

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,
Plaintiff,
v.
ELIZABETH A. HOLMES,
Defendant.

Case No. [5:18-cr-00258-EJD-1](#)

ORDER RE: MOTIONS IN LIMINE

Re: Dkt. Nos. 561-578, 588

On July 28, 2020, a federal grand jury returned a Third Superseding Indictment, charging Defendants Elizabeth Holmes and Ramesh “Sunny” Balwani with ten counts of wire fraud (“Counts 3 through 12”), in violation of 18 U.S.C. § 1343, and two counts of conspiracy to commit wire fraud (“Counts 1 through 2”), in violation of 18 U.S.C. § 1349. Third Superseding Indictment (“TSI”), Dkt. No. 469. Defendants were charged with making deceptive representations about their company, Theranos, and its technology.

In anticipation of trial, Holmes and the Government each filed motions in limine (“MIL”). Mots. in Limine, Dkt. Nos. 560-578, 588. Both parties timely opposed and replied in support of their respective motions. Dkt. Nos. 659-670, 672-678, 682, 704-721, 726, 740. The Court conducted hearings on May 4-6, 2021. Trs. of Proceedings, Dkt. Nos. 792-794. Having considered the parties’ arguments, the relevant law, and the record in this case, the Court **GRANTS** in part and **DENIES** in part the following motions in limine, as set forth below.

I. BACKGROUND

Holmes founded Theranos, a health care and life sciences company, in 2003. TSI ¶ 1. Holmes served as the company’s Chief Executive Officer. *Id.* Balwani was a board member,

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1 President, and Chief Operating Officer of Theranos. *Id.* ¶ 2.

2 Theranos' stated mission was to revolutionize medical laboratory testing through its
3 allegedly innovative methods of drawing and testing blood and diagnosing patients. *Id.* ¶ 4.
4 During the company's first ten years, its scientists worked toward developing proprietary
5 technology that could run clinical tests using only tiny drops of blood. *Id.* ¶ 5. Theranos also
6 worked toward developing a method for drawing a few drops of capillary blood from a patient's
7 finger using a small lancet. *Id.* The blood was then stored in a "nanotainer." *Id.* Theranos sought
8 to develop a second device called the Theranos Sample Processing Unit ("the TSPU," "Edison," or
9 "miniLab") that could quickly and accurately analyze blood samples stored in the nanotainer. *Id.*
10 The Government contends that the promises of these devices were never realized; the devices
11 "consistently" produced inaccurate and unreliable results. *Id.* ¶ 16. Despite this, Defendants
12 began a publicity campaign to promote the company and its devices. *Id.* ¶¶ 6-9. In September
13 2013, Theranos offered blood testing at Walgreens' "Wellness Centers" in California and Arizona.
14 *Id.* ¶ 10.

15 The Government argues that Defendants conspired to commit and committed fraud
16 through two fraudulent schemes: one to defraud investors and another to defraud doctors and
17 patients. The Court outlines these schemes below.

18 **Scheme to Defraud Investors.** Defendants allegedly made materially false and
19 misleading statements and failed to disclose material facts to investors. Based on the false
20 statements, investors invested money in Theranos. Specifically, from 2013 to 2015, Defendants
21 allegedly made misstatements regarding:

22 1. Theranos' proprietary analyzer: Defendants allegedly made misstatements about
23 Theranos' proprietary analyzer—the TSPU, Edison, or miniLab—when they claimed the analyzer
24 was presently capable of accomplishing certain tasks, with more precision than other blood tests,
25 and at a faster rate, when they knew these statements were false. *Id.* ¶ 12(A).

26 2. Theranos' financial health: Defendants allegedly misrepresented Theranos' financial
27 well-being when they told investors the company was financially strong and stable and would

1 make huge profits in 2014 and 2015 when, in fact, they knew Theranos would only generate
2 modest revenue. *Id.* ¶ 12(B).

3 3. Technology demonstrations: Defendants allegedly deceived investors through
4 misleading technology demonstrations intended to cause potential investors to believe blood tests
5 were being conducted on Theranos' proprietary analyzer when Defendants knew the analyzer was
6 operating in "null protocol." *Id.* ¶ 12(C).

7 4. Walgreens partnership: Defendants allegedly misled investors when they told them
8 Theranos had an expanding partnership with Walgreens when the Walgreens rollout had stalled
9 due to concerns with Theranos' performance. *Id.* ¶ 12(D).

10 5. United States Department of Defense ("DOD") relationship: Defendants allegedly told
11 investors the company had a profitable and revenue-generating business relationship with the
12 DOD and that Theranos technology was deployed on the battlefield. Defendants allegedly knew
13 that Theranos had limited revenue from military contracts and that its technology was not used in
14 the battlefield. *Id.* ¶ 12(E).

15 6. Food and Drug Administration ("FDA") approval: Defendants allegedly misled
16 investors when they told them that Theranos did not need the FDA to approve its proprietary
17 analyzer and tests when Defendants knew this to be false. *Id.* ¶ 12(F).

18 7. Patient testing: Defendants allegedly told investors that patient tests were conducted
19 using Theranos manufactured analyzers. Defendants allegedly knew that Theranos used third-
20 party, commercially available analyzers. *Id.* ¶ 12(G).

21 8. Peer review: Defendants allegedly falsely told investors that several national or
22 multinational pharmaceutical companies and research institutions had examined, used, and
23 validated Theranos technology. *Id.* ¶ 12(H).

24 9. Media representations: Defendants allegedly made the false and misleading statements
25 described above to reporters and then shared the resulting articles directly with potential investors
26 and via Theranos' website. *Id.* ¶ 12(I).

Scheme to Defraud Doctors and Patients. The Government argues that, from 2013 to 2016, Defendants advertised and marketed Theranos technology to doctors and patients, and falsely claimed that the tests were accurate and reliable. *Id.* ¶¶ 14-15. Their claims about Theranos technology were implicit and explicit. *Id.* ¶ 15. Despite knowing that Theranos’ technology suffered from recurring accuracy and reliability problems, Defendants allegedly advertised the tests as accurate and reliable. *Id.* ¶¶ 16-17. Specifically, Defendants used materially false and misleading marketing materials and advertisements, and transmitted Theranos blood results that Defendants knew contained, or likely contained, inaccurate information. *Id.* ¶¶ 16-18. For instance, Theranos’ public website touted its lab’s ability to perform tests “quickly and accurately on samples as small as a single drop.” *Id.* ¶ 9. Defendants also allegedly provided patients with reports that contained or were likely to contain: (1) inaccurate and unreliable results; (2) improperly adjusted reference ranges defining a normal or healthy result for a given test; (3) improperly removed “critical” results, i.e., results suggesting a patient needed medical attention; and (4) results generated from improperly validated assays, further decreasing the reliability of those tests. *Id.* ¶ 17(C).

II. LEGAL STANDARD

Motions in limine are a “procedural mechanism to limit in advance testimony or evidence in a particular area.” *United States v. Heller*, 551 F.3d 1108, 1111 (9th Cir. 2009). Like other pretrial motions, motions in limine are “useful tools to resolve issues which would otherwise clutter up the trial.” *City of Pomona v. SQM N. Am. Corp.*, 866 F.3d 1060, 1070 (9th Cir. 2017). Accordingly, “a ruling on a motion in limine is essentially a preliminary opinion that falls entirely within the discretion of the district court.” *Id.*; see *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984) (explaining that a court may rule in limine “pursuant to the district court’s inherent authority to manage the course of trials”).

In many instances, however, rulings “should be deferred until trial, so that questions of foundation, relevancy, and potential prejudice may be resolved in proper context.” *United States v. Pac. Gas & Elec. Co.* (“PG&E”), 178 F. Supp. 3d 927, 941 (N.D. Cal. 2016). For example, in

order to exclude evidence on a motion in limine, “the evidence must be inadmissible on all potential grounds.” *McConnell v. Wal-Mart Stores, Inc.*, 995 F. Supp. 2d 1164, 1167 (D. Nev. 2014). Thus, denial of a motion in limine to exclude certain evidence does not mean that all evidence contemplated by the motion will be admitted, only that the court is unable to make a comprehensive ruling in advance of trial. *Id.* at 1168. Moreover, even if a district court does rule in limine, the court may “change its ruling at trial because testimony may bring facts to the district court’s attention that it did not anticipate at the time of its initial ruling.” *City of Pomona*, 866 F.3d at 1070; *see also Ohler v. United States*, 529 U.S. 753, 758 n.3 (2000) (“[I]n limine rulings are not binding on the trial judge, and the judge may always change his mind during the course of a trial.”).

A. Federal Rule of Evidence 401

Under Rule 401 of the Federal Rules of Evidence, evidence is relevant if “it has any tendency to make a fact more or less probable than it would be without the evidence . . . and the fact is of consequence in determining the action.” Fed. R. Evid. 401(a)-(b). “Relevancy simply requires that the evidence logically advance a material aspect of the party’s case.” *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188 (9th Cir. 2019) (internal quotations omitted).

B. Federal Rule of Evidence 403

Even if evidence is relevant, it must 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.” *Old Chief v. United States*, 519 U.S. 172, 180 (1997). “Unfair prejudice can result from evidence that makes it more likely for a juror ‘to defer to findings and determinations relevant to credibility made by an authoritative, professional factfinder rather than determine those issues for themselves.’” *United States v. Sine*, 493 F.3d 1021 (9th Cir. 1992).

C. Federal Rule of Evidence 802

Hearsay evidence is inadmissible unless otherwise provided for under a federal statute, the

Federal Rules of Evidence, or “other rules prescribed by the Supreme Court.” Fed. R. Evid. 802. Hearsay is a statement “the declarant does not make while testifying at the current trial or hearing” and which “a party offers in evidence to prove the truth of the matter asserted in the statement.” Fed. R. Evid. 801. “Hearsay within hearsay” is only admissible “if each part of the combined statements conforms with an exception to the rule.” Fed. R. Evid. 805.

III. HOLMES’S MOTIONS IN LIMINE AND RELATED GOVERNMENT MOTIONS

A. Holmes’s MIL to Exclude Evidence Concerning Wealth, Spending, And Lifestyle (Dkt. No. 567)

The Government argues that during her tenure as founder and Chief Executive Officer (“CEO”) of Theranos, Holmes engaged in a widespread fraudulent scheme to defraud investors and obtain money and property under false pretenses. In addition to amassing millions of dollars for the company, Holmes obtained significant personal benefits arising from her position. She received a generous salary, which allowed her to live a luxurious lifestyle replete with an expensive rental home, a luxury SUV, and assorted high-end merchandise. Decl. of Amy Mason Saharia in Supp. of Holmes’s Mot. to Strike Rule 404(b) Notice or, in the Alternative, Compel Adequate Rule 404(b) Disclosure, Dkt. No. 421-1, Ex. A at 9. Holmes also utilized company funds to pay for luxury travel and accommodations. *Id.* Additionally, she routinely assigned her personal assistant to non-company tasks, such as personal shopping and product returns. *Id.*

The Government argues these benefits extend to non-tangible experiences that enhanced Holmes’s status in society. *Id.* In particular, she was hailed as a visionary businesswoman in numerous publications. *Id.* This increased publicity allowed her to associate with “celebrities, dignitaries, and other wealthy and powerful individuals.” *Id.*

The Government seeks to introduce evidence of these tangible and non-tangible benefits to show Holmes’s motive, opportunity, intent, preparation, plan, knowledge, identity, consciousness of guilt, or absence of mistake or accident under Federal Rule of Evidence 404(b). Holmes moves to preclude the government from introducing this evidence on two grounds. *See* Holmes’s Mot. in Limine to Exclude Evidence Concerning Wealth, Spending and Lifestyle Under Rules 401-403

1 (“Holmes 567 Mot.”), Dkt. No. 567. First, Holmes argues this evidence is irrelevant to any fact of
 2 consequence in this proceeding. Fed. R. Evid. 401, 402. Second, even if deemed relevant,
 3 Holmes argues the probative value of this evidence is substantially outweighed by the prejudicial
 4 danger of misleading the jury to base their decision on improper basis, as well as confusing the
 5 issue and needlessly wasting the Court’s time. Fed. R. Evid. 403.

6 The issue of evidence of wealth, particularly lack thereof, “is something of an old chestnut
 7 in the law of evidence.” *United States v. Mitchell*, 172 F.3d 1104, 1108 (9th Cir. 1999). In
 8 *Mitchell*, the trial court admitted evidence of the defendant’s poverty to prove motive to commit a
 9 bank robbery. *Id.* The Ninth Circuit reversed because evidence of wealth or poverty without a
 10 nexus to an “inclination, desperation, or other evidence that the person was likely to commit the
 11 crime” is not relevant. *Id.* at 1109. Ultimately, the evidence must show “more than the mere fact
 12 that the defendant is poor.” *Id.* (quoting *United States v. Jackson*, 882 F.2d 1444, 1449 (9th Cir.
 13 1989) (upholding trial court’s admission of evidence of financial difficulty given the “unexplained
 14 and abrupt change in that status”)).

15 However, the force of *Mitchell*’s holding is diminished because “wealth evidence, unlike
 16 poverty evidence, does not entail the same risk of unfair prejudice.” *United States v. Flores*, 510
 17 F. App’x 594, 595 (9th Cir. 2013). As with evidence of poverty, evidence of wealth or lavish
 18 lifestyle is not admissible standing alone but may be admissible to prove motive, knowledge, or
 19 intent. *See United States v. Weygandt*, 681 F. App’x 630, 633 (9th Cir. 2017) (evidence of wealth
 20 admissible to show defendant could have purchased necessary equipment but chose not to in order
 21 to enhance wealth); *United States v. Reyes*, 660 F.3d 454, 464 (9th Cir. 2011) (evidence of gains
 22 from stock option backdating is admissible to permit “jury to draw a reasonable inference that
 23 [defendant] knew what he was doing”). Nonetheless, evidence of an individual’s lavish spending
 24 habits, without a connection to an individual’s participation in criminal activity, is irrelevant. *See*
 25 *United States v. Hatfield*, 685 F. Supp. 2d 320, 326 (E.D.N.Y. 2010) (“[I]t is irrelevant if
 26 [defendant] spent his fortune on lavish parties, instead of donating it to starving Malawian
 27 orphans.”).

Holmes argues that evidence regarding her wealth and lifestyle is irrelevant because it has no bearing on any fact of consequence. She notes the factual issues for the jury are whether she participated in (1) a scheme to defraud investors or paying patients, through (2) the use of wire, radio or television and with (3) a specific intent to defraud those investors and paying patients. Holmes 567 Mot. at 2. Holmes argues that the evidence of wealth and lavish lifestyle lack a “particularized connection to the alleged conduct.” Holmes Reply Br. In Supp. of Holmes’s 567 Mot. (“Holmes 567 Reply”), Dkt. No. 710, at 2. The Government contends that the evidence is relevant because it represents the fruit of Holmes’s fraudulent scheme. Gov’t Opp’n to Holmes’s 567 Mot. (“Gov’t 567 Opp’n”), Dkt. No. 663, at 2. Further, the accumulation of these items indicates that “she intended to defraud in order to obtain those benefits” and further motivated her “to continue and conceal her fraud.” *Id.*

The Government’s arguments come close to the impermissible use of evidence to show Holmes was wealthy and wished to become wealthier. On its face, this does not appear to have the requisite connection to the alleged conduct required under case law. Despite this shortcoming, the Government’s theory of relevance has some merit. As in *Reyes*, each time Holmes made an extravagant purchase, it is reasonable to infer that she knew her fraudulent activity allowed her to pay for those items. *See Reyes*, 660 F.3d at 464. While the benefits of these purchases are not as directly tied to the fraud as backdating stocks was in *Reyes*, it may still be probative of Holmes’s scienter. Therefore, this evidence passes the minimal threshold for relevance.

