master further opines that "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." *Id.* at 17. Based largely on the results of a survey by the Centers for Medicare and Medicaid Services (CMS), he opines that in certain cases "the Theranos QC [quality control] system for Edison devices did not prevent samples from being run when the QC was out of the appropriate specifications" and that "Theranos did not appropriately engage in proficiency testing." *Id.* at 17-18. He also notes that "Theranos did not have FDA approval or clearance for their CTN [collection device]," *id.* at 18, expressing his disagreement with the legal position advocated by Theranos through its lawyers, *id.* at 19. All of these supposed deficiencies, he opines, had the "potential" to negatively impact test results, although he offers no explanation for this opinion. *Id.* at 17-19.

ARGUMENT

I. Expert Testimony Must Derive from the Witness's Specialized Knowledge, Relate to a Material Aspect of the Case, and Rest on a Reliable Foundation and Valid Methods

Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), govern the admissibility of expert witness testimony. 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. These requirements obligate the court to act as "gatekeeper" to enforce the bounds of permissible expert testimony. *United States v. Hermanek*, 289 F.3d 1076, 1093 (9th Cir. 2002); *see also Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014) (Rule 702 "clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify").

For starters, the testimony must be "expert" testimony—*i.e.*, it must derive from the expert's "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. Testimony that merely "parrots [a lay witness's] version of events" flunks that requirement, and should be excluded to avoid "lend[ing] the special aura of credibility associated with expert testimony to [a lay witness's] account of the event." *Sanchez v. Jiles*, 2012 WL 13005996, at *32 (C.D. Cal. June 14, 2012).

In addition to drawing from the witness's expertise, expert testimony must also be relevant to pass muster under Rule 702. *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999). In other words, the expert testimony must "fit" the question the jury must answer, by "speak[ing] clearly and directly to an issue in dispute in the case" and "logically advance[ing) a material aspect of the proposing party's case," *Daubert v. Merrell Dow Pharm., (Daubert II*), 43 F.3d 1311, 1315, 1321 n.17 (9th Cir.1995). In making that assessment, courts "must look to the governing substantive standard." *Id.* at 1320. The "fit" requirement is more stringent than the relevancy requirement of Rule 402, reflecting "the special dangers inherent in scientific expert testimony." *Jones v. United States*, 933 F. Supp. 894, 900 (N.D. Cal. 1996); *see also Daubert II*, 43 F.3d at 1321 n.17.

Finally, expert testimony must be reliable, which requires that "the reasoning or methodology

underlying the testimony is scientifically valid and . . . that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 600. "As a prerequisite to making the Rule 702 determination" of reliability, "the court must assure that the methods are adequately explained." *Hermanek*, 289 F.3d at 1093-94; *see also Claar v. Burlington N. R.R.*, 29 F.3d 499, 502 (9th Cir.1994) (experts must "explain [their] reasoning" because district court must "determine that [they] arrived at their conclusions using scientific methods and procedures"). "[A]n expert, whether basing testimony upon professional studies or personal experience, [must] employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. That means that "the analysis undergirding the experts' testimony" must "fall[] within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert II*, 43 F.3d at 1317; *see City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014); *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998). And, even where the expert invokes a methodology used by professionals in his field, the expert may not offer "overreaching" or unduly "speculative" conclusions. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1247 (11th Cir. 2005). To guard against such opinions, courts must consider whether "there is simply too great an analytical gap between the data and the opinion proffered." *G.E. Co., v. Joiner*, 522 U.S. 136, 146 (1997). An expert's "reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity" are all "[r]ed flags" cautioning against admission of expert testimony. *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012).

Together, Rule 702's requirements help ensure that proffered expert testimony is scientifically sound, adequately supported, and helpful to the jury. Even if expert testimony satisfies Rule 702, however, a court may nonetheless exclude it under Rule 403 "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." *United States v. Rincon*, 28 F.3d 921, 925 (9th Cir. 1994); *see also United States v. Cordoba*, 104 F.3d 225, 228 (9th Cir. 1997), as amended (Feb. 11, 1997). "Since scientific expert testimony can be both powerful and quite misleading due to the difficulty in evaluating it, federal judges must 'exclude proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly

to an issue in dispute in the case, and that it will not mislead the jury.'" *United States v. Baras*, 2013 WL 6502846, at *8 (N.D. Cal. Dec. 11, 2013).

These principles require excluding most of Dr. Master's opinions, for the following reasons.[3]

II. Dr. Master's Opinions about Theranos' Blood Tests Should be Excluded

Dr. Master's opinions on the accuracy and reliability of Theranos blood tests are unreliable.[4] His opinions—and the inferences he draws from his opinions about the Edison technology—should be excluded for three reasons. First, for four tests (HIV, HbA1c, hCG and Calcium), Dr. Master states that he has questions about their accuracy but lacks sufficient data to reach an opinion. That nonopinion will not help the jury. Second, for all of the tests, Dr. Master does not apply the methodology of experts in his field and bases his opinions on anecdotes or snippets of data, none of which reliably support his opinions. Finally, the inferences that Dr. Master draws related to Theranos' Edison technology are unsupported and unreliable.

