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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 CMS SURVEY FINDINGS AND SANCTIONS PURSUANT TO RULES 401-403 AND 801-803** Date: January 22, 2021 Time: 10:00 AM CTRM: 4, 5th Floor Hon. Edward J. Davila

MOTION TO EXCLUDE EVIDENCE OF CMS SURVEY FINDINGS AND SANCTIONS

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 801-803 of the Federal Rules of Evidence for an order precluding the government from introducing at trial evidence relating to the survey findings and sanctions by the Centers for Medicare & Medicaid Services. The Motion is based on the below Memorandum of Points and Authorities, the record in this case, and any other matters that the Court deems appropriate.

DATED: November 20, 2020

/s/ Amy Mason Saharia
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MEMORANDUM OF POINTS AND AUTHORITIES

Defendant Elizabeth Holmes moves, pursuant to Federal Rules of Evidence 401-403 and 801-803, to exclude evidence relating to the findings of surveys of Theranos' clinical laboratories conducted by the Centers for Medicare & Medicaid Services' ("CMS") in 2015 and 2016, including the survey reports and sanctions imposed by CMS. CMS inspectors cited Theranos' laboratories for violations of federal regulations governing clinical lab practices, as documented in the CMS survey reports. The inspectors, by their own admission, did not seek to determine whether Theranos' tests were accurate and reliable. The government could have pursued a criminal charge of intentional violation of the lab regulations cited by CMS if it believed the evidence supported such a charge. It did not. Instead it charged wire fraud. Evidence that Theranos was accused of violating federal regulations is irrelevant to the government's wire-fraud charges, as it does not tend to prove that Ms. Holmes knowingly misled investors about the capabilities of Theranos' proprietary testing technology or patients about the accuracy and reliability of Theranos tests. The evidence is also highly prejudicial and confusing. Finally, the survey reports and other documents purporting to identify violations by Theranos' laboratory are inadmissible hearsay. The evidence should be excluded.

BACKGROUND

I. Regulatory Background

Under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, all laboratories that perform clinical diagnostic testing on human samples must be certified under and, maintain compliance with, the regulations and conditions of certification as set forth by the Secretary of Health. *See* 42 C.F.R. §§ 493.2(d)(5), 493.5, 493.20. A laboratory's failure to comply with just one applicable condition may be grounds for suspension or revocation of its CLIA certificate. *Id.* § 493.1806.

Laboratories such as Theranos were required to meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1269, and §§ 493.1281 through 493.1299. *See id.* § 493.1215. These requirements run the gamut: laboratories must ensure all written complaints and problems are documented, *id.* § 493.1233; have up-to-date written policies and procedures, *id.* § 493.1235; and ensure

proper storage of "test systems, equipment, instruments, reagents, materials and supplies" consistent with the manufacturer's instructions, *id.* § 493.1252. There are also conditions that govern laboratory personnel. *See id.* §§ 493.1441, 493.1447, 493.1487.

CMS audits laboratories to identify non-compliance with CLIA's mandates. The available sanctions vary depending on the deficiency's severity and on whether CMS inspectors deem it poses immediate jeopardy to public health. *See id.* §§ 493.1812, 493.1814, 493.1816. In some cases, CMS may revoke the laboratory's ability to receive Medicare payment for its services; suspend, limit, or revoke the laboratory's CLIA certificate; impose a plan of correction; or impose civil monetary penalties. *Id.* §§ 493.1806, 493.1807, 493.1812, 493.1814. A laboratory has the right to appeal CMS's imposition of sanctions first to an administrative law judge within CMS and then to an agency appeals board. *Id.* § 493.1844. Upon a final agency action, the laboratory may seek judicial review. *Id.*

Criminal sanctions are available if "an individual . . . is convicted of intentionally violating any CLIA requirement." *Id.* § 493.1806.

II. Factual Background

On January 25, 2016, CMS issued a letter and a Form 2567 (collectively "January 2016 CMS Report") to Theranos summarizing its findings from its recent survey of Theranos' Newark, California laboratory. Ex. 12 (THPFM0002240153). The January 2016 CMS Report resulted from a recertification and complaint survey of the lab conducted by CMS in September and November 2015. Ex. 34 at 2-3 (US-REPORTS-0006781). Generally, "re-certification surveys are conducted by a state agency." *Id.* at 3. A state agency was scheduled to conduct the survey of Theranos' Newark laboratory, but CMS decided to do so instead "due to the media attention Theranos was receiving at the time and due to the complaints CMS had received about Theranos." *Id.* at 2.[1] It was unusual for CMS both to conduct the survey and to send "central office personnel . . . out on the Theranos survey." *Id.* at 3.