Nevertheless, the Court in its discretion “may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice.” Fed. R. Evid. 403. Unfair prejudice “speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged.” *Old Chief*, 519 U.S. at 180. In this particular context, evidence of Holmes’s wealth can be construed as “appeals to class prejudice” which are considered “highly improper” because they “may so poison the minds of jurors even in a strong case that an accused may be deprived of a fair trial.” *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 239–40 (1940). Appeals to class prejudice that

are “obvious” and “persistent” are unfairly prejudicial. *United States v. Stahl*, 616 F.2d 30, 32–33 (2d Cir. 1980) (discussing an overzealous prosecutor’s entire trial strategy centered on inflaming prejudice against the defendant’s wealth, readily apparent from the prosecutor’s opening argument, witness interrogation, and closing argument).

At the hearing, the Government indicated that Holmes’s desire to maintain her lifestyle as Theranos CEO and founder and all the accompanying celebrity and benefits (financial or otherwise) were motivating factors for her to continue to engage in the fraudulent conduct alleged in the indictment. The Government argues that its case does not center on a persistent appeal to class prejudice, as in *Stahl*, but rather that the desire for wealth is a piece in a complex puzzle comprising Holmes’s intent to perpetuate this broad-ranging fraud. However, this balance is complicated by the fact that the evidence of her wealth and fame is not highly (or even moderately) probative of intent to defraud. When one combines the fact that this case implicates potentially dangerous technology with an argument concerning an individual’s greed, jurors could easily “judge the merits of this matter by their attitudes about such things.” Holmes 567 Reply at 5.

The evidence of Holmes’s position as CEO and founder will undoubtedly be introduced at trial. As discussed at the hearing, it is common knowledge that CEOs and heads of Silicon Valley technology companies enjoy lifestyles commensurate with those positions that are significantly different than those of the general public. The Government may introduce evidence that Holmes enjoyed a lifestyle as Theranos CEO that is comparable to those of other tech company CEOs. This includes salary, travel, celebrity, and other perks and benefits commensurate with the position. However, references to specific purchases or details reflecting branding of clothing, hotels, or other personal items is not relevant, and the prejudicial effect of that evidence outweighs any probative value.

Based on the foregoing, the Court **GRANTS IN PART** Holmes’s MIL to exclude evidence referencing her wealth, spending, and lifestyle that is outside the general nature of her position as Theranos CEO. As noted at the hearing, the Court may revisit this ruling should

1 circumstances warrant.

2 **B. Holmes’s MIL to Exclude FDA Inspection Evidence (Dkt. No. 573)**

3 In August of 2013, “Theranos contacted [the] FDA (the Food and Drug Administration)
4 with a proposal to submit for FDA clearance the [laboratory developed tests] that would be run on
5 Theranos’ proprietary devices in its . . . laboratory.” Holmes’s Mot. in Limine to Exclude FDA
6 Inspection Evidence Under Rules 401-404 and 801-803 (“Holmes 573 Mot.”), Dkt. No. 573, at 2.
7 By the winter of 2013, “Theranos and [the] FDA agreed to a submission plan to accomplish that
8 goal.” *Id.* One aspect of this plan concerned Theranos’ nanotainer. *See id.* On August 25, 2015,
9 “FDA conducted unannounced inspections at Theranos’ laboratories in California and Arizona.”
10 *Id.* These inspections partly focused on making sure the nanotainers were properly classified and
11 identifying whether certain regulations applied to them. *Id.* at 3. The FDA ceased its inspection
12 of Theranos’ Arizona lab “without making any observations, but continued its inspection of the
13 California laboratory until September 16, 2015.” *Id.* at 2–3.

14 Holmes now moves to exclude “evidence of or reference to, [the FDA’s] 2015 inspections
15 of Theranos.” *Id.* at 1. Holmes’s motion refers specifically to 27 exhibits that “relate to FDA’s
16 inspections,” and that were “identified by the Government . . . as proposed exhibits.” *Id.* at 3.
17 These exhibits (“the FDA inspection evidence”) encompass the documented observations of the
18 FDA (Forms 483),¹ internal emails among FDA agents, and records of communications between
19 Holmes and Ramesh “Sunny” Balwani made during and about the FDA inspection. *Id.* at 1–4.
20 Holmes argues that “[t]hese documents should be excluded along with any corresponding
21 testimony offered by the government.”² *Id.* at 3–4.

22
23 ¹ In her motion, Holmes explains Forms 483 by referencing a website, “FDA Form 483 Frequently
24 Asked Questions,” [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions)
25 [investigations/inspection-references/fda-form-483-frequently-asked-questions](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions). *See* Holmes 573
26 Mot. at 3, n.6. This website states, among other things, the following: “An FDA Form 483 is
issued to firm management at the conclusion of an inspection when an investigator(s) has
observed any conditions that in their judgment may constitute violations of the Food Drug and
Cosmetic (FD&C) Act and related Acts.

27 ² Holmes specifically mentions that “the [G]overnment has indicated that it intends to elicit
28 testimony from FDA’s Director of Chemistry and Toxicology Devices, Dr. Courtney Lias, during
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Holmes argues that the FDA inspection evidence should be excluded for four reasons: it is not relevant; it is unfairly prejudicial under Rule 403; it is inadmissible character and propensity evidence, under Rule 404; and it is inadmissible hearsay.

1. Relevance

The Court finds that evidence arising out of the FDA inspection of the Theranos lab in California is relevant as to Holmes's state of mind, intent, and knowledge regarding the alleged misrepresentations about the accuracy and reliability of Theranos' blood tests. The FDA inspection evidence would have a tendency to show knowledge of issues with the nanotainer and failings in Theranos' technology. This, in turn, could support the Government's theory of the case: that Holmes made representations that Theranos could provide accurate, fast, reliable, and cheap blood tests and test results despite knowing that their technology was not capable of doing so.

Holmes asserts several reasons why the FDA inspection evidence is irrelevant. Holmes 573 Mot. at 5–6. For example, Holmes asserts that the last equity round closed before the inspection took place, and therefore, the FDA inspection evidence could not have informed her knowledge, state of mind, or motive at the time of the alleged misstatements to investors. Holmes further argues that the FDA inspection evidence does not prove FDA approvals or clearances for any Theranos product were, in fact, required. Holmes also suggests that the FDA inspection pertained primarily to nanotainers, whereas the FDA-related allegation in the indictment refers to Theranos' proprietary analyzer and tests. More generally, Holmes states that the FDA inspection is too limited in scope because, for example, "[t]he FDA inspectors made no findings regarding the performance of Theranos' laboratory or the accuracy and reliability of Theranos' blood tests." Holmes's Reply Br. in Supp. of Holmes 573 Mot. ("Holmes 573 Reply"), Dkt. No. 716, at 3. In the end, however, the Federal Rules of Evidence set a low bar for relevance. *See* Fed. R. Evid. 401 (defining "relevant evidence" as "evidence having any tendency to make the existence of any

the case in chief." Holmes 573 Mot. at 4.
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fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence”). “[T]he requirements of Federal Rule of Evidence 401 are not especially stringent.” *Rios v. Tilton*, No. 2:07-cv-0790 KJN P, 2016 WL 29567, at *6 (E.D. Cal. Jan. 4, 2016) (citing *Slaughter-Payne v. Shinseki*, 522 F. A’ppx 409, 410 (9th Cir. 2013) (noting the “low bar for relevancy under Federal Rule of Evidence 401.”)); *see also United States v. Miranda-Uriarte*, 649 F.2d 1345, 1353 (9th Cir. 1981) (same); *Sandoval v. Cty. of San Diego*, 985 F.3d 657, 666 (9th Cir. 2021) (same).

2. Unfair prejudice

Holmes argues that admitting the FDA inspection evidence would be unfairly prejudicial. According to Holmes, admitting such evidence presents a risk that the jury would perceive the FDA’s unannounced inspections of Theranos and the technical and purportedly authoritative forms and communications arising out of those inspections as indicative of guilt. Holmes cites as analogs *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 673 (5th Cir. 1999) (holding that Mississippi Department of Environmental Quality evidence was properly excluded, in part, because “[that agency’s] evidence of likely violations of environmental regulations would have been unduly prejudicial due to its apparent official nature”), and *Smith v. I-Flow Corp.*, No. 09 C 3908, 2011 WL 12627557, at *2 (N.D. Ill. June 15, 2011) (holding that an FDA warning letter was to be excluded as unfairly prejudicial). Holmes 573 Mot. at 7. These cases are unhelpful. In *Curtis*, the primary basis for evidence exclusion was that the evidence was cumulative, and *Smith* lacks a meaningful analysis.

Having weighed the risk of unfair prejudice against the probative value of the evidence, the Court finds that the evidence is more probative than prejudicial. The nature and scope of inspections can be explored through witness testimony to provide information and context of the process.

3. Inadmissible character and propensity evidence

Holmes next argues that the FDA inspection evidence should be excluded per Rule 404. Holmes is concerned that the Government will proffer evidence of purported pushback by

1 Theranos personnel on FDA's tactics and theories during the inspection as improper propensity
2 evidence against Holmes.

3 The Court finds that the FDA inspection evidence is not propensity evidence, but rather
4 evidence that is probative of Holmes's state of mind, intent, and knowledge. Specifically, the
5 evidence has a tendency to show Holmes' state of mind regarding Theranos' interactions with the
6 regulatory agencies, the extent to which Holmes knew or should have known that Theranos was
7 failing to meet certain federal regulations, and whether Holmes intended to mislead investors
8 regarding the accuracy and reliability of Theranos' technology. The Court declines to exclude the
9 evidence on Rule 404 grounds at this time.

10 **4. Inadmissible hearsay**

11 Holmes also argues that the FDA inspection evidence is inadmissible hearsay.
12 Specifically, Holmes relies on Rule 803(8)(A)(iii), which provides that public records that contain
13 factual findings from legally authorized investigations are admissible only "in a civil case or
14 against the government in a criminal case." Fed. R. Evid. 803(8)(A)(iii). Citing *United States v.*
15 *Orellana-Blanco*, 294 F.3d 1143, 1149 (9th Cir. 2002), Holmes argues that because the FDA
16 inspection evidence constitutes public records prepared by a government agency and because the
17 evidence is not being used in a civil case or against the government in a criminal case, the
18 evidence is inadmissible. Holmes 573 Mot. at 8.

19 In opposition, the Government looks to Rule 803(8)(A)(ii), which states that the rule
20 against hearsay does not exclude "[a] record or statement of a public official . . . [setting out] a
21 matter observed while under a legal duty to report, but not including, in a criminal case, a matter
22 observed by law-enforcement personnel." Fed. R. Evid. 803(8)(A)(ii).

23 The Court finds the FDA inspection was a "matter observed while under a legal duty to
24 report." Fed. R. Evid. 803(8)(A)(ii); *see, e.g., United States v. Fryberg*, 854 F.3d 1126, 1131 (9th
25 Cir. 2017) (holding that "[t]he pertinent question [as to what is a 'matter observed while under a
26 legal duty to report'] is whether the creation and maintenance of the record at issue is appropriate
27 to the function of the relevant government office, given the nature of the responsibilities assigned

to that office” (internal citations omitted)). The FDA’s inspection report consists largely of observations and, in that sense, is comparable to reports prepared by non-law enforcement civil government employees such as city building inspectors, medical examiners, and prison case managers. *See, e.g., United States v. Hansen*, 583 F.2d 325, 333 (7th Cir. 1978) (building inspectors enforcing building code did not qualify as law enforcement personnel under Rule 803(8)(A)(ii)); *United States v. Rosa*, 11 F.3d 315 (2d Cir. 1993) (medical examiners required to investigate unnatural deaths and to refer situations indicating criminality to a district attorney did not qualify as law enforcement personnel under Rule 803(8)(A)(ii)); *Manocchio v. Moran*, 919 F.2d 770, 777 (1st Cir. 1990) (medical examiner’s autopsy report should not be excluded under Rule 803(8)(A)(ii)); *United States v. Edelmann*, 458 F.3d 791, 813–14 (8th Cir. 2006) (report made by an inmate systems manager should not be excluded under Rule 803(8)(A)(ii) because the manager was not law enforcement personnel and the report was produced in the normal course of duties). There are portions of the report that go beyond mere observations and include some level of analysis by FDA inspectors; however, those portions comprise only a minor portion of the report. As noted below, the Court is open to continued discussions on this issue should Holmes wish to raise arguments to certain specific pieces of evidence within the FDA inspection evidence that involve such a high degree of observer analysis that they might not be admissible under Rule 803(8)(A)(ii).³

Holmes argues that even if Rule 803(8)(A)(ii) applies, the FDA inspectors were acting as law enforcement personnel because the inspection was unannounced, the FDA has the power to levy criminal sanctions (including terms of imprisonment), and “[t]he [G]overnment’s case agent for this prosecution is a Special Agent in FDA’s Office of Criminal Investigations.” Holmes Reply at 5–9. Holmes argues that the FDA is similar to the IRS, which the Second Circuit has described as having a “law enforcement function. *Id.* at 7 (citing *United States v. Ruffin*, 575 F.2d

³ Holmes’s reply brief inaccurately represents the holding of *United States v. Cerda-Ramirez*, 730 F. App’x 449, 452 (9th Cir. 2018). Holmes 573 Reply at 8. The Ninth Circuit’s decision hinged at least partly on the presence of an adversarial setting, and not solely on whether an independent judgment was made by the observer. *See Cerda-Ramirez*, 730 F. App’x at 452.

1 346, 356 (2d Cir. 1978)).

2 For the purposes of determining whether the FDA inspectors acted as law enforcement
3 personnel, the Court applies the case law of the Ninth Circuit and finds that the FDA inspectors
4 did not act as law enforcement personnel. Under the Ninth Circuit’s “narrow understanding of the
5 law enforcement exception [of Rule 803(8)(A)(ii)],” “the purpose of the law enforcement
6 exception is to exclude observations made by officials at the scene of the crime or apprehension,
7 because observations made in an adversarial setting are less reliable than observations made by
8 public officials in other situations.” *Fryberg*, 854 F.3d at 1132 (citations omitted). The FDA
9 inspectors, in carrying out their duties of inspecting the Theranos lab, do not appear to have been
10 making observations in an adversarial setting that raises doubts about the reliability of the
11 observations. *Compare id. with Ruffin*, 575 F.2d 346 (Second Circuit applied a relatively
12 expansive reading of the ‘law-enforcement personnel’ exclusion of Rule 803(8)(A)(ii)).

13 The FDA’s inspection appears to have been at least to some extent unannounced, and in
14 oral arguments before the court, the two parties presented differing accounts as to whether the
15 inspection is more properly characterized as having been part of a for-cause reactionary process
16 prompted by complaints and/or concerns regarding Theranos, or as part of a routine process that
17 Theranos itself requested. May 5, 2021 Hr’g Tr., Dkt. 793, at 104:22-23 (“Mr. Looby (for
18 Holmes): This [was] a for[-]cause inspection that was initiated by the FDA and [was] actually
19 more or less unannounced.”); *but see id.* at 118:14–120:3 (“The Court: So I asked Mr. Looby
20 (Counsel for Holmes) a question about the timing of this inspection and whether it was a request
21 or . . . voluntary. And I think he said no, it was not [voluntary]. . . . Didn’t Theranos . . . seek
22 approval from the FDA in 2013 and then there was – between 2013 and 2015 obviously there
23 were, I presume, some conversations [between Theranos and the FDA], and then ultimately
24 unannounced the FDA shows up to do the inspection for that request I suppose for certification. Is
25 that the event here? Mr. Leach (for the Government): That is largely correct, Your Honor. . . .
26 There was a dialogue between Theranos and the FDA throughout 2013 and 2014. The 2015
27 inspection is unannounced. The Court: Was [the FDA’s] showing up [at the Theranos laboratory],

1 it sounds like it was connected to [Theranos'] original request to approve [Theranos'] device. Mr.
 2 Leach: I guess that's a fair inference, Your Honor.")). Nevertheless, the inspectors who carried
 3 out the inspection were not part of a criminal division of the FDA. While the atmosphere at the
 4 California laboratory during the inspections may have been contentious, and while there may have
 5 been the latent threat of sanctions given the regulatory nature of the FDA, the collection of the
 6 FDA inspection evidence is more like the routine, ministerial work of the recording of the license
 7 plates in *United States v. Orozco*, 590 F.2d 789 (9th Cir. 1979), and less like the adversarial work
 8 of the administering of the immigration interview in *Orellana-Blanco*, or the filing of the criminal
 9 complaint and affidavit in *Cerda-Ramirez*.