A. Dr. Master's Opinion That There Are "Questions" About the Accuracy and Reliability of Certain Tests Would Not Help the Jury And Is Unreliable

For four tests— HIV, HbA1c, hCG, and calcium—Dr. Master fails to provide an opinion as to their accuracy or reliability at all. Dr. Master acknowledges that "there are insufficient details in the material [he] has reviewed to determine the cause" of any issues with these tests. Ex. 6 at 15. Yet he offers his musings anyway, reporting, based on anecdotes, his view that "there are substantial questions about the ability of [the] laboratory to provide patient-appropriate results" for these four tests. *Id.* at 12.

This opinion is unhelpful to the jury and will produce confusion. 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. Here the substantive charge is wire fraud, and the government alleges that Ms. Holmes represented that Theranos' "devices could provide 'accurate, fast, reliable, and cheap blood test results," when she allegedly knew the tests could not "consistently produc[e] accurate

[3] Ms. Holmes is not moving to exclude Dr. Master's opinions regarding background principles of accuracy and reliability. His application of those principles to this case, however, is unreliable for the reasons discussed herein.

[4] Attached hereto as Appendix A is a chart identifying the ten at-issue tests, his opinion as to each, and the bases for his opinions.

and reliable results." TSI ¶ 16.

The government asked Dr. Master for an opinion on whether Theranos was capable of producing accurate and reliable results for these four tests. His correspondence with the government reveals that he believed the information it provided did not allow him to answer that question. *See* p.2, *supra*. He thus opined only that he has "questions" about the tests' accuracy, while providing no way for the jury to resolve his "questions." The role of an expert is to "assist the trier of fact to understand or to determine a fact in issue," *Daubert*, 509 U.S. at 592, not to provide the jury with questions it cannot answer. Because Dr. Master's inconclusive opinion has limited (if any) probative value and is likely to confuse the jury, it must be excluded under both Rules 702 and 403.

Relatedly, even if he ventured an opinion, it would not be based on sufficient facts or data to be reliable. The reason he was unable to provide the opinion the government asked for was because, according to Dr. Master, he lacked sufficient "details" to opine about the cause of the "problems" he identifies. Ex. 6 at 15-16. For example, with respect to the hCG (pregnancy) and hBA1C (glucose) tests, he observes that "in many cases [he has] not been able to identify a clear paper trail demonstrating the root of these inaccuracies." *Id.* at 16. Similarly, Dr. Master concedes that there were "insufficient additional details in the material" to determine how the anecdotal complaints he reviewed "relat[e] to either the sample type or Theranos technology." *Id.* at 15. Without those "additional details" Dr. Master has no way of knowing if these anecdotal complaints, which are the sole source for his opinion, involved tests "perform[ed] using traditional venous samples on FDA-approved or cleared instruments from third-party vendors"—tests for which he expressly states he is offering no opinion. *Id.* at 11. These concessions are fatal. Opinions based on "unsubstantiated and undocumented information is the antithesis of . . . scientifically reliable expert opinion." *City of Pomona*, 750 F.3d at 1044 (citation omitted).

Finally on this point, Dr. Master's "questions" about the reliability of these tests stem from improper speculation about the meaning of certain fact evidence. Specifically, Dr. Master finds it "noteworthy" that the HIV, HbA1c, and hCG tests do not appear on lists of laboratory-developed tests (LDTs) that Theranos provided to FDA in 2015. Ex. 6 at 16. On that ground, he surmises that Theranos

did not find the tests "to be suitable for continued clinical use by that point." *Id.* But experts may not "testify as to the mental processes of the [parties]: what they knew, believed, assumed, or understood, on the basis of their own knowledge or communications from others." *Gonzalez v. Valenzuela*, 2001 WL 36387147, at *4 (C.D. Cal. Nov. 26, 2001). "Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony." *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004); *see also, e.g.*, *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, 2000 WL 876900, at *2 (E.D. Pa. June 20, 2000). Dr. Master cannot permissibly speculate about Theranos' motivation for not including those tests on the list he identifies.

B. Dr. Master's Opinions about All Ten Tests Lack Reliability

Dr. Master's opinions about the accuracy and reliability of all ten tests are unreliable. Rare is the expert opinion that describes the scientific methodology applied by experts in the field and then throws that methodology out the window. But, incredibly, that is what Dr. Master does. It is unclear that Dr. Master possessed the data he needed to conduct a reliable scientific analysis of the reliability and accuracy of Theranos' tests. Instead, Dr. Master cobbled together his opinions from anecdotal customer complaints, e-mails, and limited snippets of data. That is not the methodology of an expert.

1. HIV, HbA1c, hCG, calcium, sodium, chloride, and bicarbonate

For the four tests discussed above, and an additional two tests for which he offers an actual opinion about accuracy and reliability—sodium and chloride —Dr. Master's opinions rest on mere anecdotes such as "customer complaints and Theranos internal investigations" of those complaints. Ex. 6 at 15; *see* Appendix A. To provide one example, for the hCG test, Dr. Master reviewed customer complaints and concludes that "multiple inaccurate results had significant and negative clinical implications for patients." Ex. 6 at 16. He makes no attempt to determine whether those "multiple inaccurate results" were representative of Theranos' hCG results or whether they fell within the permissible total allowable error. For a seventh test, bicarbonate, Dr. Master does not identify any basis for his opinion. His analysis begins and ends with his statement that Theranos was not market ready and able to produce accurate and reliable fingerstick results for this test. *Id.* at 12.

Dr. Master's reliance on anecdotes renders his opinions unreliable and thus inadmissible.

