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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 **MS. HOLMES' MOTION TO EXCLUDE EVIDENCE OF ANECDOTAL TEST RESULTS UNDER FEDERAL RULES OF EVIDENCE 401-403** Date: January 22, 2021 Time: 10:00 AM CTRM: 4, 5th Floor Hon. Edward J. Davila

MOTION TO EXCLUDE EVIDENCE OF ANECDOTAL TEST RESULTS

PLEASE TAKE NOTICE that on January 22, 2021, 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 of the Federal Rules of Evidence for an Order excluding evidence of anecdotal test results. 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
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MEMORANDUM OF POINTS AND AUTHORITIES

Theranos generated between 7 and 10 million test results for customers. The government has not analyzed those results—whether in the aggregate or by representative sampling—to determine in a scientific fashion whether Theranos was capable of consistently producing accurate and reliable test results. Instead, the government has identified a relatively small number of cases in which customers received test results that their doctors believed were erroneous. The government's witness list identifies *eleven* such customer witnesses; it also identifies *eleven* medical professionals (doctors and nurses) as witnesses. But all blood tests produce occasional errors, and there are many factors that can cause unexpected or erroneous results. That one customer or even a number of customers received unexpected or erroneous results, out of the 7 to 10 million results generated by Theranos, has no probative value to the issue in dispute: whether Theranos' technology was capable of consistently producing accurate and reliable test results. The government cannot permissibly fill the evidentiary voids in its case with irrelevant anecdotes about incorrect test results. The Court should exclude under Rules 401-403 all anecdotal evidence regarding incorrect test results, including testimony of customers, doctors, or Theranos employees.

BACKGROUND

The government's witness list includes eleven Theranos customers. It also includes eleven medical professionals whose patients received Theranos tests—nine of whom the government has disclosed as expert witnesses. *See generally* Ms. Holmes' Mot. To Exclude Expert Opinion Testimony of Fact/Percipient Witnesses.[1]

A number of these medical professionals intend to testify about one single patient, or a small number of patients, who received test results from Theranos that the professionals believed to be in error. *See id.* As discussed in more detail in Ms. Holmes' *Daubert* motion to exclude their testimony, some of these witnesses have failed entirely to disclose the identities of the patients on which they are basing their opinions. *See id.* For other witnesses, Ms. Holmes knows from discovery the identities of

[1] Ms. Holmes is contemporaneously moving to exclude the testimony of these disclosed expert witnesses under Rules 401-403 and 702.

the patients on whom the medical professionals are basing their opinions, and some of those patients also appear on the government's witness list. In other words, there is substantial overlap between the 11 medical professionals disclosed as witnesses and the 11 patients disclosed as witnesses.

The following examples are illustrative:

The government has identified Dr. Audra Zachman, a women's health nurse practitioner, as an expert witness. She will testify about pregnancy (hCG) test results for *one* identified patient, B.G. Ex. 5 at 4 (Sept. 28, 2020 Gov't Supp. Expert Notice). Specifically, she will testify that her patient received three hCG test results that were not "biologically possible," and that it was "clear that at least one of the Theranos test results was not accurate." *Id.* She will also testify that, if accurate, the first two test results would have indicated "a nonviable pregnancy." *Id.* The government has also identified her patient, B.G., as a witness. According to an FDA memorandum of an interview of B.G., she does not recall how she paid for the Theranos tests. Much of her interview focused on her feelings of despair when she believed, after the second test result, that she was miscarrying. Ex. 72 at 2 (US-REPORTS-0010790).

The government also has disclosed Dr. Mark Burnes, an internist, as an expert. He will testify about Prostate Specific Antigen (PSA) test results for one patient (identified in interview memoranda as M.E.). Ex. 5 at 6. Dr. Burnes will testify about three PSA test results received by this patient and his opinion that there was "no medical explanation" for the jumps in the PSA level across the tests. *Id.* The government has also disclosed his patient, M.E., as a witness. Unlike B.G., M.E. did not describe any emotional harm stemming from his allegedly erroneous test result; to the contrary, his doctor "did not overreact because [M.E.] looked to be ok, so instead of taking action he sent him back to be re[]-tested." Ex. 71 at 1 (US-REPORTS-0008719).