10 Lastly, Holmes's Rule 803(8)(B) argument is undeveloped and unsupported. For the
 11 reasons given above, the Court declines to exclude the FDA inspection evidence on hearsay
 12 grounds at this time.

13 The motion to exclude FDA inspection evidence is **DEFERRED**. The Court
 14 acknowledges the possibility for further side bar discussions on this matter, should Holmes wish to
 15 specify certain exhibits within this collection of evidence and make new arguments as to why
 16 these particular exhibits should still be excluded.

17 **C. Holmes's MIL to Exclude Evidence of CMS Survey Findings and Sanctions**
 18 **(Dkt. No. 574)**

19 CMS "audits laboratories to identify non-compliance with [the mandates of the Clinical
 20 Laboratory Improvement Amendments of 1988 ('CLIA')]." Holmes's Mot. in Limine to Exclude
 21 Evidence of CMS Survey Finding and Sanctions Pursuant to Rules 401-403 and 801-803
 22 ("Holmes 574 Mot."), Dkt. No. 574, at 1–2. Because Theranos "perform[ed] clinical diagnostic
 23 testing on human samples," its laboratories were required to be in compliance with CLIA. *Id.* at 1.
 24 In September and November 2015, CMS conducted a recertification and complaint survey of
 25 Theranos' Newark lab. *Id.* at 2. According to Holmes, usually a state agency carries out
 26 recertification surveys, but in this case CMS decided to carry out the survey "due to the media
 27 attention Theranos was receiving at the time and due to complaints CMS had received about

Theranos.”⁴ *Id.* at 2 (citing Saharia Decl., Ex. 34, Dkt. No. 584 at 2-3). Holmes suggests “[i]t was unusual for CMS both to conduct the survey and to send ‘central office personnel . . . out on the Theranos survey.’” *Id.* (citing Saharia Decl., Ex. 34, Dkt. No. at 3).

On January 25, 2016, CMS issued a letter and a Form 2567 summarizing the findings of the survey. *Id.* These documents stated that “Theranos’ California laboratory was in violation of various CLIA requirements,” and “warned Theranos that if it did not remediate these deficiencies within 10 days, CMS would impose sanctions.” *Id.* at 3. Subsequently, Theranos and CMS engaged in communications that included Theranos’ “outlin[ing] steps it was taking to resolve CMS’s claimed deficiencies.” *Id.* (citing Saharia Decl., Ex. 27, Dkt. No. 583-1 at 2). CMS did impose sanctions on Theranos’ Newark laboratory. *Id.* (citing Saharia Decl., Ex. 30, Dkt. No. 583-4). Shortly thereafter, CMS surveyed Theranos’ Arizona laboratory, cited it for various CLIA violations and imposed sanctions. *Id.* (citing Saharia Decl., Exs. 31-33, Dkt. No. 584-1, 584-2). Theranos appealed both sets of sanctions, but Theranos and CMS made settlements before the adjudication of these appeals.⁵ *Id.*

Holmes moves to exclude “evidence relating to the findings of surveys of Theranos’ clinical laboratories conducted by [CMS] in 2015 and 2016, including survey findings and sanctions imposed by CMS.” Holmes 574 Mot. at 1. Holmes argues that the evidence of CMS survey findings and sanctions should be excluded as irrelevant, unfairly prejudicial, and inadmissible hearsay.

Relatedly, the Government moves to include “CMS’[s] January 26, 2016 Form CMS-2567, Statement of Deficiencies.” United States’ Mots. In Limine (“Gov’t Mot.”) at 8-10, Dkt. No. 588. The Government argues that the January 26, 2016 Form CMS-2567, Statement of Deficiencies—which appears to fall within the set of CMS evidence Holmes moves to exclude—should be

⁴ Holmes suggests that, in making this decision, CMS may have been influenced by Wall Street Reporter John Carreyrou. Dkt. No. 574 at 2, n. 1 (citing Saharia Decl., Ex. 34 at 3).

⁵ Evidence regarding these settlements and “the remedial measures that Theranos . . . adopted in response to the CMS survey findings” are the subjects of a separate motion(s) to exclude evidence. Dkt. No. 574 at 3, n. 1.

1 admitted for reasons that overlap with the arguments provided in the Government's opposition to
2 Holmes's motion to exclude the CMS survey. *See* Gov't Opp'n to Holmes 675 Mot. ("Gov't 574
3 Opp'n"), Dkt. No. 675. Accordingly, the Court will focus on the arguments both parties made
4 regarding Holmes's motion to exclude the evidence of CMS survey findings and sanctions. The
5 outcome of this analysis is also determinative of the arguments pertaining to the Government's
6 MIL No. 6 to admit the January 2016 CMS form.

7 **1. Relevance**

8 The Court finds that the evidence of CMS survey findings and sanctions meets Rule 401's
9 low bar for relevancy. Although the purpose of the CMS survey was not to assess either the
10 accuracy or reliability of Theranos technology, the CMS survey findings and sanctions indicate
11 violations of federal regulations that themselves are meant to ensure, among other things, the
12 accuracy and reliability of certain kinds of clinical laboratory work. The evidence therefore
13 appears to be relevant to questions about Holmes's state of mind, intent, and knowledge regarding
14 the alleged misrepresentations about the accuracy and reliability of Theranos' blood tests.

15 Holmes cites *PG&E*, where a court found that a report by the National Transportation
16 Safety Board was inadmissible in an action against a company because, even though the report
17 noted regulatory violations made by the company, the report did not pertain to the allegations
18 against the company. 178 F. Supp. 3d 927 (N.D. Cal. 2016). That case, however, is
19 distinguishable for the reasons the Government articulates. In *PG&E*, the court excluded a report
20 about a company's culpability for causing an explosion because the company's alleged obstruction
21 of the investigation was at issue, not the explosion. *Id.* at 947–48. Whereas a report about a
22 company's role in causing an explosion may not be relevant to that company's alleged obstruction
23 of an investigation, a report indicating a company's CLIA violations may be relevant to that
24 company's alleged misrepresentations of the accuracy and reliability of its products.

25 Holmes also argues that the evidence of CMS survey findings and sanctions cannot be
26 used to show her intent for alleged actions that occurred prior to the CMS surveys, because there
27 is no showing that she was aware of the information in the reports. The argument misconstrues

the Government's point. The Government is not arguing that Holmes's actual knowledge of the evidence of CMS survey findings and sanctions indicates that Holmes must have known she was participating in a fraudulent scheme. The Government is instead arguing that the evidence tends to show Holmes's state of mind, knowledge, and intent regarding her representations to investors regarding the accuracy and reliability of Theranos' technology.

2. Unfair prejudice

Holmes argues that the evidence of CMS survey findings and sanctions is unfairly prejudicial, raising the same points she stated to argue relevancy, which the Court will not revisit here. Holmes makes the additional argument that the potential for unfair prejudice is great primarily because (1) the jury will put special weight on the CMS survey findings and (2) 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. Holmes is particularly concerned with the Government's repeated references to the CMS's finding of "immediate jeopardy." Holmes cites to *United States v. Wolf*, 820 F.2d 1499, 1504 (9th Cir. 1987), *United States v. White Eagle*, 721 F.3d 1108, 1114 (9th Cir. 2013), *United States v. Christo*, 614 F.2d 486, 492 (5th Cir. 1980), and *United States v. Riddle*, 103 F.3d 423, 431 (5th Cir. 1997).

The Court does not see that the evidence in question raises the same kind of unfair prejudice concerns indicated in *Wolf*, *White Eagle*, and *Christo*. In each of these cases except *Riddle*, the courts found Rule 403 violations when parties relied on evidence of violations of civil regulations to prove similar criminal violations. Here, the Government is attempting to introduce evidence of violations of civil regulations for the purposes of showing Holmes's state of mind, intent, and knowledge, not for the purpose of arguing that Holmes is guilty of committing a criminal violation parallel to the civil violations indicated by the CMS survey findings and sanctions. *Riddle* is inapposite because in that case the court found that the evidence in question was largely irrelevant to the charges brought. 103 F.3d at 431. Having weighed the risk of unfair prejudice against the probative value of the evidence, the Court at this time finds that the evidence is more probative than prejudicial.

3. Inadmissible hearsay

Holmes argues that evidence of CMS survey findings and sanctions is hearsay. Holmes's arguments are effectively the same hearsay arguments made with respect to the FDA inspection evidence, and the Court will not address them again here.⁶ *See supra* Section III.B. Holmes relies on an additional case, *United States v. Murgio*, No. 15-cr-769(AJN), 2017 WL 365496, at *7, 9 (S.D.N.Y. Jan. 20, 2017), in support of her hearsay objection; however, the case is distinguishable. In *Murgio*, the court found that the evidence alleged to be hearsay not only included legal conclusions and evaluative conclusions, but also was itself based partially on evidence not directly observed by the relevant public agency. *See id.* at *9–10 (“[T]he Government itself admits that the findings in the [evidence alleged to be inadmissible hearsay] are based upon (1) the [agency’s] own observations and records gathered during the course of [the] examinations . . . and (2) the [agency’s] independent evaluation of evidence gathered in the criminal investigation, which the Government supplied to the [agency].” (internal quotation marks removed)). Moreover, *Murgio* appears to follow the Second Circuit’s relatively expansive reading of the ‘law-enforcement personnel’ exclusion of Rule 803(8)(A)(ii), which contrasts with the Ninth Circuit’s more narrow reading. *Compare Ruffin*, 575 F.2d at 356 with *Fryberg*, 854 F.3d at 1132.

For the reasons given above, the Court **DENIES** Holmes’s motion to exclude the evidence arising out of the CMS surveys in question. The Court **GRANTS** the Government’s motion to admit the January 26, 2016 Form CMS-2567, Statement of Deficiencies. The Court acknowledges the possibility for further side bar discussions on this matter, should parties wish to specify certain exhibits within this collection of evidence and make new arguments as to why these particular exhibits should still be excluded.

⁶ Holmes raises one additional argument: that the Evidence of CMS Survey Findings and Sanctions itself contains out-of-court statements made by Theranos personnel that are inadmissible hearsay within hearsay. In response, the Government argues that the statements by Theranos employees that were included in CMS’s Form 2567 report are not inadmissible hearsay because the statements were authorized admissions and statements of an agent or employee within the meaning of Federal Rule of Evidence 801(d)(2). This argument is addressed later in the context of the Government’s MIL No. 8.

D. Holmes’s MIL to Exclude Evidence Relating to Theranos’ Interactions with Government Regulatory Agencies (Dkt. No. 575)

Holmes moves to exclude certain evidence relating to Theranos’ interactions with government agencies. Holmes’s Mot. in Limine to Exclude Certain Evidence Relating to Theranos’ Interactions with Government Regulatory Agencies Under Rules 401-404 and 801-803 (“Holmes 575 Mot.”), Dkt. No. 575, at 1. Specifically, she seeks to exclude three categories of evidence involving two agencies over a period of two years: (1) an on-site inspection performed by the California Department of Public Health (“CDPH”) in December 2013; (2) interactions between Theranos representatives and the Centers for Medicare & Medicaid Studies (“CMS”) in September 2015; and (3) Theranos’ decision to employ a CMS-qualified laboratory director, Dr. Sunil Dhawan, in 2014 and 2015. *Id.* Holmes also refers to a fourth category of evidence that includes unidentified evidence of representations made by Theranos to other regulatory organizations. *See id.* at 16. The Court addresses each category in turn.

1. Evidence relating to the December 2014 CDPH inspection

Under the Clinical Laboratory Improvement Amendments Act of 1988 (“CLIA”), 42 U.S.C. § 263a, CMS regulates all laboratory testing performed on human samples in the United States. Holmes 575 Mot. at 2. CMS deputizes certain accreditation responsibilities to qualified state agencies—in California, the CDPH’s Laboratory Field Services section is responsible for accreditation and compliance of CLIA-certified laboratories. *Id.* As part of the accreditation and compliance process, CDPH generally performs biennial onsite inspections for CLIA laboratories in California. *Id.*

In December 2013, CDPH inspected a Theranos laboratory. *See id.* at 5. Pursuant to this inspection, CDPH produced a report that identified three deficiencies, which the Government seeks to introduce this report as evidence probative of Holmes’s state of mind, intent, and knowledge regarding the status of Theranos’ laboratories and technology. *Id.* (citing Decl. of Amy Saharia in Support of Holmes’s Mots. in Limine and *Daubert* Mots. to Exclude Expert Testimony (“Saharia Decl.”), Dkt. No. 579, Ex. 2 at 12–13 (Apr. 3, 2020 Gov’t Supp. Rule 404(b) Notice)). The Government also seeks to introduce (1) an FBI report summarizing an interview of

1 a Theranos CLIA lab employee, and (2) an email from Theranos employee Daniel Young to then-
 2 laboratory director Adam Rosendorff. *Id.* (citing Saharia Decl., Ex. 3 at 13, 65). The Government
 3 seeks to introduce this memorandum and email as evidence probative of Holmes’s state of mind,
 4 intent, and knowledge, under the theory that the memorandum and email show that Balwani and
 5 others “misled an inspector into believing that the Theranos CLIA laboratory was limited to a
 6 single area.” *Id.* (citing Saharia Decl., Ex. 1 at 7 (Mar. 6, 2020 Gov’t Rule 404(b) Notice)).

7 Holmes argues that the CDPH inspection evidence should be excluded as irrelevant under
 8 Rules 401 and 402, as unfairly prejudicial under Rule 403, as improper propensity evidence under
 9 Rule 404, and inadmissible hearsay.

10 **a. Relevance**

11 Holmes argues the evidence is irrelevant for four reasons. First, she argues the CDPH
 12 report does not indicate that Holmes made misrepresentations about Theranos’ ability to provide
 13 accurate and reliable results. Holmes 575 Mot. at 6. Second, Holmes contends the CDPH
 14 inspection findings do not tend to show that Theranos was unable to provide accurate and reliable
 15 results. *Id.* (citing Saharia Decl., Ex. 3 at 65). Third, Holmes says the Government has not
 16 sufficiently shown that the alleged misleading of the CDPH inspector amounted to a false
 17 representation, or that Holmes had sufficient knowledge or intent regarding that incident. *Id.* at 7–
 18 8. Fourth, Holmes contends that “the evidence relating to . . . Balwani’s supposed directions to
 19 staff [allegedly misleading the CDPH inspector] does not bear on the accuracy and reliability of
 20 Theranos’ test results,” suggesting that any directions regarding where to lead an inspector may
 21 have been made for legitimate and regulation-compliant reasons, such as avoiding the disruption
 22 of lab work. *Id.* at 8–9.

23 Holmes’s arguments go to the weight of the evidence, not admissibility. The Court finds
 24 that the CDPH inspection evidence is relevant under Rule 401. The CDPH report appears to
 25 indicate violations of federal regulations that themselves are meant to ensure, among other things,
 26 the accuracy and reliability of certain kinds of clinical laboratory work. The fact that the CDPH
 27 later noted that the violations had been addressed satisfactorily does not negate the report’s

1 probative value regarding Holmes's state of mind, intent, and knowledge as to the accuracy and
 2 reliability of Theranos' laboratory procedures and blood tests. The FBI memorandum and
 3 Young's email also appear relevant to and probative of her knowledge, intent, notice, and absence
 4 of mistake regarding the status and capabilities of Theranos' laboratories and technology.
 5 Holmes's position at Theranos and her pre-inspection communications with Young connect her to
 6 the email.