Experts must ground their analysis in "sound data," rather than "limited anecdotal evidence." *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993); *see Velazquez v. Costco Wholesale Corp.*, 2012 WL 13059928, at *2 (C.D. Cal. Oct. 12, 2012) ("A collection of 25 anecdotal experiences is not a sufficient basis to express an opinion."). This is because anecdotal evidence "does not tend to show that a problem is pervasive" or that the evidence is representative of the expert's opinions. *Wessmann v. Gittens*, 160 F.3d 790, 805 (1st Cir. 1998); *see also Pecover v. Elec. Arts Inc.*, 2010 WL 8742757, at *7 (N.D. Cal. Dec. 21, 2010) (holding that expert's opinion based on anecdotal evidence was unreliable when expert provided no methodology by which she determined the evidence to "be representative of all or even most … opinions").

Dr. Master cannot base an opinion about accuracy or reliability (or for that matter "questions" regarding accuracy or reliability) on such "limited anecdotal evidence." *Vollrath Co.*, 9 F.3d at 1462 (excluding expert opinion when opinion was "inconclusive" and "based on anecdotal evidence"). That is especially true here, where, as Dr. Master admits, there is a certain amount of expected error in laboratory blood testing. *See* Ex. 6 at 6-7. Some number of unexpected or erroneous results—and corresponding complaints about such results—is to be expected. Dr. Master, however, cannot identify "the root cause of these inaccuracies." *Id.* at 15. He applies no methodology whatsoever to determine whether the anecdotal complaints are "representative" of a "pervasive" problem or simply an expected part of a laboratory practice. *Wessmann*, 160 F.3d at 805.

Dr. Master does not even acknowledge this problem, much less resolve it. He fails to provide even basic information regarding the complaints that he reviewed, such as the number of complaints for each test or the date each complaint was lodged. He does not assess whether the complaint reflected a statistically representative sample of test results or whether they covered the entire three-year period of the charged conspiracy. He does not ask whether the number of complaints were statistically significant rather than the result of mere chance. Dr. Master similarly fails to address how the volume of consumer complaints compare with the amount of error typically associated with certain laboratory tests. In short, Dr. Master has failed to put forward any methodology by which he determined that the cited complaints were representative of a larger problem. His opinions based on those complaints and other anecdotal

evidence are unreliable.[5] *See Pecover*, 2010 WL 8742757, at *7.

Nor, as already discussed, does Dr. Master even purport to be applying the scientific methodology he describes in his report. *See* Ex. 6 at 6-7. Conspicuously, he does not opine that an expert in his field would rely on "consumer complaints" to determine accuracy and reliability of a laboratory test. This, standing alone, renders his opinions on these tests inadmissible. *See Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998) (expert analysis that does not "follow[] a scientific method embraced by at least some other experts in the field" "does not satisfy *Daubert* or Rule 702").

Dr. Master purports to support his opinion with the observation that "there are inherent limitations to the approach that Theranos had taken for small-volume testing using diluted specimens compared with the original assays." Ex, 6 at 15. But that says nothing about whether any individual test was accurate or reliable. Dr. Master concedes that "there might be technical solutions to ameliorate this problem," *id.*, yet he conducts no scientific analysis of the technical solutions employed by Theranos. His speculation that "inherent limitations" to Theranos' testing methods rendered any particular test inaccurate or unreliable is just that: speculation.

Rather than employ the methodology that he applies "independent of [this] litigation," Dr. Master appears to have arrived at his opinions "expressly for purposes of testifying." *Daubert II*, 43 F.3d at 1318. Given that context, the government "must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" *Id.* at 1317-18. Yet Dr. Master fails to point to a single study, or any other "objective, verifiable evidence," to support his opinion that the tests were not accurate or reliable. *Id.* Dr. Master therefore has not carried his burden to "explain precisely how [he] went about reaching [his] conclusions and point to some objective source . . . to show

[5] With respect to sodium, Dr. Master bases his opinion on both consumer complaints and on an October 2014 email from Theranos' laboratory director. *Id.* According to Dr. Master, the email "indicates that the laboratory had instituted a policy of canceling significantly high or low sodium values" because the lab had "'no way of knowing for sure whether the result is truly abnormal or artifactual to the [test result], or related to a specimen integrity issue.'" Ex. 6 at 15. Dr. Master does not explain how a single e-mail from October 2014 supports his broader opinion that the sodium test was inaccurate and unreliable throughout the period of the charged conspiracy. He also does not claim that experts in his field would typically draw such a conclusion from one e-mail.

that he has followed the scientific method" for these tests. *Id.* at 1319. His opinions must be excluded.[6]

2. Cholesterol

The Court should also exclude Dr. Master's opinion that the cholesterol test was not accurate and reliable. This opinion, in Dr. Master's words, rests on two "strands of evidence [that] support the idea that there were significant accuracy limitations to the Theranos fingerstick cholesterol test." Ex. 6 at 14. First, Dr. Master cites a "published report from a group at the Icahn School of Medicine." *Id.* Second, Dr. Master cites an incident in which an inaccurate testing result was brought to the attention of the lab director. Neither provides reliable support for Dr. Master's conclusion.