In addition to the testimony of these and similar patient and medical professional witnesses, Ms. Holmes expects that the government may attempt to introduce evidence of similar anecdotal test results through the testimony of Theranos representatives who fielded questions from doctors about test results.

ARGUMENT

I. Evidence of Anecdotal Test Results Is Irrelevant.

This anecdotal evidence of specific Theranos patients who received allegedly incorrect blood test results is not probative of any issue in dispute in this case. As even the government's hematology expert acknowledges, there is a certain amount of expected error in laboratory blood testing. *See* Ex. 6 at 6-7 (Master Rpt.). One study, for example, 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). Accordingly, any given laboratory will necessarily produce some number of incorrect test results.[2] Additionally, there are a number of factors other than defective technology that can produce inaccurate or unexpected test results in any given case, including improper specimen handling, human processing error, reagent defects, and patient-specific considerations such as diet.

Because lab error is expected, the fact that a Theranos customer received an incorrect (or unexpected) test result says nothing about what *caused* that result. An incorrect result may well fall within the expected error rate and/or may have resulted from factors other than Theranos' technology. Indeed, applying the 0.1% to 3.0% expected error rate set forth above to the 7 to 10 million tests performed by Theranos, yields between 7,000 and 300,000 expected errors. This makes plain that to prove that a defect in Theranos technology caused the incorrect result, more than anecdotes is required. "Anecdotal evidence usually amounts to reports that events of one kind are followed by events of another kind"—here, that the patient had a test at Theranos, and that the patient received an incorrect test result. Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 217-18 (3d ed.). But "[t]ypically, the reports are not even sufficient to show association, because there is no comparison group." *Id.* The Federal Judicial Center's *Reference Manual on Scientific Evidence* provides an on-

[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).

point example. As it explains, the fact that "some children who live near power lines develop leukemia" cannot show causation "because leukemia also occurs among children without exposure." *Id.* The same problem exists here; all laboratories occasionally return errors, so the fact that the government has identified a relatively small number of Theranos customers who received allegedly incorrect results does not tend to prove what caused those errors.

That is why courts do not allow experts to draw scientific opinions from mere anecdotes. Part and parcel of the reliability requirement is the principle that 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."). Anecdotal evidence is suspect because it "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 McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) ("Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation."); *cf. Casey v. Home Depot*, 2016 WL 7479347, at *23 (C.D. Cal. Sept. 15, 2016) (denying motion for class certification because "the declarations submitted by Plaintiff only provide anecdotal evidence that may not necessarily be representative of the Proposed Class").

For the same reason, FDA has cautioned against drawing conclusions from mere reports of adverse events suffered by people taking medications. *See, e.g.*, FDA, Questions and Answers on FDA's Adverse Event Reporting System (FAERS) ("Existence of a report does not establish causation: For any given report, there is no certainty that a suspected drug caused the reaction.")[3]; *see also, e.g.*, *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 664 (S.D.N.Y. 2017) ("[T]he mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events." (omission in original) (citation omitted)); *Casey v. Ohio Medical Products*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("Case reports are not reliable scientific evidence of causation, because they

[3] https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.

simply describe reported phenomena without comparison to the base rate at which the phenomenon occurs in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain mechanism of causation.").