7 **b. Unfair prejudice**

8 Holmes argues that the CDPH inspection evidence is unfairly prejudicial under Rule 403
 9 because it may give the jurors the "misimpression that the laboratory was unsafe" or confuse the
 10 jurors with "industry-specific jargon." Holmes 575 Mot. at 9–10. In particular, she says that
 11 without an expert witness to properly interpret and contextualize the report, the jury would
 12 "overestimate its probative value by equating regulatory citations with proof of fraud"
 13 Holmes Reply Br. in Supp. of Holmes's 575 Mot. ("Holmes 575 Reply"), Dkt. No. 718, at 9–10.
 14 Holmes relies on *United States v. Riddle*, in which the Fifth Circuit held that the district court
 15 erred in permitting extensive evidence about a federal regulator's appraisal of a bank's general
 16 health and its failure to comply with regulations. 103 F.3d 423, 431 (5th Cir. 1997).

17 The Court finds that the evidence in question does not raise the same unfair prejudice
 18 concerns indicated in *Riddle*. In that case the court found that the evidence in question was largely
 19 irrelevant to the charges brought. *See id.* As described above, the Court has determined that the
 20 CDPH report is relevant. While the CDPH report may contain technical information that may be
 21 difficult for jurors to interpret, such a challenge is unavoidable in a case involving purportedly
 22 innovative and advanced technology. Having weighed the risk of unfair prejudice against the
 23 probative value of the evidence, the Court at this time finds the CDPH inspection evidence is more
 24 probative than prejudicial. The parties will have the opportunity to examine and cross-examine
 25 witnesses to clarify and assist the jury in understanding the evidence.

26 **c. Inadmissible character and propensity evidence**

27 Holmes argues that the CDPH inspection evidence should be excluded under Rule 404.

1 See Holmes 575 Mot. at 10. She references Rule 401 arguments, suggesting that “[t]he
2 [G]overnment’s theory of relevance hinges on propensity: the notion that, because others at
3 Theranos allegedly misled CDPH officials in December 2013, [Holmes] is more likely to have
4 possessed the specific intent to defraud investors and patients as alleged in the indictment.” *Id.*
5 Holmes contends that the evidence in question does not qualify as “inextricably intertwined” with
6 the charged crime under the Ninth Circuit’s interpretation of the concept as articulated in *United*
7 *States v. Vizcarra-Martinez*, 66 F.3d 1006 (9th Cir. 1995). Dkt. No. 718 at 5 (citing *Vizcarra-*
8 *Martinez*, 66 F.3d at 1012–13). Instead, she argues more generally that the evidence in question is
9 “classic other-acts evidence that should be excluded as irrelevant or unfairly prejudicial.” *Id.*

10 Assuming without deciding that the CDPH inspection evidence does not meet the Ninth
11 Circuit’s interpretation of the term “inextricably intertwined” with the charged crime, the evidence
12 as described nevertheless appears probative of Holmes’s intent, state of mind, and knowledge.
13 Specifically, the evidence has a tendency to show her state of mind regarding Theranos’
14 interactions with regulatory agencies, the extent to which she knew or should have known that
15 Theranos was failing to meet certain federal regulations, and whether she intended to mislead
16 investors regarding the accuracy and reliability of Theranos’ technology. The Court therefore
17 declines to exclude the evidence on Rule 404 grounds at this time.

18 **d. Inadmissible hearsay**

19 Holmes argues that the CDPH inspection evidence is inadmissible hearsay in violation of
20 Rule 803(8), as the report constitutes “factual findings from a legally authorized investigation” and
21 it is not being used in a civil case or against the government in a criminal case. Holmes 575 Mot.
22 at 10–11. This argument is effectively the same hearsay argument Holmes made in her motions in
23 limine concerning FDA inspection evidence and evidence of CMS survey findings and sanctions.
24 Holmes 573 Mot.; Holmes 574 Mot.

25 The Court declines to exclude the CDPH inspection evidence on hearsay grounds at this
26 time for the same reasons it denied Holmes’s MILs to exclude FDA inspection evidence and
27 evidence of CMS survey findings and sanctions. See *supra* Section III.B, C. The evidence in

question appears to be objective observations, rather than the factual findings of an investigation. The CDPH inspector, in carrying out the duties of inspecting the Theranos lab, did not make observations in an adversarial setting that raises doubts about the reliability of the observations. The inspector who carried out the inspection was not part of a criminal division of the CDPH. The collection of the CDPH inspection evidence appears to have been routine, ministerial, and non-adversarial. *See Orellana-Blanco*, 294 F.3d at 1150.

Moreover, as explained in the Court's ruling on the Government's MIL No. 8, *see infra* Section IV.H, the Court sees insufficient reason at this time to exclude the statements of Theranos employees captured within or in response to the CDPH report. The statements as described satisfy Federal Rule of Evidence 801(d)(2).

2. Evidence relating to Theranos' September 2015 communications with CMS

In September 2015, Theranos provided to CMS a document ("the CMS Letter") stating that the company's decision to use different devices in its CLIA laboratory "does not reflect on the reliability or accuracy of any platform." Holmes 575 Mot. at 11 (citing Saharia Decl., Ex. 3 at 64). The Government seeks to introduce this letter as Rule 404(b) evidence indicating an "intent to defraud" and "consciousness that full regulatory scrutiny would expose that Theranos' [proprietary device] was unable to provide accurate and reliable test results." *Id.* (citing Saharia Decl., Ex. 3 at 65); *see also* Gov't Opp'n to Holmes's 576 Mot. ("Gov't 575 Opp'n"), Dkt. No. 677, at 14. Holmes contends that the CMS Letter is irrelevant, unfairly prejudicial under Rule 403, and introduced for improper propensity arguments. Holmes 575 Mot. at 11–12.

a. Relevance

Holmes argues that the CMS Letter is irrelevant for two reasons. Holmes 575 Mot. at 11–12. First, she says that the Government has not connected her to the statement in the CMS Letter. *Id.* at 11–12. Second, Holmes contends that the Government has not shown that the CMS Letter evinces an intent to defraud or consciousness of guilt, but rather may indicate only negligence or some other "less culpable mental state." *Id.* at 12. In response, the Government points to evidence that Holmes monitored and directed Theranos' responses to the CMS survey. Gov't 575

1 Opp'n at 13–14 (citing Dkt. No. 596 at THER-2566768–769). The Government asserts that the
2 CMS Letter is “an admission that Theranos was not even using its blood analyzer at the time of
3 the [CMS] survey,” which tended to show that the technology was not as Holmes claimed it was
4 to investors and that Theranos could not consistently produce accurate and reliable tests. *Id.*

5 The Court finds that the CMS Letter meets Rule 401's low bar for relevance. Holmes's
6 communications with Theranos employees and her involvement in the inspection process
7 sufficiently links her to the CMS Letter, such that the CMS Letter is probative of Holmes's state
8 of mind, knowledge, intent, and lack of mistake regarding the alleged misrepresentation of the
9 accuracy and reliability of Theranos' technology. The CMS Letter also appears relevant for its
10 truth—that is, it is relevant because it indicates the nature and extent of Theranos' use of its
11 analyzer, a piece of technology about which Holmes made various representations. The Court
12 agrees with the Government that *Miller* and *Brown* are inapposite. For the purposes of
13 determining the relevancy of the CMS Letter, it is not necessary for the Court to decide here
14 whether the Government has sufficiently established a foundation for making a hearsay exclusion
15 argument. The Court finds no reason to exclude the evidence as irrelevant at this time.

16 **b. Unfair prejudice**

17 Holmes argues that the CMS Letter would be unfairly prejudicial under Rule 403 in that its
18 admission would “invite[] the jury to convict based on the acts of persons other than [Holmes],”
19 since the Government has not connected Holmes to the CMS Letter. *See* Holmes 575 Mot. at 12–
20 13. Holmes also complains that “it would mislead and confuse the jury to admit this document
21 into evidence without substantial context on the responsibilities of CMS, the requirements under
22 the CLIA statute, implementing regulations and relevant guidance, the nature of the specific
23 disclosure requests made by CMS to Theranos, and the legal justification for those requests.” *Id.*

24 As discussed above, the Court finds that the Government has sufficiently linked Holmes to
25 the CMS Letter for the purposes of introducing the CMS Letter. The CMS Letter also appears
26 relevant for its truth. While the evidence may be complicated and may require contextualization,
27 such challenges are inevitable for a case involving allegations of misrepresentations of purportedly

advanced technology. Moreover, communications from Theranos to CMS regarding the use of Theranos' technology, or lack thereof, appears probative as to Holmes's knowledge of the accuracy and reliability of Theranos' technology. Therefore, the Court at this time declines to exclude the CMS Letter. The probative value of the evidence outweighs any potential prejudicial effect to Holmes.

c. Inadmissible character and propensity evidence

Holmes argues that the CMS Letter should be excluded per Federal Rule of Evidence 404 because the Government has not shown that the CMS Letter is connected to Holmes and has not explained how the CMS Letter "constitute[s] a false or misleading representation under CMS regulations." Holmes 575 Mot. at 13 (internal quotation marks omitted). Holmes argues that "this evidence does little more than show propensity, [i.e.], suggest that because [Holmes'] associates may have committed one 'bad act,' [Holmes] is likely to have committed another." *Id.*

For the reasons stated above, the Court finds that the Government has sufficiently demonstrated Holmes's connection to the CMS Letter. To the extent that the CMS Letter indicates a prior bad act, the Court finds that the CMS Letter as described is probative of Holmes's intent, state of mind, and knowledge. Specifically, the CMS Letter has a tendency to show Holmes's state of mind regarding Theranos' interactions with the regulatory agencies, the extent to which Holmes knew or should have known that Theranos' technology had deficiencies, and whether Holmes intended to mislead investors regarding the accuracy and reliability of Theranos' technology. The evidence also appears relevant for its truth. The Government does not appear to argue that the CMS Letter indicates that Holmes made a misrepresentation and therefore Holmes has a propensity for making misrepresentations or that the CMS Letter is admissible because it indicates a violation of CMS regulations.

3. Evidence relating to the hiring and retention of Dr. Dhawan

In addition to regulating laboratory practices, CMS administers regulations concerning laboratory personnel, including laboratory directors. 42 C.F.R. § 493.1443. The Government seeks to introduce evidence concerning the employment of Dr. Sunil Dhawan, Theranos' former

laboratory director. Holmes 575 Mot. at 13. Holmes now seeks to exclude this evidence as irrelevant, unfairly prejudicial, and introduced for improper propensity arguments. *Id.* at 13–16.

a. Relevance

Holmes argues that the Dhawan evidence is irrelevant under Rule 401. Holmes 575 Mot. at 13–15. She asserts that the Government fails to show that the employment of Dr. Dhawan amounted to a violation of CMS regulations, and that even if the Government had so demonstrated, the evidence in question would still not be relevant for what she believes are “inflammatory Rule 404(b) purposes.” Holmes 575 Reply at 14. She contends that the employment of Dr. Dhawan does not reveal anything about her control of Theranos.

The Government responds that it intends to introduce this evidence not to show that Holmes violated CMS regulations, but rather for her intent and state of mind. Gov’t 575 Opp’n at 11, 12. The Government argues that Defendants’ decisions to hire Balwani’s friend who was previously in private practice rather than a laboratory manager, give him little responsibility pay him handsomely, and often not require him to be present at the laboratory all indicate that Defendants were not serious about keeping a professional laboratory and/or had a desire to place someone they could control in the position. *See id.*

The Court finds that the Dhawan evidence meets the low bar for relevance under Rule 401, because the evidence has a tendency to show Holmes’s state of mind and intent regarding alleged misrepresentations about Theranos’ technology. Specifically, the evidence tends to show Holmes’s state of mind regarding the management of Theranos’ CLIA laboratory, and whether Holmes intended to mislead investors regarding the accuracy and reliability of Theranos’ technology. As the Government correctly observes, the evidence need not indicate a regulatory violation in order to be relevant. The Court finds Holmes is sufficiently connected to the hiring of Dhawan for the evidence of Dhawan’s employment to be relevant.

b. Unfair prejudice

Holmes argues that the Dhawan evidence is unfairly prejudicial, misleading, and confusing under Rule 403. *See* Holmes 575 Mot. at 15. Holmes argues that the evidence the Government

1 seeks to introduce is unfair because it “preys on lay impressions of the role a lab director should
2 play, rather than what the law actually requires.” *Id.*

3 Although the Government does not directly address Rule 403 arguments in its opposition
4 brief, the Court finds the Government’s arguments on relevance and probity persuasive. *See Gov’t*
5 *575 Opp’n* at 11–12. Having weighed the risk of unfair prejudice against the probative value of
6 the evidence, the Court finds that the evidence is more probative than prejudicial at this time. The
7 Court does not find that the Dhawan evidence is meant to, or is likely to, mislead a jury about the
8 nature of a lab director’s role. In contrast, the probative value of the evidence as Holmes’s state of
9 mind and intent is clear.

10 **c. Inadmissible character and propensity evidence**

11 Holmes argues that the Dhawan evidence should be excluded under Rule 404 for reasons
12 similar to her arguments concerning Rule 401. *See Holmes 575 Mot.* at 16 (referencing
13 “foregoing reasons [given in the motion]”; citing *Brown*, 880 F.2d at 1016). Holmes argues that
14 the Government seeks to introduce this “bad act” as evidence that Holmes failed to properly
15 address problems in Theranos’ CLIA laboratory. *See Holmes 575 Reply* at 8–9 (citing *Gov’t 575*
16 *Opp’n* at 11, 12). This argument is similar to her argument concerning the CDPH inspection
17 evidence, stating that the evidence in question does not qualify as “inextricably intertwined [with
18 the charged crime]” under the Ninth Circuit’s interpretation of the concept. *Id.* at 5 (citing
19 *Vizcarra-Martinez*, 66 F.3d at 1012–13).

20 The Dhawan evidence does not appear to indicate a prior bad act. To the extent that it
21 does, and regardless of whether the evidence meets the Ninth Circuit’s interpretation of the term
22 “inextricably intertwined” with the charged crime, the evidence as described appears probative of
23 Holmes’s state of mind and intent. Specifically, the evidence tends to show her state of mind
24 regarding the management of Theranos’ CLIA laboratory, and whether she intended to mislead
25 investors regarding the accuracy and reliability of Theranos’ technology. The Government does
26 not appear to argue that the Dhawan evidence is admissible because it indicates a violation of
27 CMS regulations that in turn reveals a propensity for Holmes to engage in other wrongdoing. The

1 Court declines to exclude the evidence on Rule 404 grounds at this time.

2 **4. Evidence relating to other unidentified regulatory agencies**

3 Holmes asserts that the Government's Rule 404(b) correspondence included a notice of
 4 intent to introduce evidence relating to "representations made to FDA, CMS, CDPH, and other
 5 regulatory organizations." Holmes 575 Mot. at 16 (citing Saharia Decl., Ex. 1 at 7; Ex. 2 at 12;
 6 Ex. 3 at 63) (internal quotation marks omitted). Because the Government has failed to identify
 7 any of the unspecified "other regulatory organizations," Holmes seeks to exclude such evidence.
 8 *See id.*; Fed. R. Evid. 404(b)(2)(A) (requiring "reasonable notice of the general nature of any . . .
 9 evidence that the prosecutor intends to offer at trial").

10 Neither the Government's opposition brief nor Holmes's reply address this issue further.
 11 The Court will not issue a broad exclusion at this time. If the Government seeks to introduce
 12 evidence not yet disclosed, it must provide notice to Holmes and the Court and include its reasons
 13 for late disclosure. The Court will revisit the issue with counsel at the appropriate time.

14 **5. Summary**

15 For the reasons given above, the Court **DENIES** the motion to exclude certain evidence
 16 relating to Theranos' interactions with government agencies. The Court acknowledges the
 17 possibility for further discussions on these matters, should the parties wish to specify certain
 18 exhibits under this broad category of evidence and offer new arguments as to why those particular
 19 exhibits should still be excluded.