First, Dr. Master discusses the Icahn Report, an observational study of 60 adults in Phoenix that sought to "compare the uncertainty and accuracy in 22 common clinical lab results between [Theranos] and [Quest and LabCorp]." *See* Ex. 11 ("Icahn Report"). The Report concluded that Theranos' "testing services return results that mostly agree with other services with the exception of lipid panels," a panel that includes cholesterol. *Id.* at 1735. It did not reach a definitive conclusion that Theranos' lipids panel or cholesterol test was inaccurate or unreliable. *See id.* at 1734. Rather, the "result[]" of the report was that it "found nonequivalent lipid panel test results between Theranos and other clinical services." *Id.* The report further concluded that the "disparities between testing services [it] observed could ***potentially*** alter clinical interpretation and health care utilization," and noted that "greater transparency is needed for how Theranos calibrates its test to interpret the lipid panels properly." *Id.* at 1740 (emphasis added). In other words, the Icahn study concluded that further investigation was needed before a firm conclusion on the accuracy of Theranos' cholesterol tests could be reached. Yet Dr. Master draws a conclusion anyway, purportedly based on the Icahn study. Dr. Master's willingness to draw conclusions from the Icahn study weighs against the reliability of his opinion. *Cf. Joiner*, 522 U.S. at 146 ("Given that [the

[6] Together with his opinion that Theranos' tests were not accurate or reliable, Dr. Master opines that the tests were not "market ready." Ex. 6 at 12. He does not define that concept, nor does he provide "sufficient detail" about the basis for his conclusion that Theranos' tests do not satisfy it. *United States v. Rincon*, 28 F.3d 921, 924 (9th Cir.1994). Dr. Master also provides no basis to conclude that he is qualified to offer an opinion regarding "market readiness." Dr. Master thus should be precluded from offering an opinion on the undefined concept.

authors of the report] were unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the experts' conclusion that Joiner's exposure to PCB's caused his cancer.").

Moreover, the report identifies several limitations that Dr. Master failed to consider—an omission that further undercuts his reliance on the study. These self-identified limitations include: (1) the lack of technical replicates in the Theranos data; (2) the fact that the Theranos samples were shipped from Arizona to California; and (3) the inability to "manipulate collection variables to determine their imprecision contribution." Ex. 11 at 1740-41. The study further observes that the difference found between Theranos results and other laboratories "could arise from multiple sources: collection (low-volume finger prick versus venipuncture), processing (how the samples were prepped by the laboratory technicians), instrumentation (new versus existing technology), or some combination of these factors." *Id.* That Dr. Master fails to address significant limitations of the Icahn study highlights the "speculative" and "overreaching" nature of his conclusions. *McClain*, 401 F.3d at 1247 ("expert's inclination to draw overreaching conclusions from self-limiting medical articles[] show[s] the speculative nature of his opinions"); *see also LeClercq v. Lockformer Co.*, 2005 WL 1162979, at *4 (N.D. Ill. Apr. 28, 2005) (The expert's] failure to discuss the import of, or even mention, these material facts in his reports amounts to "cherrypick[ing] the facts he considered to render his opinion, and such selective use of facts fail to satisfy the scientific method and *Daubert*.")

Second, Dr. Master relies on evidence that "inaccuracies in a lipid testing result" were brought to the attention of the lab director in late 2014, and the director "noted" that the inaccuracies were inconsistent "with commonly-utilized estimates of the relationship between the various components of the lipid test." Ex. 6 at 14. Again, one snippet of evidence about an abnormal "lipid testing result" in 2014 falls far short of the type of data from which an expert can reliably determine whether a test was consistently accurate or reliable. *Wessmann*, 160 F.3d at 805 (anecdotal evidence suspect because it "does not tend to show that a problem is pervasive"). Dr. Master's reliance on patently insufficient evidence further impugns the reliability of his cholesterol opinion.

3. Potassium

Dr. Master's opinion regarding the potassium assay should also be excluded because the data on which he relies are woefully inadequate and his extrapolations from the limited data are unsupported and unsound. *See Joiner*, 522 U.S. at 146 (opinion unreliable when "there is simply too great an analytical gap between the data and the opinion proffered"). "[B]oth unsound methods *and* unjustified extrapolations from existing data can require the Court to exclude an expert." *In re Roundup Prods. Liab. Litig*, 390 F. Supp. 3d 1102, 1112 (N.D. Cal 2018).

Dr. Master opines that the potassium assay was inaccurate and unreliable because "[i]n April 2014, potassium fingerstick results were shown to be abnormally high 17% of the time." Ex. 6 at 14. He extrapolates from this unsourced data point from a single month to opine that there are "two possible explanations" for this result: the assay was inaccurate or "the fingerstick collection modality, possibly including the CTN, led to hemolysis rates which artifactually elevated the potassium." *Id.*

This is sheer speculation and based on flawed methodology. First, it is unclear what "data" Dr. Master reviewed in forming his opinion about the potassium assay. He simply states that potassium fingerstick measurements "were shown to be abnormally high" for one month in 2014. *Id.* Was this 17% figure derived from a report, a peer-reviewed study, an email? Does this figure reflect data from the hundreds of devices employed by Theranos or just one device? Would experts in his field rely on the source of that data in forming an opinion as to the accuracy of an assay? Is this one data point enough? Without this information, the Court does not have sufficient information to determine whether Dr. Master's opinion is reliable.

Second, Dr. Master provides no methodology for extrapolating data for one month to an opinion about whether Theranos could *consistently* produce accuracy and reliability potassium results for a three-year period. He presents no corroborating data for any other time period, an no explanation for why he concludes that the assay was inaccurate or unreliable during those other time periods. He just assumes the April 2014 data is representative of a three-year period. That speculation is utterly unreliable.