Just like with adverse event reports in the pharmaceutical context, one cannot draw any conclusions about causation from isolated, anecdotal examples of incorrect or unexpected blood tests. The government cannot show that its anecdotal examples fall outside the expected error rate for laboratories; it cannot show that Theranos' error rate was meaningfully different than that of other laboratories (in fact, it has not even attempted to identify Theranos' error rate); and it cannot show what caused these anecdotal incorrect or unexpected results. Because these anecdotes do not tend to prove that "Theranos's technology was, in fact, not capable of consistently producing accurate and reliable results," Third Superseding Indictment, ECF 469, ¶ 16, they are irrelevant. All anecdotal evidence of incorrect test results should be excluded.

II. Rule 403 Bars Admission of Evidence of Anecdotal Test Results.

Even if these anecdotes had some minimal probative value, the Rule 403 considerations would substantially outweigh that probative value. Under Rule 403, "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403; *see United States v. Hitt*, 981 F.2d 422, 424 (9th Cir. 1992) ("Where the evidence is of very slight (if any) probative value, it's an abuse of discretion to admit it if there's even a modest likelihood of unfair prejudice or a small risk of misleading the jury."). Here, the evidence will confuse and mislead the jury and will unfairly prejudice Ms. Holmes.

First, this evidence will confuse and mislead the jury about what is at issue in this case. As this Court has recognized, a scheme to defraud has as its object the deprivation of "'property in the hands of the victim.'" ECF No. 330 at 27 (quoting *Cleveland v. United States*, 531 U.S. 12, 15 (2000)); *see also United States v. Miller*, 953 F.3d 1095, 1102-03 (9th Cir. 2020) (holding that "wire fraud requires the intent to deceive and cheat—in other words, to deprive the victim of money or property by means of deception"). The government has not charged Ms. Holmes with any crimes involving patient harm or

safety. And yet the government intends to subject the jury to testimony by more than 20 medical professionals and patients about allegedly incorrect test results that, they will testify, *could* have harmed patients. In many cases, the government's anecdotes do not even relate to money or property; B.G., for example, did not recall how she paid for her Theranos blood tests. *See* p. 2, *supra*. After hearing days and days of these anecdotes, the jury will undoubtedly be confused about what this case is about.

So too, the jury will be confused about the scientific relevance of this evidence. The jury will be tempted to infer from this evidence that Theranos was incapable of generating accurate and reliable test results—even though one cannot reliably draw that inference from this evidence. That unreliable inference would not only prejudice Ms. Holmes; it is the very purpose of this evidence. The government intends to use these anecdotes to fill the holes in its case. To provide one conspicuous example: the government's retained hematology expert was unable to reach an opinion that Theranos' hcG (pregnancy) tests were inaccurate and unreliable.[4] It thus should come as no surprise that the government has disclosed four medical professionals, including Dr. Zachman, to testify about isolated examples of incorrect pregnancy tests, in many cases for unidentified patients.

Finally, for the reasons detailed at length in Ms. Holmes' Motion To Exclude Customer Impact Evidence, this evidence will be highly prejudicial. Patients like B.G. will testify about the emotional impact of receiving allegedly inaccurate tests. *See United States v. Pac. Gas & Elec. Co.*, 178 F. Supp. 3d 927, 941 (N.D. Cal. 2016) (evidence is unfairly prejudicial when it has "an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one" (citing *Old Chief v. United States*, 519 U.S. 172, 180 (1997))). And, although the government has identified *no* evidence of physical harm to any Theranos patient, its doctor witnesses intend to testify about inflammatory, hypothetical ramifications of hypothetical, incorrect blood tests. *See, e.g.*, Ms. Holmes' Motion To Exclude Customer Impact Evidence at 2 ("coma from the brain shutting down"; "hemorrhaging"; "patient could die on the table"). This emotional effect of this evidence will swamp any probative value of these isolated examples.

[4] *See* Ms. Holmes' Motion To Exclude the Expert Testimony of Dr. Stephen Master, filed contemporaneously herewith.

CONCLUSION

For the foregoing reasons, the Court should exclude evidence of anecdotal test results received by Theranos customers.

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
AMY MASON SAHARIA
Attorney for Elizabeth Holmes