20 **E. Holmes's MIL to Exclude Evidence of Remedial Measures and Settlements** 21 **(Dkt. No. 572)**

22 Holmes requests an "order precluding the [G]overnment from introducing any evidence of
 23 subsequent remedial measures taken by Theranos, including voiding or refunding of tests, and the
 24 settlements with CMS and the Arizona Attorney General Office." Holmes's Mot. in Limine to
 25 Exclude Evidence of Remedial Measures and Settlements Under Rules 401-403, 407, and 408
 26 ("Holmes 572 Mot."), Dkt. No. 572, at 10. For the reasons stated below, the motion is granted in
 27 part.

1. CMS findings and settlement

On January 25, 2016, CMS issued a letter to Theranos summarizing its finding of a recent review of Theranos' laboratory in Newark, California, pursuant to the CLIA which specifies the legal requirements for engaging in medical testing and is broadly administered under the CMS. Saharia Decl., Ex. 12. The letter stated that as a result of the onsite survey of the laboratory, "it was determined that [Theranos] is not in compliance with all of the Conditions required for certification in the CLIA program." *Id.* at 2. In addition, the letter stated:

[I]t was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.)

Id. The letter listed five CMS findings Theranos was instructed to correct. *Id.* at 1–2. Three of the condition-level requirements concerned issues with Theranos laboratory personnel. *Id.* at 1. The other two condition-level requirements concerned Theranos' compliance with CLIA regulations governing laboratory issues. *Id.*

The letter included a 121-page "Form CMS-2567" with a list of numerous deficiencies. The Government highlights five of the listed deficiencies:

(1) Theranos ran patient tests after failing QC (ECF No. 581-1 at 43-46); (2) QC results for multiple assays, for weeks on end, were at least two standard deviations from the mean (*id.* at 45-46); (3) QC results for multiple assays had coefficients of variation as high as 63.8% (*id.* at 55-56); (4) the overall percentage of QC samples on all tests on all devices was at or in excess of 20% (*id.* at 57-58); and (5) accuracy, precision, reportable range, and allowable bias for multiple assays did not meet even Theranos's criteria (*id.* at 80-81).

Gov't Opp'n to Holmes's 572 Mot. (Gov't 572 Opp'n"), Dkt. No. 673, at 3.

CMS did not include any findings regarding the accuracy or reliability of Theranos' blood tests. CMS warned Theranos that if it did not provide "a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies" within 10 days, CMS

would impose sanctions. Saharia Decl., Ex. 12 at ECF p. 3.

In a letter to CMS dated April 1, 2016, Theranos Laboratory Director Dr. Kingshuk Das stated:

The laboratory has undertaken aggressive corrective actions. For example, out of an extreme abundance of caution and based on its dissatisfaction with prior [quality assurance] oversight the laboratory . . . voided all results reported for the assays run on the Theranos Proprietary System 3.5 (TPS) in 2014 and 2015 and all reported PT/INR tests run on the Siemens Advia BCS XP instrument [from] October 2014 through September of 2015.

Saharia Decl., Ex. 27, Dkt. No. 583-1 at ECF p. 3. Elsewhere in the letter, Dr. Das stated:

The laboratory has conducted a thorough re-review of QC data for each assay run on the TPS 3.5 from January 1, 2014 until the TPS 3.5 was fully retired in early-August 2015. As explained further in the attached patient assessment analysis, the laboratory is not satisfied with its old quality assessment's program's ability to effectively flag and promptly address QC imprecision, QC failures, and QC trends with the TPS 3.5. . . . Based upon its re-review of QC data for the TPS 3.5, the laboratory has determined that its prior QA program failed to satisfactorily address these types of QC issues for assays run on the TPS 3.5 in 2014 and 2015. As corrective action, the laboratory has, out of an extreme abundance of caution, voided results reported for assays run on the TPS 3.5 in 2014 and 2015."

Id. at ECF pp. 14–15.

Despite Theranos' corrective actions, CMS imposed sanctions. Theranos appealed the sanctions, and on April 14, 2017, CMS entered a civil settlement ("the CMS Settlement") with Theranos, Dr. Sunil Dhawan, and Balwani. The preamble to the CMS Settlement recited, among other things, that Dr. Dhawan directed the Newark Laboratory during the relevant period; that Balwani owned the Newark Lab; that Theranos had decided to close the Newark Laboratory; that "Theranos, Dhawan, and Balwani, in order to avoid the costs and burden of litigation, and without admitting or contesting the underlying actions, desire to settle this matter and acknowledge that the imposition of sanctions against Theranos, Dhawan, and Balwani is solely as described in the Agreement." Saharia Decl., Ex. 29, Dkt. No. 583-3 at ECF pp. 2–3. The CMS Settlement: (i) resolved all outstanding legal and regulatory proceedings between CMS and Theranos; (ii) reduced Theranos' total civil monetary penalty to \$30,000; (iii) prevented Theranos from owning

or operating a clinical lab for two years; (iv) withdrew CMS's revocation of Theranos' CLIA operating certificates; and (v) withdrew Theranos' appeal of CMS's sanctions. *Id.* Holmes was not a party to the CMS Settlement.

2. Arizona Attorney General's Office settlement

After the CMS Settlement, the Arizona Attorney General's Office ("AGO") brought a consumer fraud action against Theranos that also resolved through a settlement. The Arizona AGO alleged that:

- 1) Between 2013 and 2016, Defendant sold approximately 1,545,339 blood tests to approximately 175,940 Arizona consumers, which yielded 7,862,146 test results.
- 2) Defendant ultimately voided or corrected approximately 834,233, or 10.6% of these test results.
- 3) The sales of the blood tests were made without the informed consent of the consumers because Defendant misrepresented, omitted, and concealed material information regarding its testing service's methodology, accuracy, reliability, and essential purpose.
- 4) Defendant intended for its customers to rely on its misrepresentations, omissions, and concealments in their decision to purchase its testing services.

Saharia Decl., Ex. 28, Dkt. No. 583-2 at ECF p. 3. Theranos expressly denied the Arizona AGO's allegations. *Id.* The settlement with the Arizona AGO included a consent decree ("the Arizona Settlement") requiring that Theranos: (i) not own, operate, or direct any CLIA lab in Arizona for two years; and (ii) pay \$4.65 million in consumer restitution. *Id.* at 4. Theranos reimbursed each Arizona customer the full amount paid for testing—regardless of whether the results were voided or corrected. *Id.* at 5.

3. The Government's proffer of evidence

The Government notified Holmes of its intent to introduce evidence of Theranos' voiding of test results "to show Theranos was unable to produce accurate and reliable test results." Saharia Decl., Ex. 3, Dkt. No. 580-2 at ECF p. 5. The Government's Rule 404(b) notice specifically points to five Theranos customers who allegedly received voided test results. *Id.* at 3–6. The

Government also asserts that “[e]vidence Theranos voided tests is an admission its prior statements [regarding the accuracy and reliability of Theranos technology] were false.” *Id.* at 69. The Government also intends to introduce evidence of voided tests to show “Defendants’ intent to defraud patients by depriving them of the information they believed they would receive when patronizing Theranos’[] services.” *Id.* at 75–76. Holmes also expects the Government to introduce evidence of Theranos’ decision to provide refunds to customers as part of the Arizona Settlement to show that Theranos’ technology was not capable of producing accurate and reliable test results. *See* Dkt. No. 267 at 2–3.

4. Evidence of Theranos’ voiding of tests

a. Rule 407

Under Rule 407, evidence of subsequent remedial measures is not admissible to prove culpable conduct by the party taking those measures or “a defect in a product or its design,” but is admissible for another purpose, such as impeachment. Fed. R. Evid. 407. The purpose of Rule 407 is to encourage parties to improve safety conditions “without fear that subsequent measures will be used as evidence against them.” *Gauthier v. AMF, Inc.*, 788 F.2d 634, 637 (9th Cir. 1986). “An exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority . . . because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence.” *O’Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir. 1990); *see also In re Aircrash in Bali, Indonesia*, 871 F.2d 812, 817 (9th Cir. 1989) (“The purpose of Rule 407 is not implicated in cases involving subsequent measures in which the defendant did not voluntarily participate. . . . In this case, Pan Am’s management, although to be commended for its cooperation, nonetheless was legally obligated to cooperate with the FAA’s investigation.”).

Here, Holmes relies on Rule 407 to support her argument that Theranos made a voluntary decision to void test results, and therefore evidence of the void test results is inadmissible to prove culpability—i.e., to prove the Government’s allegation that she falsely stated that Theranos’ tests were accurate and reliable and as an admission that their prior statements about Theranos’

1 technology were false. In contrast, the Government relies on the exception to Rule 407, asserting
 2 that the voiding of blood tests was not voluntary. Thus, the applicability of Rule 407 turns on
 3 whether Theranos' decision to void the test results was voluntary or involuntary—an issue the
 4 parties strongly dispute.

5 There is evidence in the record to support both parties' position. Holmes cites to a portion
 6 of a FDA Office of Criminal Investigation interview with CMS employee Sarah Bennett that
 7 states, "Theranos made the decision to void the test results; CMS didn't tell them to do that."
 8 Saharia Decl., Ex. 34, Dkt. 584-3 at ECF p. 7. Read in isolation, this statement tends to support
 9 Holmes's position. When it is read in a fuller context, however, it also lends support to the
 10 Government's position that CMS required Theranos to cooperate with the inspection, to take
 11 immediate action to fix deficiencies, to remove the immediate jeopardy Theranos was causing
 12 patients, and to come into condition-level compliance:

13 In Theranos's written responses to CMS in which they attempted to
 14 show they had corrected the cited deficiencies, Theranos would send
 15 CMS a copy of a faxed sheet saying something was corrected along
 16 with a corrected report, but CMS could never marry the two together;
 17 so, CMS never knew if Theranos actually notified all of their affected
 18 patients. Bennett said that over 50,000 patient test results were
 implicated. To date, CMS doesn't know if all of the affected patients
 have been notified. Theranos made the decision to void the test
 results; CMS didn't tell them to do that. CMS tells the laboratory they
 must fix a deficiency and the laboratory decides how they're going to
 fit it.

19 *Id.* Even if Theranos had a choice in how to "fix" the deficiency, it was nonetheless required to
 20 address the deficiency.

21 Holmes asserts separately that Theranos did not void tests in response to CMS's January
 22 2016 finding of immediate jeopardy, but rather took that step voluntarily months after the 10-day
 23 deadline to cure. *Id.*, Ex. 27 at 3. This argument overlooks the fact that CMS found Theranos'
 24 initial response to the January 2016 finding insufficient and that "the evidence did not support a
 25 credible allegation of compliance." *Id.*, Ex. 27 at 1; Saharia Decl., Ex. 34 at 6. CMS sent
 26 Theranos another letter in March 2016 that "tells them exactly why their response was not
 27 credible." *Id.*, Ex. 34 at 6. Theranos' April 1, 2016 letter notifying CMS of the decision to void

1 tests was sent in response to CMS’s March letter. Therefore, the timing of Theranos’ decision to
2 void tests does not, without more, suggest that the decision was entirely voluntary.

3 Because there is a factual dispute over the voluntariness of Theranos’ decision to void
4 tests, it is premature for the Court to decide now whether evidence of the voided tests must be
5 precluded under Rule 407.

6 **b. Rule 403**

7 Holmes next contends that evidence of the invalidated test results is irrelevant because it
8 was the product of an investigation into whether Theranos deviated from lab operating procedures
9 and documentation, not from a finding that the tests were inaccurate or unreliable or that
10 Theranos’ tests negatively affected a statistically significant number of customers. Moreover,
11 Holmes contends that evidence of the invalidated test results will confuse the issues in the case
12 and invite the jury to assume that Theranos admitted that the testing data was invalid—an
13 assumption Holmes contends would be misleading and highly prejudicial.

14 The Court agrees with the Government that Holmes’s decision to void blood tests is
15 relevant. She made the decision to void tests in the context of discussions with CMS regarding
16 deficiencies in lab procedures, including quality controls and quality assurance programs. These
17 deficiencies were so serious that CMS found that the Theranos lab posed “immediate jeopardy to
18 patient health and safety.” *Id.*, Ex. 12 at 1. It is reasonable to infer that test results from a lab
19 fraught with quality control and quality assurance issues are, at a minimum, unreliable. And it is
20 reasonable to infer that Theranos’ decision to void the test results after CMS issued its findings is
21 an implicit acknowledgement that the test results were unreliable.

22 Holmes argues that Theranos did not specifically admit its lab produced inaccurate results.
23 Nevertheless, that is a reasonable inference from Theranos’ decision to void test results. As the
24 Government points out, if Holmes had confidence in the test results, or if she could ascertain the
25 correct value, there would have been no need to void the test results. Indeed, the Form CMS-2567
26 indicates that Theranos was able to ascertain corrected values for certain tests. *See id.*, Ex. 12 at
27 ECF p. 80 (“VitD, HCG[,] and SHBG validation reports included ‘Theranos-corrected’ results”).

Holmes offers alternative explanations for voiding the tests, including that it was “due to uncertainty with how prior lab leadership operated the laboratory and in an abundance of caution.” Holmes 572 Mot. at 4. Holmes attempted “to show a willingness to take seriously the cited issues in the Report, the majority of which concerned negligent lab practices such as failure to maintain proper documentation—issues that the [G]overnment’s own witness stated are common among laboratories.” *Id.* Although Holmes may have alternative explanations for voiding the tests that are unrelated to the accuracy and reliability of the tests, the fact remains that the circumstances surrounding the decision to void the tests are relevant to show whether Theranos was able to produce reliable and accurate test results. As such, evidence of Theranos’ decision to void tests meets the “very low bar” of Rule 401. *United States v. Rodriguez-Soler*, 773 F.3d 289, 293–94 (1st Cir. 2014) (relevancy requirement is “a very low bar” that “is not very hard to meet”).

Holmes next cites *PG&E* for the proposition that evidence of remedial measures a government agency imposes on a defendant is unduly prejudicial. 178 F. Supp. 3d 927. In *PG&E*, the defendant was charged with, among other things, violating federal safety standards for transportation of natural gas by pipeline. The court excluded remedial measures that the California Public Utilities Commission (“CPUC”)—“an authoritative government agency”—specifically ordered, reasoning that although remedial measures aimed at charged Pipeline Safety Act regulations would be highly probative, there was a substantial risk that the jury might assume that if CPUC imposed the remedial measures, then PG&E “is deserving of punishment.” *Id.* at 949. The court concluded that this risk substantially outweighed the probative value of the CPUC remedial measures. *Id.* (citing *Angelo v. Bacharach Instrument Co.*, 555 F.2d 1164, 1176 (3rd Cir. 1977)). Although evidence of Theranos’ decision to void test results has some potential to be unduly prejudicial, this case is distinguishable from *PG&E* in that Holmes has taken the position that CMS did not require Theranos to void the test results; rather, Holmes asserts that Theranos did so voluntarily—a position that undercuts Holmes’s claim of prejudice.

Holmes’s most persuasive argument is that admitting evidence of Theranos’ decision to void tests would be unfairly prejudicial because that decision was not made until 2016 and

therefore is not probative of her intent during 2010-2015—the years that are the subject of the indictment. The Court shares Holmes’s concern that the jury could convict her for failing to uncover laboratory issues, a negligence standard, rather than for knowingly misrepresenting false, material information during the charged conspiracy.

Moreover, Holmes raises other legitimate concerns about admitting Theranos’ decision to void test results, including (a) confusion of the issues because Theranos’ lab practices were not placed at issue in the indictment, and (b) undue consumption of time because it would require Holmes to present extensive evidence about the decision to void the tests, including the regulatory backdrop for CMS’s actions.

Accordingly, the Court defers ruling on the admissibility of Theranos’ decision to void test results until the Government makes a proffer of evidence that clearly ties the events in 2016 to the charged conduct, as well as presents a factual basis for its assertion that Theranos’ decision was involuntary for purposes of Rule 407.