4. Vitamin D

Dr. Master's opinion as to the Vitamin D assay extrapolates from equally paltry data. In support of his opinion that Theranos was "not market ready and *able to produce accurate and reliable* fingerstick test results for tests such as Vitamin D," he points only to a CMS report following a survey of a Theranos laboratory. Ex. 6 at 12. Master observes that "Theranos QC measurements for a single instrument demonstrated a CV (coefficient variation, *see* p.3, *supra*) as high as 63.8%" for the Vitamin D assay. *Id.* From this observation, Master opines that Theranos' Vitamin D assay was inaccurate and unreliable. A simple review of the CMS report shows that his opinion does not withstand scrutiny.

The CMS report identifies Vitamin D QC measurements from three (out of hundreds of) Theranos devices from the periods 6/29/14 through 7/24/14, 6/29/14 through 7/25/2014, and 8/21/14 through 8/30/2014. The 63.8% QC measurement on one device on which Master relies was limited to the week of "8/21/14 through 8/30/14." Ex. 12 at 54 (Jan. 25, 2016 CMS Report-THPFM0002240153). Nine days' worth of data for one device is patently insufficient to support an opinion that Theranos' technology was incapable of consistently producing accurate and reliable results over a three-year period. As for the other two instruments, the data were limited to one month and conflicting: one was less than 19% (an acceptable rate under Theranos standards) and the other approximately 30%. *Id.* at 54-55. Dr. Master incorrectly states that these CVs were above Theranos standards, Ex. 6 at 12-13; as just discussed, one of the devices was within Theranos standards. But more broadly, Dr. Master fails to explain why it is sufficient for an expert to rely on this limited set of data to extrapolate to an opinion that Theranos technology was not able *consistently* to produce accurate and reliable results over the three years charged in this case. He fails entirely to grapple with alternate explanations for these limited data; to assess any measures in response to these data; or to review any data from any other device or time period. Nor does he ground his review in this limited set of data in the methodology applied by experts in his field that he discusses in his report.

Finestone v. Florida Power & Light Co. is instructive. 2006 WL 267330 (S.D. Fla. Jan. 6, 2006). In *Finestone*, plaintiffs alleged that chemical exposure to radioactive sludge allegedly disposed by the defendants caused injuries. *Id.* at *12. One of the plaintiffs' experts opined that the sludge

contained radioactive isotopes based upon a sampling of the waste collected from the site. The expert however, failed to consider other samples, which if included would have reduced the average concentration of the isotope. The Court held that the "[the expert] cannot adequately explain why he chose only the 32 samples with [the isotope] and not the remaining samples that had no [trace of that isotype] to compute the average . . . at the Glades Cutoff site." *Id.* at 12. Therefore, the expert's opinion was not reliable. *Id.*

Dr. Master's opinion is equally unreliable. Rather than reviewing Vitamin D results over the charged period of 2013 through 2015, Dr. Master's opinion is limited to just over a month's worth of data on isolated devices for Vitamin D. He identifies no methodology accepted in his field to extrapolate from that limited data to a three-year period. His opinions are based on "unjustified extrapolations from existing [and extremely circumscribed] data." *See In re Roundup*, 390 F. Supp. 3d at 1112. The Court should therefore exclude his opinion as to the Vitamin D assays as unreliable.

C. Dr. Master's Opinions as to "Problems" with the Edison Are Unreliable Speculation

Beyond his opinions about particular tests, Dr. Master also offers opinions about Theranos' technology writ large. In particular, Dr. Master opines that alleged problems with certain tests were caused by systemic defects with Theranos' Edison testing technology, and not other variables. Ex. 6 at 13-14. But Dr. Master himself acknowledges that he cannot be sure about that conclusion. Because Dr. Master's opinion as to the Edison requires speculation based on limited data, it should be excluded.[7]

As a general matter, Dr. Master does not identify any methodology by which to determine the *cause* of an allegedly inaccurate test—*i.e.*, whether observed inaccuracies resulted from a defective device, defective reagents, operator error, flawed blood collection, or some other cause. He simply reviews limited CV data and then opines, without any explanation, on the causes for alleged inaccuracies. *See id.* He does not explain how the methodology that experts use to assess accuracy can

[7] On the subject of Theranos' technology, Dr. Master also observes that "[i]nternal emails and documentation show that Theranos were struggling with a number of ongoing technical issues involving hemolysis, sample leakage, variations in materials that affected function, and other issues with the CTN [collective tube]." Ex. 6 at 16. But he offers no opinion regarding the collection tube, and it is not the role of an expert simply to parrot "[i]nternal emails and documentation." Dr. Master cannot permissibly offer an opinion on Theranos' collection tube at trial.

be used to assess causation of inaccuracies, nor does he suggest that an expert would determine causation with such methods. Absent any application of an actual methodology for determining causation, his opinion about causation is simply his *ipse dixit*.

To the extent Dr. Master bases his opinion on actual data, the "gap" between the data and his opinion is too great to support the opinion. *Joiner*, 522 U.S. at 146. First, he opines that the high %CV of the Vitamin D assay on three Edison devices over a one-month period in 2014 "suggests a broader problem with Theranos manufacturing and maintenance, whether at the level of the Edison itself or of the reagent/consumable production." Ex. 6 at 13. But he identifies no reliable methodology by which he turned this "suggestion" into a definitive opinion. Nor does he explain how data from a one-month period relating to just one test on just three devices can support an opinion about the reliability of the Edison technology writ large.