[1] A CMS witness told the government that CMS was in contact with Wall Street Journal reporter John Carreyrou about Theranos. Ex. 34 at. 3.

In its January 2016 Report, CMS asserted that Theranos' California laboratory was in violation of various CLIA requirements. Ex. 12 at 1-2. CMS warned Theranos that if it did not remediate these deficiencies within 10 days, CMS would impose sanctions. *Id.* at 2.

Theranos and CMS then engaged in further communications, during which Theranos outlined the steps it was taking to resolve CMS's claimed deficiencies. *See* Ex. 27 at 2 (THER-0534700). Nevertheless, on July 7, 2016, CMS imposed the threatened sanctions. Ex. 30 (THPFM0004806442). Theranos appealed the sanctions to an administrative law judge; Theranos and CMS later settled the appeal before adjudication.[2]

Soon after the imposition of sanctions on Theranos' Newark laboratory, the same CMS employees surveyed Theranos' Arizona laboratory. Ex. 33 (CMS2022128); Ex. 31 at 188:13-20 (Jan. 28, 2020 Bennet Dep.) CMS cited the Arizona laboratory for various CLIA violations, Ex. 33, and ultimately imposed sanctions, Ex. 32 (CMS3-000671). Theranos later settled its challenge to these sanctions as part of a global settlement with CMS before the adjudication of its challenge by an administrative law judge.

The government intends to use CMS's deficiency findings and Theranos' subsequent correspondence with CMS about those findings to support its allegation that "Theranos' technology was . . . not capable of producing accurate and reliable results." Ex. 3 at 67-68 (Sept. 28, 2020 Gov't Supp. Rule 404(b) Notice). Category 14 of the government's Rule 404(b) notice is replete with references to the CMS inspections; CMS's survey findings; and Theranos' responses and correspondence with CMS. *Id.* at 66-67. Additionally, the government has identified the CMS employees who conducted the California and Arizona laboratory surveys on its witness list, and the government's hematology expert relies on the CMS findings as the sole basis for his opinion about Theranos' Vitamin D assay.

ARGUMENT

CMS's findings that Theranos had violated CLIA regulations are irrelevant to the allegations against Ms. Holmes. The government has not charged Ms. Holmes with operating a laboratory that

[2] Ms. Holmes is separately moving to exclude evidence relating to the settlement and the remedial measures that Theranos voluntarily adopted in response to the CMS survey findings.

failed to comply with CLIA regulations. As relevant here, it has charged her with allegedly misrepresenting that Theranos was capable of producing accurate and reliable test results. *CMS did not assess whether Theranos was capable of producing accurate and reliable test results, let alone pass judgment on the accuracy or reliability of Theranos' test results.* Its findings thus do not advance the government's case. Even if they were marginally probative, the prejudicial nature of seemingly authoritative government findings of noncompliance would swamp any probative value. Finally, the CMS survey reports and other documents reporting the CMS findings are inadmissible hearsay.

I. Evidence of CMS Survey Findings and Sanctions Is Inadmissible Under Rules 401-403

Evidence is relevant if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. If evidence does not pass this standard, it is inadmissible. Fed. R. Evid. 402. Even if evidence has some relevance, it may still be excluded "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury." Fed. R. Evid. 403. Evidence is unfairly prejudicial when it has "an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." *United States v. Pac. Gas & Elec. Co.,* (*PGE*) 178 F. Supp. 3d 927, 941 (N.D. Cal. 2016) (quoting *Old Chief v. United States*, 519 U.S. 172, 180 (1997)).

A. The CMS Survey Findings and Sanctions Are Irrelevant

CMS's survey findings and the sanctions it imposed as a result of those findings are irrelevant to the wire-fraud allegations in this case. The Indictment alleges that Ms. Holmes represented to investors, doctors, and patients that Theranos could provide accurate and reliable blood tests despite allegedly knowing that "Theranos's proprietary analyzer had accuracy and reliability problems" and "was, in fact, not capable of consistently producing accurate and reliable results." Third Superseding Indictment, ECF No. 469, ¶¶ 12(A), 16. *The CMS survey findings, critically, do not assess accuracy and reliability of Theranos technology*. One CMS inspector has explained that the purpose of the CMS inspections was only to evaluate whether the laboratory was compliant with federal regulations, and not to determine if Theranos' tests were accurate. Ex. 31 at 185: 16-22 ("[I]t's not [CMS's] job to determine whether a