5. CMS Settlement and Arizona Settlement

Rule 408 limits the admission of evidence of compromise offers and negotiations. It provides:

- (a) Prohibited Uses. Evidence of the following is not admissible – on behalf of any party – either to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction:
 - (1) furnishing, promising, or offering – or accepting, promising to accept, or offering to accept – a valuable consideration in compromising or attempting to compromise the claim; and
 - (2) conduct or a statement made during compromise negotiations about the claim – except when offered in a criminal case and when the negotiations related to a claim by a public office in the exercise of its regulatory, investigative, or enforcement authority.
- (b) Exceptions. The court may admit this evidence for another purpose, such as proving a witness’s bias or prejudice, negating a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution.

Fed. R. Evid. 408. “Rule 408 is designed to ensure that parties may make offers during settlement

1 negotiations without fear that those same offers will be used to establish liability should settlement
2 efforts fail.” *Rhoades v. Avon Prods.*, 504 F.3d 1151, 1161 (9th Cir. 2007). If, however,
3 statements made during settlement are introduced for a purpose unrelated to liability, then “the
4 policy underlying Rule 408 is not injured.” *Id.*

5 In response to Holmes’s motion, the Government represents that it does not presently
6 intend to offer evidence of the CMS Settlement or the Arizona Settlement. The parties also agree
7 that Rule 408(a)(2) makes an exception for statements made in negotiations related to a claim by a
8 public office in the exercise of its regulatory, investigative, or enforcement authority when offered
9 in a criminal case. *See* Holmes 572 Mot. at 6; Gov’t 572 Opp’n at 8. Thus, statements by
10 Theranos and Holmes to the Arizona AGO in the course of its investigation and CMS in the
11 course of its survey and subsequent proceedings are not subject to exclusion under Rule 408. At
12 present, the Government has not identified any such statements that it seeks to admit.

13 Because the Government does not oppose Holmes’s motion to exclude the two settlements,
14 the Court grants her motion. Holmes’s motion for an order precluding the Government from
15 introducing any evidence of subsequent remedial measures taken by Theranos, including voiding
16 or refunding of tests, and the settlements with CMS and the Arizona AGO is **GRANTED in part**.
17 The Government is precluded from introducing the CMS Settlement and the Arizona Settlement
18 (including the refunds associated with the Arizona Settlement). The Court **DEFERS** any ruling as
19 to the admissibility of statements by Theranos and Holmes to the Arizona AGO in the course of its
20 investigation and CMS in the course of its survey and subsequent proceedings. As to the
21 admissibility of Theranos’ decision to void the tests, the Court **DEFERS** ruling until the
22 Government proffers evidence to show the voluntariness of Theranos’ decision and to tie the
23 events in 2016 to the charged conduct.

24 **F. Holmes’s MIL to Exclude Certain News Articles (Dkt. No. 578)**

25 Holmes moves to exclude certain news articles under Federal Rules of Evidence 403 and
26 802. Holmes’s Mot. in Limine to Exclude Certain News Articles Under Rule 403 and 802
27

(“Holmes 578 Mot.”), Dkt. No. 578. Holmes seeks a blanket order excluding over fifty articles by journalists not testifying at trial. *Id.* at 1. The Court held a hearing on this motion on May 6, 2021. May 6, 2021 Hr’g Tr., Dkt. No. 794. Having considered the parties’ papers, the arguments made at the hearing, and the relevant legal authority, the Court issues the following order.

1. Articles not specifically identified and submitted to the Court

Holmes generally seeks a broad exclusion of “over 50 articles” written by “journalists who will not testify at trial” (those being “journalists other than Mr. Parloff and Dr. Topol”). Holmes 578 Mot. at 1. Holmes only specifically identified and submitted to the Court seven of the fifty plus articles. “The failure to specify the evidence that a motion in limine seek[s] to exclude constitutes a sufficient basis upon which to deny th[e] motion.” *Shenwick v. Twitter, Inc.*, No. 16-cv-05314-JST, 2021 WL 1232451, at *12 (N.D. Cal. Mar. 31, 2021) (quoting *Bullard v. Wastequip Mfg. Co. LLC*, No. 14-CV-01309-MMM (SSx), 2015 WL 13757143, at *7 (C.D. Cal. May 4, 2015) (internal quotations omitted)). It would be premature to address a motion in limine when the defendant has not identified any “particular objectionable statement” she seeks to preclude. *Engman v. City of Ontario*, No. EDCV 10–284 CAS (PLAx), 2011 WL 2463178, at *4 (C.D. Cal. June 20, 2011).

Given that Holmes largely fails to identify the evidence that would be excluded should her motion be granted, the Court **DENIES** the motion without prejudice as to all the articles not specifically identified and filed with the motion and its accompanying declarations and exhibits. The Court next addresses the specifically identified articles in turn.

2. Articles specifically identified and submitted to the Court (Saharia Decl., Ex. 48, Dkt. No. 586)

a. “Blood, Simpler” (Saharia Decl., Ex. 48 at ECF pp. 32-49)

“Blood, Simpler” appeared in the December 15, 2014 issue of *The New Yorker*. Saharia Decl., Ex. 48. It was published ten months prior to the article from *The Wall Street Journal* (“WSJ”) which the Government says “exposed” Holmes’s alleged fraud. Gov’t Opp’n to Holmes’s 578 Mot. (“Gov’t 578 Opp’n”), Dkt. No. 667, at 2. The Government intends to use

1 articles published prior to the WSJ article for the non-hearsay purposes of showing “the favorable
2 press coverage of Theranos” in the public realm prior to the discovery of the fraud, and the
3 articles’ effects on the readers. *Id.* Additionally, the Government claims that Holmes and/or her
4 employees disseminated some articles published prior to that WSJ article to potential investors and
5 the public, though there is no indication in the record that the “Blood, Simpler” article was among
6 them.

7 News articles themselves are generally held to be inadmissible hearsay as to their content.
8 *Larez v. Los Angeles*, 946 F.2d 630, 642 (9th Cir. 1991). Articles that feature quotations from
9 people other than their authors constitute hearsay within hearsay when the article and the
10 quotations within are offered to prove the truth of the matter asserted, and therefore the articles
11 and the quotations within are inadmissible unless both levels of hearsay fall under an exception to
12 the rule against hearsay. *See id.*

13 The Government relies on judicial notice cases to provide support for its assertion that
14 articles can be used to show the favorable press coverage available in the public realm. Generally,
15 when courts take judicial notice of what information is “available in the public realm,” they take
16 notice of the fact that articles on the topics in question *were written*⁷, and do not take notice of the
17 actual articles or their contents. In cases involving a market fraud theory,⁸ courts take judicial
18 notice of articles and/or their contents to show what information was available to the market, as all
19 information available to the public impacts the market and stock prices regardless of whether
20 people actually rely and act on that information. Because the Government intends to use the
21

22 ⁷ *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir.
23 2010), *overruled on other grounds by Galbraith v. Cty. of Santa Clara*, 307 F.3d 1119, 1125–26
24 (9th Cir. 2002); *Ochoa v. Santa Clara Cty. Office of Educ.*, No. 16-cv-03283-HRL, 2017 U.S.
Dist. LEXIS 131658, at *4–5 (N.D. Cal. Aug. 17, 2017).

25 ⁸ *Basic Inc. v. Levinson*, 485 U.S. 224, 244–47 (1988) (discussing the admission of news articles
26 because they show what information the market was aware of, which—regardless of its truth—
27 impacts the market, and adopting fraud on the market theory); *Heliotrope Gen., Inc. v. Ford Motor
Co.*, 189 F.3d 971, 981 n.18 (9th Cir. 1999) (taking judicial notice “that the market was aware of
the information contained in news articles” and of the contents of the articles).

1 article itself and show that it had an effect on the reader(s)—investors and/or consumers were
2 influenced by and/or relied on that information when making decisions—the judicial notice cases
3 the Government cites are not applicable here.

4 However, articles offered not for the truth of the matter asserted but to show their effect on
5 the reader are not hearsay and are therefore not subject to exclusion. *See, e.g., United States v.*
6 *Payne*, 944 F.2d 1458, 1472 (9th Cir. 1991) (statement introduced not for the truth of the matter
7 but rather to show the effect on the listener was not hearsay). Thus, the use of the article “Blood,
8 Simpler” to show its effect on the reader constitutes a non-hearsay use.

9 Holmes argues that admission of this particular (overall positive) article would be unfairly
10 prejudicial, given the author’s “subjective opinions”⁹ about Holmes and quoted statements¹⁰ of
11 concern and skepticism in the article. “The term ‘unfair prejudice,’ as to a criminal defendant,
12 speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring
13 guilt on a ground different from proof specific to the offense charged.” *Old Chief*, 519 U.S. at
14 180. Evidence is unfairly prejudicial if it has “an undue tendency to suggest decision on an
15 improper basis, commonly, though not necessarily, an emotional one.” *Id.* (citation and internal
16 quotation marks omitted). Neither statements about Holmes’s appearance or mannerisms nor
17 claims of concern or skepticism suggest guilt or innocence on an improper basis, and they would
18 not provide the jury with grounds to make a determination that goes against offense-specific proof.
19 Therefore, admission of this article would not be unfairly prejudicial.

20 Holmes also argues generally that admission of any article would result in confusion of the
21 issues. This particular article largely contains information about Holmes and her family’s history,
22

23 ⁹ Holmes says the author has “subjective opinions” about “how Ms. Holmes presents both in her
24 physical presentation and how she presents when talking to rooms full of people.” May 6, 2021
25 Hr’g Tr., Dkt. No. 794, at 99:4-8.

26 ¹⁰ One quotation Holmes finds troubling is the statement “some observers are troubled by
27 Theranos’[] secrecy.” May 6, 2021 Hr’g Tr., Dkt. No. 794, at 99:2-3. Holmes is also concerned
28 about “quotes from Quest Diagnostics executives taking issue with several of Theranos’[] claims
about its technology and [their] saying broadly that fingerstick blood tests aren’t reliable for
clinical diagnostic tests.” *Id.* at 99:9-12.

her mission in founding Theranos, and the company's work and goals, with a few questions and statements of concern or skepticism. This largely biographical article will not cause confusion of the issues regarding Holmes's alleged fraud.

Because any prejudicial effect is outweighed by the article's high probative value for the purpose stated—showing its effect on readers—there is no basis for this article's exclusion under Rule 403. A limiting instruction will issue at the appropriate time. The Court **DENIES** the motion as to the "Blood, Simpler" article.

b. Remaining six identified articles (Saharia Decl., Ex. 48 at ECF pp. 2–31, 50–58)

The Government stated it intends to use articles published between 2015 and 2016 "that portray Theranos negatively" only "sparingly," and not for the truth of the matter asserted in the articles but for the non-hearsay purpose of providing "*context*" for subsequent events. Gov't 578 Opp'n at 8 (emphasis added). In particular, the Government states that the jury's review of the WSJ article¹¹ that "exposed Theranos'[] deception" is "necessary in order to understand Holmes's response to that reporting in the months that followed—a time period that saw Holmes double down on her fraud and make additional misleading statements about recent press coverage." *Id.* at 8.

However, for the articles to provide context, one would need to look past the mere existence of the articles to the contents of the articles for their truth. If the authors of these articles do not testify to the articles' contents, the articles are inadmissible as hearsay, unless they fall within an exception to the rule against hearsay.

If "the inference the plaintiff [seeks] to draw[] depend[s] on the truth of [the third party's] statement," the statement is hearsay, regardless of the purpose for which the party proffering the evidence offers it. *Mahone v. Lehman*, 347 F.3d 1170, 1173 (9th Cir. 2003) (quotation and internal quotation marks omitted). But "[i]f the significance of an out-of-court statement lies in

¹¹ The Government calls this article an "important landmark . . . [that] shows when knowledge of the alleged fraud became public." May 6, 2021 Hr'g Tr., Dkt. No. 794, at 110:9-11.

the fact that the statement was made and not in the truth of the matter asserted, then the statement is not hearsay.” *Calmat Co. v. U.S. Dep’t of Labor*, 364 F.3d 1117, 1124 (9th Cir. 2004). For the statement to truly be offered for a non-hearsay purpose, its significance must come solely from the fact the statement was made, and the truth of the statement must be entirely irrelevant.

The inference the Government seeks to draw depends on the truth of the articles’ contents. The Government intends to show that, because the articles’ contents were true, Holmes “double[d] down” on the fraud. Thus presented, the articles’ significance lies not in the fact they were written, but in the truth of the matter asserted within them. These articles and their contents are inadmissible hearsay (and hearsay within hearsay) not subject to any exception. Therefore, the Court **GRANTS** the motion as to the remaining six articles.

For the foregoing reasons, the Court **DENIES** the motion without prejudice as to the articles not specifically identified and filed with the motion and its accompanying declarations and exhibits. Regarding the articles specifically identified and submitted to the Court, the Court **DENIES** the motion as to the “Blood, Simpler” article (Saharia Decl., Ex. 48 at ECF pp. 32–49) and **GRANTS** the motion as to the other six articles (*Id.* at ECF pp. 2–31, 50–58).

G. Holmes’s MIL to Exclude Evidence of Settlements (Dkt. No. 571)

Holmes moves to exclude evidence regarding civil or regulatory settlements entered into by Theranos, Holmes, or Balwani, including evidence regarding the negotiation of those settlements and any evidence pertaining to Theranos’ ongoing civil litigation.¹² Holmes’s Mot. in Limine to Exclude Evidence of Settlements Under Rules 401-403 and 408 (“Holmes 571 Mot.”), Dkt. No. 571. Holmes is party to multiple lawsuits arising from Theranos’ alleged fraudulent schemes, some of which have settled and some of which continue to be litigated. *See Partner Invs. v. Theranos, Inc.*, (defendants agreed to settle the litigation with a payment); *Colman v. Theranos, Inc.*, Case No. 16-CV-6822-NC, Dkt. No. 314 (N.D. Cal. July 24, 2018) (defendants agreed to a stipulation leading to the dismissal of the case); *see also* Jan. 8, 2021 Decl. of AUSA

¹² The Court took the motion under submission on the papers after the parties did not request oral argument.

Robert S. Leach in Supp. of United States' Opp'ns to Def.'s Mots. in Lim. ("Leach Opp'ns Decl."), Dkt. No. 679, Ex. 2 (settlement agreement with investor Keith Rupert Murdoch); *id.*, Ex. 3 at THPFM0003022508 (discussing defendants' negotiated agreement with Safeway in which Safeway released its claims against Theranos in return for a payment); *Walgreens Co. v. Theranos, Inc.*, No. 16-CV-1040-RGA, Dkt. No. 26 (D. Del. Aug. 25, 2017) (stipulated dismissal upon settlement); *SEC v. Holmes*, No. 18-CV-1602-EJD, Dkt. Nos. 9, 10 (N.D. Cal. Mar. 27, 2018) (defendants agreed to settle allegations against them by paying monetary penalties in addition to agreeing to reduce corporate voting rights and individual equity); *In re Ariz. Theranos, Inc. Litig.*, No. 16-CV-2138 HRH (D. Ariz.) (ongoing class action litigation against defendants).

Holmes argues against the inclusion of settlement evidence on three grounds. First, she contends that Rule 408 prohibits any evidence of settlements and settlement negotiation. Even if Rule 408 does not apply, Holmes says such evidence of settlements is irrelevant under Rules 401 and 402. Holmes notes that neither she nor Theranos ever admitted liability in those settlements, nor did they admit to any of the allegations in the complaints of the lawsuits. Finally, Holmes argues that the prejudicial nature of the settlement evidence substantially outweighs any minimal probative value, rendering such evidence inadmissible under Rule 403. Specifically, she contends that admission of settlement evidence would lead to jury confusion, improperly influence the jury into believing that the settlements show a consciousness of guilt, or create prolonged unnecessary litigation on collateral matters during the trial.