Similarly, Dr. Master points to a reference in the CMS report related to quality control (QC) results for an Edison device that ran a Vitamin D reference assay that "delivered QC results [greater than] two standard deviations from the target mean for 15 days in a row, suggesting a bias in the instrument." *Id.* Again, he does not explain what methodology he used to turn this suggestion into an opinion. He concedes that "it is not possible to be certain" whether the cited QC results arose "due to inherent issues with the technology, or with poor lab operational practice," but then nonetheless opines that it is "reasonable to conclude that the instrument problems were not merely a result of poor operational practice, but were related to the quality of the instruments and assays themselves." *Id.* at 13-14. This is "*ipse dixit*, pure speculation, or both": Dr. Master fails to explain why that conclusion is reasonable, and sets forth "no methodology" to support it. *Scentsational Techs. v. PepsiCo, Inc.*, 2018 WL 1889763, at *6 (S.D.N.Y. Apr. 18, 2018).

Lastly, Dr. Master supports his opinion about the Edison technology by pointing to the fact that Theranos voided tests performed on the Edison platform. According to Dr. Master, Theranos' decision to void those tests "effectively acknowledg[ed] that the results were not sufficiently accurate and

reproducible for patient care." Ex. 6 at 13. For the reasons already set forth, Dr. Master cannot permissibility speculate about Theranos' motivations for taking certain action. *See* pp. 9-10, *supra*.[8]

III. Dr. Master's Opinions About "Normal Industry Standards" Must Be Excluded

Dr. Master also offers opinions about Theranos' laboratory practices generally. Specifically, he opines that "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." Ex. 6 at 17. The former opinion rests on impermissible legal opinions, involving complicated questions of law, while the latter is not relevant or helpful to the jury. Both warrant exclusion under Rule 702.

A. Dr. Master's Opinions About Theranos' Compliance with Industry Standards Rest on Improper Legal Opinions

Dr. Master's opinions about Theranos' compliance with "industry standards" are intertwined with his opinions about the content of federal law and its application to Theranos. His background discussion of industry practice purports to explain the legal requirements under CLIA and FDA regulations. Ex. 6 at 8-11. His cited basis for this opinion is his "knowledge of standards and best practices *as established by federal regulations* and by the College of American Pathologists ("CAP")." *Id.* at 3 (emphasis added). But experts may not "usurp either the role of the judge in instructing on the law or the role of the jury in applying the law." *United States v. Locascio*, 6 F.3d 924, 939 (2nd Cir. 1993). Dr. Master's subjective, non-lawyer interpretation of what federal law requires and how it applies to Theranos are thus "inappropriate subjects for expert testimony." *Aguilar v. Int'l Longshoremen's Union Local No. 10*, 966 F.2d 443, 447 (9th Cir. 1992); *see also S.E.C. v. Capital Consultants, LLC*, 397 F.3d 733, 749 (9th Cir. 2005) ("[E]xperts may interpret and analyze factual evidence but may not testify about the law.") *Religious Tech. Ctr. v. Netcom On-Line Commc'n Servs., Inc.*, 1997 WL 34605244, at *8 (N.D. Cal. Jan. 6, 1997) ("interpretations and explanations of the law"

[8] Ms. Holmes is contemporaneously moving in limine to exclude evidence of the voiding of test results is irrelevant, unfairly prejudicial, and an inadmissible remedial measure. *See* Fed. R. Evid. 401-403, 407. Dr. Master's proffered testimony about that action is further inadmissible for all the reasons set forth in that motion.

are "inappropriate subjects for expert testimony").

As an initial matter, Dr. Master is not qualified to offer the legal opinions he offers. He is not a lawyer and has never worked for CMS or FDA. His experience as an individual regulated by federal law does not permit him to testify about the content of federal law or to draw reliable conclusions about the application of that law to Theranos' novel technology. The application of CLIA and FDA regulations to Theranos' technology and its contemplated business model involved complex and evolving questions of law[9] on which Theranos engaged leading regulatory lawyers to engage with the agencies.[10] It would be error for Dr. Master to venture his own opinions on these complex legal questions. Because his proffered testimony does not relate to a matter within his "scientific, technical, or other specialized knowledge," it must be excluded. Fed. R. Evid. 702.

Even if Dr. Master were qualified to provide general background testimony regarding how FDA and CMS operate, his application of federal law to the facts of this case is squarely impermissible. "While expert testimony may be permissible to describe department or agency processes and procedures, such testimony should not prescribe legal standards to apply to the facts of the case." *N.W. v. City of Long Beach*, 2016 WL 9021966, at *2 (C.D. Cal. June 7, 2016); *see also United States v. Caputo*, 374 F. Supp. 2d 632, 646 (N.D. Ill. 2005) (stating "[expert] may not testify about whether Defendants met their obligations under the Safe Medical Devices Act of 1990, because such testimony would constitute an impermissible legal conclusion"). Critically, an expert cannot evade this restriction by dressing up his opinions about legal compliance in the language of "industry practice." *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").

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[9] *See, e.g.*, Ex. 13 (FDA-0005633) (FDA e-mail acknowledging that there may be questions about whether FDA would "require [Theranos] to obtain approval/clearance under [its] *proposed* oversight framework" (emphasis added)); Ex. 14 (FDA-005757) (e-mail between FDA officials and Wall Street Journal journalist discussing evolving regulatory framework and acknowledging "loophole" in FDA regulations).