result is accurate."). Notably, many of the deficiencies asserted by CMS did not concern Theranos' technology at all, but instead relate to lab personnel issues. Ex. 12 at 1-2; *see id.* at 93 (citing failures for not having updated training records for 31 lab workers). Whether lab directors or personnel had the correct qualifications does not bear on the capabilities of Theranos technology. Other cited deficiencies concerned regulations regarding lab operational practices and procedures. For example, CMS claimed that Theranos did not have "written policies and procedures detailing [its] patient specimen labeling policy," *id.* at 9; and did not have procedure manuals signed, dated, and approved by the laboratory director prior to use, *id*. at 12. None of that suggests that Theranos technology was not consistently capable of producing accurate and reliable test results. In fact, a CMS inspector confirmed that CMS commonly cites these deficiencies at laboratories. Ex. 31 at 98:16-22 [3]

More fundamentally, CMS assessed only whether Theranos was following its own procedures as laid out in its manuals. Ex. 34 at 4-5. As one CMS inspector explained, CMS only "looks at a laboratory's procedures," such as its own training, documentation, or quality control procedures, and "looks to see that they are running them when they say they are supposed to be running them." *Id.* Its findings thus are framed in terms of failure to follow corrective action policies or other procedures and to document that action. *See generally* Ex. 12. Importantly, "CMS doesn't look to the patient data." Ex. 34 at 4-5. CMS accordingly issued no findings regarding accuracy and reliability of any of Theranos' tests, let alone Theranos' technology. Because the CMS survey was not designed to, and did not, assess accuracy and reliability of a laboratory's tests, it is not probative of a fact of consequence in this case and would be particularly misleading to a jury.

[3] Several survey findings concerning the Prothrombin Time/International Normalized Ratio (PT/INR) test cited laboratory staff for failing to use the correct mean normal prothrombin time (MNPT) value when calculating patient results, resulting in a "fail[ure] to ensure that the reported [INR] was calculated accurately prior to reporting final patient results" for the time period 4/3/15 through 9/21/15. Ex. 12 at 70. Because Theranos used FDA-approved, commercially available devices and reagents for its PT/INR test, this computational error unique to the PT/INR test does not reflect any underlying technological or operational issues with Theranos' proprietary devices or other FDA-approved devices or tests in the CLIA lab. Even with respect to PT/INR, CMS' findings did not include a determination that patient test results necessarily were inaccurate. *See* Ex. 31 at 185:1-22 (describing PT/INR results based on her calculations as "different" than those reported by Theranos but emphasizing that "[i]t's "not [CMS'] job to determine whether a result is accurate").

United States v. Pacific Gas & Elec. Co., 178 F. Supp. 3d 927 (N.D. Cal. 2016), considered similar issues in determining whether a report by the NTSB was admissible in an action against PG&E alleging knowing and willing violations of federal safety regulations. The court held that the probative value of the report's conclusion that "PG&E's Integrity Management program was both deficient and ineffective, and was a probable cause of the accident," was minimal "because the ultimate issue of the NTSB investigation—the cause of the San Bruno explosion—is not at issue in this case." *Id.* at 947-48. Similarly, here, the "ultimate issue" of the CMS surveys—whether Theranos' lab practices were in compliance with CMS regulations—"is not at issue in this case." CMS did not investigate the real issue—whether Theranos technology could produce accurate and reliable results. CMS's findings and ultimate sanctions are thus irrelevant.

B. The Risk of Unfair Prejudice and Jury Confusion Substantially Outweighs Any Probative Value

Because CMS did not investigate or issue findings on the accuracy and reliability of Theranos technology, the probative value of its findings relating to CLIA violations is, at best, minimal. Even the government's hematology expert, Dr. Master, does not opine that CMS's findings of regulatory violations establish that Theranos' tests were inaccurate or unreliable. Dr. Master offers only the speculative pseudo-opinion that violations of CLIA regulations had the *potential* to render Theranos tests' inaccurate and unreliable. *See* Ex. 6 at 17 (Master Rpt.). The probative value of this evidence is marginal at best.

On the other hand, the potential for unfair prejudice is great. It is likely the jury will put special weight on the assertions of a federal agency in the laboratory testing space even if those assertions are not directly relevant to the issues in dispute. There is a significant risk that the jury will assume that Theranos, and Ms. Holmes by extension, was deserving of punishment since CMS, an authoritative government agency, cited it for deficiencies and eventually imposed sanctions.