The Government agrees that neither party should use evidence of settlements to prove the validity or invalidity of a disputed claim and maintains that any order should be limited to prohibiting the use of settlement agreements for that purpose. Nonetheless, the Government opposes the motion insofar as it seeks to prevent the Government from using settlement evidence for purposes not prohibited by Rule 408, namely using conduct or statements from past litigation that are outside the scope of "compromise negotiations," using settlement evidence that arose from a public office exercising its enforcement authority, and for cross-examination purposes.

1 Rule 408 governs the admissibility of evidence of conduct or statements made during
2 settlement negotiations. It provides that such evidence is not admissible when offered to prove
3 liability but may be admitted for other purposes. Fed. R. Evid. 408; *see also Rhoades*, 504 F.3d at
4 1161. Other purposes for which settlement evidence is admissible and not prohibited under Rule
5 408 can include “proving a witness’s bias or prejudice.” *See Rhoades*, 504 F.3d at 1161 (citing
6 *United States v. Technic Servs., Inc.*, 314 F.3d 1031, 1045 (9th Cir. 2002)).

7 Turning to the settlement evidence that Holmes seeks to prohibit in its entirety, Rule
8 408(b) is clear that there are instances in which settlement evidence is permissible, particularly
9 when “proving a witness’s bias or prejudice.” Fed. R. Evid. 408(b). Assuming that such evidence
10 does not run afoul of any other Federal Rule of Evidence (e.g., Rule 403), the Government is
11 entitled to use such settlement evidence for purposes permissible under Rule 408(b). Gov’t Opp’n
12 to Holmes’s 571 Mot. (“Gov’t 571 Opp’n”), Dkt. No. 671, at 3, Dkt. No. 671 (“Cross-examination
13 of witnesses may make one or more of the Settlement Agreements relevant to a witness’s bias or
14 credibility.”). The Government suggests that it may seek to introduce Theranos’ settlement
15 agreements with Safeway and Walgreens to rebut any potential argument that Safeway or
16 Walgreens believed that Theranos performed adequately under their service agreements. *Id.* at 4.
17 It remains to be seen whether any of these scenarios will come to pass. At this stage of the
18 proceedings, a broad limitation on the Government’s ability to fully cross-examine witnesses
19 would be inappropriate in the absence of information on exactly how and for what purpose any
20 potential settlement evidence may elicited.

21 Furthermore, Rule 408 provides that does not bar “conduct or a statement made during
22 compromise negotiations . . . related to a claim by a public office in the exercise of its regulatory,
23 investigative, or enforcement authority.” Fed. R. Evid. 408(a)(2). The Securities and Exchange
24 Commission (“SEC”) qualifies as such a public office. Thus, evidence relating to Holmes’s
25 conduct or statements made during the compromise negotiations with the SEC fall squarely within
26 Rule 408’s public office exception and are not inadmissible under Rule 408—although such
27 evidence may still be inadmissible for other reasons, such as unfair prejudice under Rule 403.

1 However, a Rule 403 analysis cannot be conducted in a vacuum without knowing how and for
2 what purpose the evidence is offered.

3 Because Rule 408 permits certain comment on ongoing litigation when unrelated to a
4 compromise offer or negotiation, the Court declines at this time to completely bar the Government
5 from commenting on or presenting evidence related to Holmes's ongoing civil litigation. The
6 Government is not precluded from its use of Holmes's compromise negotiations with the SEC as
7 conduct or statements made during settlement negotiations with a public entity exercising its
8 enforcement authority, as those communications do not fall under Rule 408's prohibitions.
9 Finally, the Court reserves judgment on the remainder of Holmes's motion as it pertains to the
10 Government's desire to potentially use settlement evidence for impeachment purposes. The
11 motion is **DEFERRED**.

12 **H. Holmes's MILs to Exclude Anecdotal Evidence of Test Results, Customer**
13 **Impact, Expert Testimony of Physician Witnesses, and the Laboratory**
14 **Information System (Dkt. Nos. 561, 562, 563)**

15 As evidence of the scheme to defraud doctors and patients alleged above, the Government
16 anticipates presenting testimony from approximately eleven patients who received inaccurate tests
17 from Theranos and nine treating physicians whose patients received inaccurate tests from
18 Theranos, all during the period of the charged conspiracy.

19 In separate motions in limine, Holmes seeks to preclude these witnesses from providing
20 "anecdotal testimony" regarding inaccurate results or testimony regarding the ramifications of
21 inaccurate results on customers. Holmes's Mot. in Limine to Exclude Evidence of Anecdotal Test
22 Results Under Rules 401-403 ("Holmes 563 Mot."), Dkt. No. 563; Holmes's Mot. in Limine to
23 Exclude Customer Impact Evidence Under Rules 401-403 ("Holmes 562 Mot."), Dkt. No. 562.
24 Holmes further seeks to exclude the expert physician witnesses entirely. Holmes's Mot. in Limine
25 to Exclude Expert Opinion Testimony of Fact/Percipient Witnesses Under Rules 401-403 and 702
26 ("Holmes 561 Mot."), Dkt. No. 561. Relatedly, the Government's MIL No. 10 seeks to admit
27 testimony from these (and perhaps other) patient witnesses regardless of whether those patients
28 paid for their test themselves. Gov't Mot. at 20-24.

1 Because these motions raise overlapping arguments as to relevance and prejudice, the
2 Court addresses all four together as follows.

3 **1. Anecdotal evidence of test results (Dkt. No. 563)**

4 As noted above, the Government plans to introduce testimony from both patients and
5 physicians who received inaccurate test results from Theranos during the period of the charged
6 conspiracy. Holmes seeks to exclude all such “anecdotal” testimony as irrelevant and unduly
7 prejudicial under Rules 401-403.

8 **a. Relevance**

9 Holmes argues that anecdotal patient or physician testimony about inaccurate results does
10 not “tend to prove that ‘Theranos’s technology was, in fact, not capable of consistently producing
11 accurate and reliable results.’” Holmes 563 Mot. at 5 (quoting TSI ¶ 16). According to Holmes,
12 Theranos generated 7 to 10 million test results for patients. Both parties agree that all blood tests,
13 regardless of laboratory, produce some amount of expected error. *See generally* Saharia Decl., Ex.
14 6 (Expert Report of Stephen Master explaining that some “bias” or deviation from pure accuracy
15 “is a normal and expected feature of laboratory tests”). Holmes argues that the Government
16 “cannot show that its anecdotal examples fall outside the expected error rate for laboratories; [and]
17 it cannot show that Theranos’ error rate was meaningfully different than that of other
18 laboratories.” Holmes 563 Mot. at 5. Thus, Holmes concludes that evidence of individual
19 inaccurate results, without more, does not tend to prove that Theranos tests were inaccurate or
20 unreliable overall, and is therefore not relevant to proving that her statements were false.

21 The Court does not find this argument persuasive. The Government alleges that Holmes
22 committed fraud by making misrepresentations about the accuracy and reliability of Theranos’
23 tests, inducing customers to pay for tests. Testimony describing patients’ inaccurate test results,
24 therefore, tends to prove the fraud by showing that patients did not get what they paid for.
25 Although these eleven inaccurate results may not amount to statistical proof that the Theranos
26 tests were generally inaccurate, the Court finds that consideration to affect the weight of the
27 evidence, not its admissibility. Evidence of even one inaccurate result tends to show that

1 Theranos was producing inaccurate results, even if it does not fully prove the point. Holmes is
2 correct to conclude that this evidence does not demonstrate that Theranos tests produced
3 inaccurate results at an unacceptable rate, but that does not render the “anecdotal” testimony
4 irrelevant.

5 Holmes next argues that the patient testimony should be excluded because there is no
6 evidence about what caused the erroneous results. Inaccurate results might stem from
7 mishandling, human error, patient-specific conditions like diet, or any number of other potential
8 factors. A juror “cannot draw any conclusions about causation from isolated, anecdotal examples
9 of incorrect or unexpected blood tests.” *Id.* Holmes cites to *Daubert* decisions in which courts
10 found various expert opinions unreliable because they were based on “anecdotal” evidence. For
11 example, she cites *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993), an antitrust
12 case in which the plaintiff alleged attempted monopolization of the “stainless steel steamer”
13 market. The *Vollrath* court found that the expert’s opinion that stainless steel steamers could be
14 treated as a product distinct from other steamers such that they constituted a market of their own to
15 be unpersuasive, in part because “[t]here was no detailed examination of market data or any
16 analysis of cost . . . The opinion was based on limited anecdotal evidence.” *Id.*

17 The plaintiff in *Vollrath*, however, was required to define and prove the relevant market
18 and the parties’ market share as an element of the monopolization claim, which necessarily
19 required concrete market data and analysis. The same is not true in the present case. Causation is
20 not an element of wire fraud that the Government must prove. Each time a Theranos customer
21 allegedly paid for an accurate and reliable blood test based on Holmes’s representations and did
22 not receive such a test, that experience on its own is evidence of the fraud.

23 Moreover, because expert witnesses are intended to help the jury understand the facts,
24 courts act as a gatekeeper to ensure that experts’ opinion of those facts is reliable and based on
25 sound scientific methodology. Holmes in this case appears to be arguing that the Court should
26 similarly act as a gatekeeper to prevent the Government from presenting fact evidence and
27 argument that is not based on sound scientific methodology. That is not the Court’s role. The
28 Court, therefore, finds the *Daubert*-related cases Holmes cites distinguishable.

b. Prejudice

Holmes further asserts that “[e]ven if these anecdotes had some minimal probative value, the Rule 403 considerations would substantially outweigh that probative value.” Holmes 563 Mot. at 5. Rule 403 allows the Court to exclude relevant evidence if its probative value is “substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.” Fed. R. Evid. 403.

Holmes argues that the patient testimony could confuse and mislead the jury about what is at issue in this case. “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.” Holmes 563 Mot. at 6. Testimony about eleven inaccuracies (out of millions of tests) may have relatively low probative value towards proving that the tests were inaccurate overall, but for the same reason, they are unlikely to create unfair prejudice.

Finally, Holmes objects that patient and physician testimony about receiving inaccurate test results are likely to be emotional and therefore highly prejudicial. For example, one proposed patient witness would potentially testify about receiving test results indicating that she had miscarried, when in fact, she later found out her pregnancy was still viable. As discussed further with respect to Holmes’s motion to exclude evidence of customer impact below, the Court agrees with Holmes that such testimony would be unfairly prejudicial and of limited probative value. Evidence is unfairly prejudicial when it has “an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one.” *See PG&E*, 178 F. Supp. 3d at 941 (citing *Old Chief*, 519 U.S. at 180). While the fact of inaccurate test results in itself is relevant to proving that Theranos tests were unreliable, the collateral consequences of receiving an inaccurate test result are not.

The Court finds that anecdotal evidence of test results is relevant and admissible. Accordingly, the Court DENIES the Motion. Patients, physicians, and other witnesses who may testify about receiving test results will not be permitted to testify about any physical, financial, or emotional harm they may have experienced beyond simply paying for the test.

2. Evidence of customer impact (Dkt. No. 562)

Holmes brings this separate motion seeking to exclude evidence of collateral emotional effects suffered by Theranos customers who believe that they received erroneous results as well as hypothetical harms that can result from medical decisions based on erroneous results. Holmes notes that because this is a wire fraud case, the only harm that is relevant to the case is the financial harm allegedly caused by paying for an unreliable test.

As an initial matter, the Government recognizes, as it must, that Rule 403 would undoubtedly “step in” at some point to prevent certain evidence of such collateral consequence. *See* May 5, 2021 Hr’g Tr., Dkt. No 793, at 150:25–151:4. The Government nevertheless argues that this type of testimony must be allowed for three reasons: (1) customers experienced harm in the form of not only pure financial loss but also by not receiving the “benefit of the bargain” that they expected to receive, namely the ability to make timely and important medical decisions; (2) some evidence of impact on customers is relevant to show materiality; and (3) customer impact is relevant to Holmes’s fraudulent intent.

The Court generally agrees with Holmes that the limited relevance and high risk of prejudice likely to result from evidence about the impact of inaccurate results; however, the Court also agrees with the Government that the Court need not take an “all or nothing” approach. At the May 5, 2021 hearing, the Court engaged in a line-drawing exercise with the parties, which Government counsel summarized as follows:

Mr. Schenk: . . . If I can repeat back what the court said? I think if a patient were to take the stand and say, to use the court’s example, I received a Theranos test and I thought I had cancer, or I thought I had a severe condition, and one thing I did in response to it was to go get other tests, and after I received a second test and then consulted with my physician, I determined, or my physician told me I didn’t have cancer. I think that’s appropriate and the court could limit it there. I agree with the Court, there is not the need then for the patient to say, there was two weeks between those two tests and here’s how I felt during those two weeks.

May 5, 2021 Hr’g Tr., Dkt. No. 793, at 156:3–157:22. Holmes also agreed that as to the Rule 403 analysis, “that is potentially a fair line to draw.” *Id.* at 157:4-10.

Accordingly, the Court **GRANTS** Holmes's motion to the extent it seeks to exclude emotional, graphic, or otherwise inflammatory evidence relating to the impact or potential impact on customers of inaccurate test results.

3. Expert testimony of physician witnesses (Dkt. No. 561)

As noted above, the Government has disclosed as experts nine medical professionals whose patients received allegedly inaccurate Theranos tests results during the period of the charged conspiracy. Holmes seeks to exclude testimony from these doctors because the doctors do not meet the standards for expert witness testimony under Rule 702, and their testimony is irrelevant and unfairly prejudicial. She further contends that the testimony should be excluded because the Government failed to provide adequate disclosures regarding the proposed testimony under Federal Rule of Criminal Procedure 16.

a. Rule 702

Holmes argues that pursuant to Rule 702, (1) these witnesses are not qualified to testify about the accuracy and reliability of Theranos tests overall, and (2) the opinions that they are qualified to give—i.e., opinions about their patients' specific test results—are irrelevant to this case. In its opposition brief, the Government clarified that it did not intend for the physician witnesses to opine about the accuracy or reliability of the tests overall, explaining that "the doctors on the [G]overnment's expert list will be called primarily as fact witnesses to testify about their experiences reviewing certain results from Theranos in connection with patients under their care." Gov't Opp'n to Holmes's 561 Mot. ("Gov't 561 Opp'n"), Dkt. No. 660, at 3. The Government further clarified that the physicians' testimonies will be limited to the specific results their own patients received from Theranos. The physicians will only act as expert witnesses to the extent they provide background information that the jury needs in order to understand the use and significance of the blood test being discussed and to explain why the doctor believed the test results to be inaccurate.

At the hearing on this motion, the Government affirmed these representations; however, the parties diverged on whether the physicians would be permitted to conclude that an inaccurate

1 test result was due to “lab error.” *See* May 5, 2021 Hr’g Tr., Dkt. No. 73, at 112:4–115:21.
 2 Because of the possible confusion involved in attributing an inaccurate result to “lab error,” the
 3 Court finds it unnecessary for these physicians to use that particular phrase. More broadly, as
 4 established at the hearing, the physicians are not permitted to testify about accuracy or reliability
 5 of testing overall or about any flaw in the Theranos technology. *Id.* at 115:17-20.

6 Holmes also challenged certain physician’s ability to provide any testimony about whether
 7 even an individual test results was inaccurate based on the physician’s background and experience.
 8 The Court finds that a physician may testify about her patients’ test results and her conclusions
 9 about those results as a matter of fact, not opinion, even where they involve an explanation of the
 10 witness’s medical judgment. Holmes may challenge the physician’s credibility or judgment
 11 through cross-examination. The Court finds no need for a *Daubert* hearing to assess these
 12 physicians’ ability to offer what is essentially factual testimony.

13 **b. Relevance**

14 Holmes’s relevance arguments as to the physician witnesses is substantially the same as
 15 her relevance arguments with respect to anecdotal evidence, discussed above. The difference is
 16 that these witnesses are offered as both fact and expert witnesses, meaning that not only must their
 17 testimony be relevant, but their opinions must also “fit the case.” *Daubert v. Merrell Dow*
 18 *Pharms., Inc. (Daubert II)*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995); *Messick v. Novartis Pharms.*
 19 *Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014) (expert testimony “logically advance[] a material
 20 aspect of the proposing party’s case”) (citation omitted).