[10] *See, e.g.*, Ex. 16 (THER-0957500) (letter from Hyman, Phelps, & McNamara, P.C. to FDA); Ex. 15 (SEC2-USAO-EPROD-001297920) (memorandum from Covington & Burling LLP to CMS).

In other words, Dr. Master cannot opine that Theranos failed to adhere to "industry practice" when that "practice" is informed by the "legal meaning" of federal requirements or his attempt to "interpret . . . policies." *McHugh v. United Service Auto. Ass'n*, 164 F.3d 451, 454 (9th Cir.1999). Yet that is precisely what he purports to do. Dr. Master offers three opinions regarding Theranos' supposed lack of compliance: (1) that Theranos' QC system inappropriately did not prevent samples from being analyzed when the QC was out of the supposed specifications, (2) that Theranos "did not appropriately engage in proficiency testing," and (3) that Theranos should have received FDA clearance for its collection device. Ex. 6 at 17-19. Each of those opinions rests on Dr. Master's view of federal law.

Dr. Master's view of what constitutes "industry practice" with respect to QC and proficiency testing is governed by CLIA's requirements. *See id.* at 10-11 ("A third requirement of CLIA is that laboratories engage in proficiency testing"; "CLIA also mandates that a lab perform a quality control check at various intervals (daily, or even more often)."). Indeed, with respect to proficiency testing, Dr. Master admits that Theranos' development of alternative proficiency testing rested on its "interpretation" of federal law, *id.* at 18 ("Even granting Theranos' interpretation . . . . "), and he purports to offer opinions about legal principles such as "the burden of proof," *id.* ("In my opinion, the burden of proof would be on the laboratory to demonstrate to the [proficiency testing] provider that a significant commutability issue exists for their method."). Dr. Master's opinions about Theranos' compliance with "industry standards" governing QC and proficiency testing are self-evidently impermissible legal opinions.

Likewise, Dr. Master's opinion about whether Theranos was required to obtain FDA clearance for its collection tube under FDA regulations is a legal opinion that he is not qualified to offer. *See* Ex. 6 at 19. Dr. Master acknowledges that Theranos advanced the legal position—through its lawyers—that its collection tube was "a laboratory-developed test" and thus did not require FDA clearance. *Id.* He apparently disagrees with that position. He identifies no experience that would qualify him as an expert in FDA's regulatory framework governing medical devices. Even if he were qualified in the field of medical devices, it is not the role of an expert, let alone a clinical pathology expert not trained as a lawyer, to opine that Theranos' counseled interpretation of federal law was incorrect.

B. Dr. Master's Opinions about Industry Standards Would Mislead, Rather Than Help, the Jury

Dr. Master's opinions about industry standards, and Theranos' alleged lack of compliance with them, should be excluded for the independent reason that they do not "assist the trier of fact to understand or to determine a fact in issue." *Daubert*, 509 U.S. at 592. Given that expert evidence has the potential to mislead the jury due to its powerful nature, this "fit" test is even more demanding than the basic relevance test of Rule 402.

Dr. Master opines only that Theranos' alleged "lack of adherence" to industry standards "had the *potential* to adversely impact test accuracy and reliability"—not that any failure in fact led to inaccurate or reliable results. Ex. 6 at 17 (emphasis added). The distinction is an important one because, as the Ninth Circuit has recognized, testimony that something *could* have an effect is materially different from testimony that something did, or was likely to, have an effect. *See Daubert II*, 43 F.3d at 1321 (experts' testimony that medication *could* possibly have caused plaintiffs injuries was not helpful to the jury). While the latter may be permissible expert testimony if supported by a reliable methodology and offered by a qualified expert, the former is speculation and is not helpful to the jury. *Id.*

Daubert II is instructive. On remand from the Supreme Court, the plaintiffs offered statistical evidence to prove that their birth defects were caused by their mothers' ingestion of a medication during pregnancy. *Id.* at 1320–22. The Ninth Circuit concluded that the expert evidence showed, at most, that the medication "*could possibly* have caused plaintiffs' injuries." *Id.* at 1322 (emphasis added). According to the Court, Rule 702 barred that kind of speculative testimony: The question for the jury was whether the medication likely caused the injuries at issue in the case, not merely whether it might have done so. *Id.*

Like the speculative testimony in *Daubert II*, Dr. Master's opinion that Theranos' industry-practice failings had the *potential* to adversely affect the accuracy of its tests fails Rule 702. Whether Theranos needed FDA clearance for certain technology, for example, tells the jury nothing about the tests' accuracy and reliability. This is why Master is forced to say that it had the "potential" to affect accuracy and reliability. To be helpful to 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. An opinion that Theranos' alleged noncompliance had the "potential to affect accuracy," whatever that may mean, falls well short of that mark. The jury will be left to guess whether it did in fact affect accuracy of Theranos' blood tests. And Dr. Master's testimony will mislead the jury into convicting Ms. Holmes for something that the government did not charge—*i.e.*, violations of federal law governing CLIA labs and FDA clearance requirements. As a result, the opinions must be excluded under both Rules 702 and 403.