Additionally, the jury might improperly equate CMS's findings with the government's allegation that Theranos technology was not capable of producing accurate and reliable results. But, as a CMS witness explained, CMS specifically does not reach that ultimate conclusion: "we only need to

determine if there was *potential* or the *likelihood* [that a laboratory practice] has caused or *could have caused* harm to a patient." Ex. 31 at 135:16-22; 149 (emphasis added); *see also* 42 C.F.R. § 493.2. Accordingly, at best CMS's findings show only that "[t]here was a *potential* because of the noncompliance to have issues with the results." *Id.* at 179:21-24 (emphasis added). At bottom, as one CMS witness explained, "it's not CMS' job" to "decide if any patients have been affected" by the issues cited in its findings. Ex. 34 at 7. The risk that the jury will draw unwarranted inferences from this evidence is substantial and highly prejudicial.

For these reasons, "admitting the [agency's] conclusions [would] invite[] the jury to improperly substitute the [agency's] findings—under a different standard and for a different purpose—for its own findings about" the charges in this case. *PG&E*, 178 F. Supp. 3d at 947–48. There is "a substantial risk that the jury would 'punish' [Ms. Holmes] on the basis of [CMS's] conclusion" about CLIA violations, which is precisely the sort of improper basis that renders evidence unfairly prejudicial. *Id.* (citing *Old Chief*, 519 U.S. at 180); *see also Angelo v. Bacharach Instrument Co.*, 555 F.2d 1164, 1176 (3d Cir. 1977) (affirming exclusion of EEOC report under Rule 403).

The subjective nature of CMS's survey findings only amplifies the prejudice of admitting the findings. As one CMS witness explained, there is no standard for the "particular amount of evidence required under CLIA to make a condition-level finding." Ex. 31 at 33:1-10. According to the witness, CMS surveyors may "have differences of opinion about . . . whether [a deficiency] should be cited as a standard or condition." *Id.* at 167:11-16. It would be highly improper for the jury to substitute the subjective findings of *particular* CMS surveyors (which were never affirmed on appeal) regarding Theranos' compliance with CLIA violations for the jury's findings on the actual issues in this case.

The CMS survey findings of non-compliance with CLIA regulations also fail to demonstrate Ms. Holmes' knowledge of any such deficiencies before they were cited by CMS. This is because, as one CMS witness explained, "[w]hether or not the lab director [or owners of the laboratory] knew about the deficient practice does not enter into the determination of whether condition-level noncompliance exists." Ex. 31 at 36:14-25; 37:2-8. The imprimatur of authority inherent in a federal government agency's report of violations could cause the jury impermissibly to infer that Ms. Holmes knew about, or

even caused, the cited deficiencies. The risk that the jury will reach conclusions about Ms. Holmes' knowledge and intent about the deficiencies cited by CMS—which are not even at issue in this case—is serious. The even greater risk that the jury may infer knowledge and intent by Ms. Holmes from the uncharged CMS findings in relation to the actual wire-fraud charges regarding the accuracy and reliability of Theranos tests is intolerable and unfairly prejudicial.

Because any probative value of the findings and associated sanctions is substantially outweighed by the risk of unfair prejudice and jury confusion, the CMS findings and sanctions should be excluded under Rule 403.

II. The CMS Reports and Other Documentation of CMS's Findings Are Inadmissible Hearsay

Even if this evidence were otherwise admissible, the CMS reports and other documentation of CMS's findings must be excluded as hearsay. Under Federal Rules of Evidence 801 and 802, an out-of-court statement offered for the truth of the matter asserted is inadmissible unless it falls within a hearsay exception. The CMS reports are public records, and the Ninth Circuit has held that "[w]hen public records are used against a defendant in a criminal prosecution, the public records exception is the exclusive applicable hearsay exception." *United States v. Orellana-Blanco*, 294 F.3d 1143, 1149 (9th Cir. 2002). This is because Rule 803(8), governing public records, "speaks directly to public records and carefully delineates the distinction between criminal and civil proceedings in order to protect a defendant's rights under the confrontation clause." *Orellana-Blanco*, 294 F.3d at 1149; *see also United States v. Orozco*, 590 F.2d 789 (9th Cir. 1979) ("While governmental functions could be included within the broad definition of 'business' in rule 803(6), such a result is obviated by rule 803(8)")

The CMS reports contain "factual findings from legally authorized investigations" and thus are governed by Rule 803 (8)(a)(iii) As relevant here, public records that contain factual findings from legally authorized investigations are admissible "in a civil case ***or against the government in a criminal case.***" Fed. R. Evid. 803(8)(a)(iii) (emphasis added). Accordingly, under Rule 803(8), reports of public agencies setting forth factual findings from legally authorized investigations are inadmissible against a

criminal defendant. *Id.*; *United States v. Sims*, 617 F.2d 1371, 1377 (9th Cir. 1980); Fed. R. Evid. 803(8)(C) advisory committee's note.[4]

In this case, Rule 803(8) bars admission of the CMS survey reports and other CMS records documenting its survey findings. As just explained, when the public record at issue is an evaluative report by a public agency, the report is only admissible in a criminal case if offered against the government. The CMS reports were prepared by a government agency and contain factual findings from legally authorized investigations. The reports were based on surveys conducted by CMS, a federal agency, and the purpose of the surveys was to determine whether the laboratory was in compliance with CLIA requirements as delineated in 42 C.F.R. § 493.1215 and in response to a complaint received about the lab. Ex. 12 at 1; Ex. 34 at 2. The reports expressly state that the surveyors conducted the survey pursuant to a legally authorized investigation: "[f]ederal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations." *E.g.*, Ex. 12 at 1. The reports contain findings from the surveys: each cited deficiency provides a "Findings Include" section that details CMS's findings. *See, e.g.*, *id.* at 52. Accordingly, the government may not introduce the reports against Ms. Holmes.

No exception to Rule 803(8) applies here. The Ninth Circuit has held that public records that relate to "routine, nonadversarial matters made in a nonadversarial setting, reflecting ministerial, objective observations," may be admitted against a criminal defendant. *Orellana-Blanco*, 294 F.3d at 1150. The exception, however, is inapplicable to public records generated by agencies or law enforcement that contain "subjective observations, summaries, opinions and conclusions." *Id.* For example, in *Orozco*, the Ninth Circuit held that Rule 803(8) did not bar admission against a criminal defendant of a Treasury Enforcement Communications System data report that captured the license plates of vehicles crossing the border, because the report simply recorded license plate numbers of all cars that passed by and therefore concerned routine, nonadversarial matters. 590 F.2d at 793. By

[4] The current Rule 803(8)(A)(iii) is functionally equivalent to the provision formerly styled as Rule 803(8)(C), which applied to "factual findings resulting from an investigation made pursuant to authority granted by law." *Nipper v. Snipes*, 7 F.3d 415, 417 (4th Cir. 1993).

contrast, in *Orellana-Blanc*, the Ninth Circuit held that the public-records exception barred admission of an immigration form generated after agency personnel interviewed the defendant because the report contained a subjective recordation of the preparer's observations and the government offered the report to show that the charged crime had been committed. 294 F.3d at 1150. Because the report was not based on routine non-adversarial matters, the admission of the report was reversible error. *Id*.

In this case, there was nothing "routine" or "ministerial" about the investigations that led to the CMS findings. CMS personnel were substituted for the state officials who were initially scheduled to inspect the Theranos lab. Ex. 34 at 2. CMS took the "unusual" step of sending central office personnel to conduct the survey. *Id.* Critically, the CMS findings were based on the same types of subjective observations, summaries, and opinions at issue in *Orellana-Blanco*. A CMS witness explained that the standard for a deficiency-level finding is entirely up to whoever is surveying the lab. The surveyor explained that "once there's a determination of non-compliance, you have to use your professional surveyor judgment to determine what evidence you need to support that noncompliance and there's no standard set . . . it's very situational." Ex. 31 at 157. The findings in a CLIA survey can vary from surveyor to surveyor, and surveyors may "have differences of opinion about . . . whether it should be cited as a standard or condition." *Id.* at 167:16-22. These subjective determinations are nothing like the routine matter of recording by rote all license plate numbers that cross the border in *Orozco*.

Even if the CMS documents are themselves admissible as agency records, the reports themselves contain out-of-court statements of Theranos personnel presented for the truth of the matter asserted. *See, e.g.*, Ex. 12 at 7 ("The QC/QA Manager confirmed on 11/18/15 that an investigation was not done or documented."). The government cannot admit such statements for the truth of the matter asserted. Nor can CMS witnesses testify about such out-of-court statements. *See United States v. Morales*, 720 F.3d 1194, 1202 (9th Cir. 2013) ("In general, statements by third parties who are not government employees (or otherwise under a legal duty to report) may not be admitted pursuant to the public records exception but must satisfy some other exception in order to be admitted.").

CONCLUSION

For the foregoing reasons, Ms. Holmes respectfully requests an order precluding evidence relating to the CMS survey findings and sanctions, including but not limited to the CMS survey reports, Theranos' written responses to the survey reports, and other CMS documentation of its findings.

DATED: November 20, 2020

Respectfully submitted,

/s/ Amy Mason Saharia
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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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