IV. Dr. Master's Miscellaneous Observations Are Irrelevant

Dr. Master offers a few observations that are irrelevant and inadmissible for additional reasons. Specifically, he states that

- "[T]he testimony of Adam Rosendorff indicates that Theranos did not adequately distinguish on reports whether a reported value came from a fingerstick or venous sample, and the reference ranges were not all appropriately adjusted to account for fingersticks." Ex. 6 at 16.
- In 2016, Theranos publically announced an additional device (minilab) in a public session at the Annual Meeting of the American Association for Clinical Chemistry. "There was no clear data on the robustness of the machines in an operational setting," and that "would raise concerns based on the fact that previous Edison instruments" did not "yield reproducibly accurate, reliable results." *Id.* at 17.
- "[A] disclaimer is always added to LDT results indicating that the test is not FDA approved or cleared, but has been validated by the laboratory," but Theranos did not include a disclaimer. *Id.* at 19.

The first observation impermissibly parrots lay witness testimony. *Sanchez*, 2012 WL 13005996. Dr. Master identifies neither a methodology for determining whether reference ranges were properly adjusted, nor an industry standard requiring lab reports to identify the method of collection.

The second observation is not relevant because it is outside the relevant time frame, and it merely identifies a "concern," not an opinion. Dr. Master himself recognizes that he is providing opinions about Theranos' practices only from 2013-2015. Ex. 6 at 3. It is also flawed to the extent it rests on his unreliable opinion, discussed above, that the previous Edison instruments did not "yield reproducibly accurate, reliable results." *Id.* at 17.

The final observation is similarly irrelevant to whether Theranos' tests were accurate and

reliable. Dr. Master does not opine as to how the non-inclusion of such a disclaimer affected the reliability of accuracy of Theranos' tests. He cites to no rule, regulation, or industry guidelines requiring any such disclaimer, and says nothing about what recipients of lab reports would do with it. And, to the extent Dr. Master bases this opinion on federal law, he is not qualified to offer such an improper legal opinion for all the reasons set forth above.

V. Dr. Master Is Not Qualified to Opine on Fingerstick Testing on Theranos Technology

Last but not least, Dr. Master's expert testimony should be excluded because he has not demonstrated that he is qualified to provide opinions regarding the accuracy and reliability of fingerstick testing on Theranos devices. One "key inquiry is whether the witness has sufficient skill or knowledge related to the pertinent field so that his inference will probably be of some assistance to the untrained layman." *Enyart v. Nat'l Conf. of Bar Examn'rs, Inc.*, 823 F. Supp. 2d 995, 1001 (N.D. Cal. 2011). Opinions outside a witness's expertise are inadmissible. *See, e.g.*, *United States v. Redlightning*, 624 F.3d 1090, 1115 (9th Cir. 2010) (holding witness with expertise in psychological effects of a disorder was not qualified to offer opinions related to physical or medical symptoms of that disorder).

Dr. Master states that his opinions are based on "his training in clinical pathology and chemistry, [his] experience as a laboratory medical director, and [his] knowledge of best practices as established by federal regulations and by the College of American Pathologists." Ex. 6 at 3. However, Dr. Master expressly disclaims providing *any* opinion about Theranos testing using traditional venous samples on FDA-approved or cleared devices of the sort he presumably uses in his laboratory. *Id.* at 11. Rather, the government retained Dr. Master to "provide opinions on whether Theranos was market ready and able to produce accurate and reliable fingerstick results" on its proprietary technology. *Id.* Dr. Master, however, does not identify any relevant experience with fingerstick blood testing. He does not claim to have any knowledge of Theranos' proprietary technology, nor does he explain any steps he took to become familiar with its technology.

Courts in this district routinely exclude expert testimony when the expert fails to provide a connection between his or her background and experience and the precise subject on which the expert will testify. In *Salinas v. Amteck of Kentucky, Inc*., for example, a witness with over thirty years of

experience in construction safety was not permitted to provide expert testimony regarding the adequacy of warning labels in a construction site. 682 F. Supp. 2d 1022 (N.D. Cal. 2010). The court held that despite the witness's experience in workplace safety, there was no indication that the witness had professional training or qualifications in the design or adequacy of warning or safety labels. *Id.* at 1030. The court also found it significant that there was no indication that the witness had investigated a case with similar facts or had ever testified as a safety warnings expert. *Id.*

Similarly, although Dr. Master may be qualified to discuss hematology generally, or traditional blood testing methods with which he is familiar, he does not indicate any familiarity with fingerstick testing for the assays on which he ventures an opinion. Additionally, Dr. Master does not reveal any relevant experience analyzing new testing technologies. Dr. Master is not qualified to offer opinions on the accuracy and reliability of fingerstick testing on Theranos technology.

VI. At a Minimum, the Court Should Hold a *Daubert* Hearing

As stated above, Dr. Master's opinions raise more questions than answers, including with respect to the completeness on the data on which he relies (if any); the speed with which he generated his opinions after the government gave him a roadmap of desired conclusions; and his failure to apply the stated methodology to any of the at-issue tests. The Court, at a minimum, should hold a *Daubert* hearing. "Where the opposing 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)). Ms. Holmes has put into dispute the admissibility and reliability of Dr. Master's opinions. Ms. Holmes respectfully requests that the Court conduct a *Daubert* hearing.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Master's opinions concerning the HIV, HbA1c, hCG, calcium, bicarbonate, chloride, sodium, potassium, Vitamin D, and cholesterol assays; his opinions about problems with the Edison device; and his opinions about Theranos' compliance with "industry standards."

DATED: November 20, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2020, a copy of this filing was delivered via ECF on all counsel of record.

/s/ Amy Mason Saharia
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