21 For the same reasons that the Court concluded that anecdotal evidence of inaccurate test
 22 results is relevant, the Court finds that the physician testimony sufficiently “fits” the questions that
 23 the jury must answer.

24 **c. Prejudice**

25 Holmes argues that even if this expert testimony has some probative value, it should be
 26 excluded under Rule 403 because that value is outweighed by the prejudicial effect of the
 27 emotional charged anecdotes that these witnesses may share. Specifically, Holmes argues that the

1 experts should not be permitted to hypothesize about “the potentially catastrophic medical
2 consequences that could follow from inaccurate blood tests that were not flagged as inaccurate—
3 even though those hypothetical consequences did not occur in this case.” Holmes 561 Mot. at 20.

4 For example, the Government anticipates that Dr. Szmuc might provide testimony
5 concerning the potential consequences of ectopic pregnancies, including rupturing, significant
6 hemorrhaging “or the worst-case scenario of patient death.” Dr. Linnerson might similarly testify
7 that in cases of ectopic pregnancy, a doctor “must poison the embryo and cause it to dissolve in
8 the tube to avoid danger to the mother.” *Id.* at 21.

9 The Court finds these excerpts to be of little value to the jury and to present a significant
10 risk of unfair prejudice. Much of this potential testimony is covered by the Court’s ruling on
11 customer impact evidence outlined above. For the same reasons and for the avoidance of doubt,
12 the physicians will not be permitted to testify about emotional, graphic, or inflammatory harms
13 that could hypothetically result from an inaccurate blood test. The physicians will, however, be
14 permitted to provide general background on a test, including what it is used for, when it is
15 prescribed, and what medical decisions may flow from the results.

16 **d. Rule 16**

17 Lastly, Defendant argues that the Government has failed to provide adequate disclosures
18 about the physician witnesses pursuant to Federal Rule of Criminal Procedure 16. Rule 16
19 requires the government to provide a “written summary of any testimony that the government
20 intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence during its case-in-
21 chief at trial.” Fed. R. Crim. P. 16(a)(1)(G). The “summary provided . . . must describe the
22 witness’s opinions [and] the bases and reasons for those opinions.” *Id.*; *see also United States v.*
23 *Cervantes*, No. CR 12-792 YGR, 2015 WL 7734281, at *2 (N.D. Cal. Dec. 1, 2015) (“Rule 16
24 requires that the government summarize each specific opinion to be offered along with the basis
25 for it.”). This requirement “is intended to minimize surprise that often results from unexpected
26 expert testimony, [to] reduce the need for continuances, and to provide the opponent with a fair
27 opportunity to test the merit of the expert’s testimony through focused cross-examination.” Fed.

1 R. Crim. P. 16 advisory committee's note to 1993 amendment.

2 The Government served its Rule 16 summaries on March 6, 2020. Holmes asserts that for
3 a number of the physicians, these disclosures do not identify the number of patients the physician
4 will testify about, the patient names, or the test results on which the physician is basing the
5 opinions. According to Holmes, she repeatedly requested that the government provide more
6 information to no avail. In July 2020, Holmes moved to compel adequate summaries. Dkt. No.
7 435. At the hearing on that motion, the Court stated that "it may be necessary to have the
8 government offer additional information in regards to some of the witness's testimony and the
9 basis and reasons if that testimony is going to leave and move from treatment into other opinions
10 that they wish to speak about." July 20, 2020 Hr'g Tr., Dkt. No. 463, at 59:12-18; *see also id.* at
11 59:26–60:3 ("I do think that the government is going to be required to produce some additional
12 foundational information and background on some of this testimony."). The Court did not rule on
13 the motion because the Government's decision to issue a superseding indictment would require
14 revised disclosures in any event. *See id.* at 60:4-9.

15 The Government maintains that it has provided the Defendant with all of the information
16 available to it. The Government claims that there is no deficiency of information with respect to
17 Drs. Zachman, Burnes, Couvaras, and Asin, though it acknowledges that "there is still information
18 outstanding from several of these providers regarding the specific patients who received inaccurate
19 Theranos tests." Gov't 561 Opp'n at 9. The Government further argues that it has made
20 significant efforts to obtain the missing information but that these doctors are under extraordinary
21 demands due to the pandemic. In its January 8, 2021 opposition brief, the Government noted that
22 it "plans to serve Rule 17 subpoenas on the medical service providers immediately" and requested
23 that the Court defer ruling on the motion until the witnesses have had time to produce the
24 requested information. As of the May 6, 2021 hearing, the Government had not served Rule 17
25 subpoenas, and had provided some but not all of Holmes's requested additional information.

26 The Court agrees with Holmes that the disclosures are lacking in information necessary for
27 her to adequately prepare for trial. The Government has represented that it will make every effort

1 to timely supplement the disclosures. May 5, 2021 Hr’g Tr., Dkt. No. 793, at 105:25–106:2 (“It is
2 our plan to continue those efforts [to obtain information] and also to provide updated disclosure to
3 the defense listing the new details that we have obtained from those doctors”). In light of the
4 Government’s representation and the time remaining before trial, the Court finds no need to
5 exclude any testimony on the basis of an inadequate disclosure at this stage.

6 The Court, therefore, **DENIES** Holmes’s motion without prejudice, subject to renewal
7 should the Government fail to provide updated disclosures in advance of trial.

8 **4. Laboratory Information System**

9 Animating much of the conversation about the relevancy of anecdotal testimony in general
10 is Holmes’s overarching argument that the Government lacks the necessary scientific evidence to
11 prove the scientific proposition that Theranos tests were inaccurate and unreliable. According to
12 Holmes, the Government lacks that information because of its failure to investigate and preserve
13 the Laboratory Information System (“LIS”) database—a bespoke database that housed, among
14 other things, all patient test results and all quality control data at Theranos. According to the
15 Government, Theranos improperly destroyed that database while it was subject to a grand jury
16 subpoena without providing a working copy of the database to the Government.

17 The parties generally dispute the importance of the database to the Government’s case.
18 *Compare* May 5, 2021 Hr’g Tr., Dkt. No. 793, at 47:20-21 (defense counsel stating that the
19 “failure to obtain this evidence is a gaping hole in the Government’s case”), *with id.* at 82:15-16
20 (Government counsel stating that “the LIS was not critical to the charging in this case nor is it
21 critical to the proof at trial”). The parties also dispute the factual background leading up to the
22 deconstruction of the LIS database. *See* Gov’t 561 Opp’n at 2–8; Holmes Reply Br. in Supp. of
23 Holmes’s 561 Mot. (“Holmes 561 Reply”), Dkt. No. 575 at 7–20.

24 The Court need not wade into the disputed issue of fault at this stage. The questions
25 presently before the Court are (1) whether to preclude evidence of the destruction of the LIS
26 database offered by the Government in its case-in-chief (*see* Holmes’s Mot. in Limine to Exclude
27 Bad Acts and False or Misleading Statements of Theranos Agents and Employees (“Holmes 565

1 Mot.”), Dkt. No. 565, at 4); (2) whether to preclude Holmes from raising the Government’s failure
2 to obtain the LIS evidence in her defense; and (3) if Holmes is permitted to raise such a defense,
3 whether the Government will then be permitted to offer evidence of Theranos’ destruction of the
4 database in response. The Court address each in turn.

5 First, the Government has argued that large-scale statistical analysis of Theranos’ test
6 results is not necessary to prove the elements of wire fraud in this case. *See, e.g., id.* at 79:10–80:9
7 (Government explaining that while the LIS database would have been a “powerful tool” to identify
8 patient victims and identify which assays Theranos was running and when, “the Government has
9 been able to capture that information in various other ways”); *id.* at 80:14–81:2 (stating that “this
10 case is not about overall failure rate” nor about “determining what percentage of Theranos’ tests
11 were inaccurate”). Moreover, the Government has not presented any evidence tending to show
12 Holmes’s involvement in what the Government would characterize as the nefarious destruction of
13 the LIS database. As discussed in more detail above on Holmes’s MIL regarding Rule 404(b)
14 evidence, the Government must establish some connection between an alleged bad act and Holmes
15 before evidence of that bad act becomes relevant. Thus, the Court finds that evidence tending to
16 show Theranos’ nefarious destruction of the LIS database, without more, is not relevant under
17 Rules 401 and 404(b). The Court **GRANTS** Holmes’s motion to exclude such evidence without
18 prejudice. The Government may seek to introduce such evidence upon a foundational showing
19 establishing a connection to Holmes.

20 Second, the Government argues that Holmes should not be permitted to argue that the
21 Government’s evidence is “anecdotal” because it failed to conduct a statistical analysis of
22 Theranos test results. The Government contends that such an analysis is not necessary, would
23 likely not have been possible on the LIS database, and risks misleading the jury about what the
24 Government is required to prove. Holmes maintains that fundamentally, she must be permitted to
25 argue that the Government has failed to meet its burden of proof in this case. The Court agrees.
26 Holmes has a right to put on a defense of her choosing, including an argument that the
27 Government has failed to meet its burden of proof. *See, e.g., Conde v. Henry*, 198 F.3d 734, 739

(9th Cir. 2000) (“precluding [defendant’s] attorney from arguing his theory of the defense in closing arguments” “violated [defendant’s] right to counsel”); *United States v. Solorio-Soto*, 300 F. App’x 487, 488–90 (9th Cir. 2008) (limitation on cross-examination “prevented [defendant] from arguing” that government’s Rule 404(b) evidence did not establish element of the offense and violated his right to present a complete defense).

The Court declines to preclude Holmes from raising the lack of “statistical” or “scientific” evidence as a defense, from characterizing that missing evidence as critical to the Government’s case, or from arguing about the statistical insignificance of individual patient or physician testimony. Thus, to the extent the Government’s opposition brief seeks to preclude Holmes from offering such arguments, the Court denies that request.

Finally, the question remains whether, if Holmes argues that the LIS database is unavailable because of the Government’s failure to obtain it, that argument opens the door to the Government presenting evidence of Theranos’ culpability in the destruction of the LIS. At the motion hearing, the Court expressed its preliminary view that an argument of this nature from the Holmes would likely introduce a fact issue for the jury to decide. Whether it is necessary for the jury to hear evidence regarding fault in the destruction of the database will depend on what arguments Holmes raises at trial and whether she seeks any sort of jury instruction on the issue. The Court will defer ruling on this question unless and until it becomes relevant at trial.

5. Summary

In conclusion, the Court finds evidence of anecdotal testimony relevant and admissible, and therefore **DENIES** Holmes’s motion to exclude evidence of anecdotal test results.

The Court **GRANTS** Holmes’s motion to exclude customer impact evidence, but will permit witnesses to testify in accordance with the parameters laid out above.

The Court **DENIES** Holmes’s motion to exclude expert physician witnesses without prejudice to renewal if the Government fails to timely supplement its Rule 16 disclosures.

Finally, the Court further **GRANTS** Holmes’s motion to preclude evidence of Theranos’ involvement in the destruction of the LIS database, unless and until the Government lays a proper

foundation at trial or Holmes puts the factual dispute in issue.

I. Holmes's MIL to Exclude Bad Acts and False or Misleading Statements of Theranos Agents and Employees (Dkt. No. 565)

Holmes moves to preclude the Government from introducing "evidence of bad acts or false or misleading statements of Theranos agents or employees other than her alleged co-conspirators and alleged accomplices, at least absent a sufficient advance showing from the [G]overnment pursuant to Rule 104." Holmes Reply Br. in Supp. of Holmes's 565 Mot. ("Holmes 565 Reply"), Dkt. No. 708, at 4; *see also* Holmes 565 Mot. Holmes contends that the evidence is irrelevant, and even if it has some probative value, the combined prejudice, confusion, and time lost in mini-trials resulting from admitting the evidence would together substantially outweigh the limited probative value. In particular, Holmes provides the following examples of anticipated evidence and arguments regarding Theranos agents and employees that she contends the Government has not connected to any knowledge or conduct on her part.

1. "The government identifies the experiences of seven patients as evidence that Ms. Holmes knew Theranos was unable to provide accurate and reliable test results, [sic] but it does not identify any evidence that Ms. Holmes was ever informed about three of these patients' experiences. Ex. 3 at 5-6 (Sept. 28, 2020 Rule 404(b) Notice). For example, with respect to R.G., the government claims only that '[n]umerous employees reporting to Holmes and Balwani became aware of the test.' *Id.* at 6."
2. "The government again alleges that 'Defendants *and their agents* made statements directly to doctors in connection with Theranos's tests and specific results.' Ex. 3 at 12-15 (emphasis added). This portion of the supplemental 404(b) disclosure identifies numerous statements by unidentified 'Theranos representatives' that the government intends to introduce. Illustrative examples include the following: *id.* at 12 ('A Theranos representative told Dr. Jessica Bramstedt that Theranos would conduct micro-testing on blood samples drawn from the fingertip; that Theranos was equivalent to other major labs like LabCorp and Sonora Quest, and that when Theranos lost its lab license, it was merely a slap on the wrist that would have a temporary effect on the company.' (internal quotation marks omitted); *id.* ('Theranos representative Kimberly Alfonzo told Dr. Gerald Asin that Theranos could do all blood tests with a fingerstick draw . . .'); *id.* ('A Theranos sales representative told Dr. Nathan Matthews that Theranos's testing was accurate . . .'); *id.* at 13 ('Theranos representatives told Dr. Steve Linnerson that the company's device was FDA-approved and that it had met all

the national laboratory standards . . .'); *id.* at 14 ('Results from each of these types of HbA1c tests were provided to doctors without explanation as to the types of analyzers used to conduct the assays, creating a situation where doctors did not have the information they needed to place the results in context.')."

3. "The government makes various allegations related to Theranos' process for setting reference ranges that have no connection to Ms. Holmes (or Mr. Balwani). *Id.* at 71."
4. "The government alleges that '[w]hen Theranos obtained critical test results for chloride, it conducted a redraw and/or rerun rather than reporting the critical value,' with no connection to Ms. Holmes. *Id.* at 73."
5. "According to the government, 'Results from . . . HbA1c tests were provided to doctors without explanation as to the types of analyzers used to conduct the assays, creating a situation where doctors did not have the information they needed to place the results in context. This was especially problematic in situations where a single patient had multiple Theranos assays conducted using different methods, yielding different results that falsely suggested to the doctor that the patient's analyte values had changed. This was the case with a patient treated by Dr. Phelan, who was the subject of internal emails at Theranos.' The government does not tie this allegation to Ms. Holmes."
6. "The government asserts, in inflammatory language, that Theranos 'senior managers' destroyed Theranos' database of patient data in 2018. *Id.* at 79-80. According to the government, Theranos produced the database to the government but failed to provide a password needed to access the database; Theranos employees and consultants then dissembled the hardware that housed the database. *Id.* The government claims that these actions 'place the government's evidence in context as part of a larger fraud scheme, one which Theranos was attempting to hide and conceal even after the indictment in this case.' *Id.* at 81. The government does not tie these wild accusations to Ms. Holmes, nor could it, as Ms. Holmes had not been part of company management for several months and had no involvement in responding to these requests."
7. "The government alleges that acts by David Boies, a lawyer for Theranos and Ms. Holmes, and by Theranos' then-General Counsel Heather King are evidence of Ms. Holmes' mental state. Specifically, it alleges that '[o]n or about September 8, 2015, David Boies, at Theranos's direction, wrote to the Editor-in-Chief of Dow Jones [which publishes the *Wall Street Journal*] in an attempt to quash [journalist John] Carreyrou's pending story' on Theranos. *Id.* at 60. The government further alleges that '[o]n or about October 8, 2015, Boies and Heather King (Theranos's General Counsel) spoke to the Dow Jones' Editor-in-Chief and others in an attempt to quash Carreyrou's pending story.' *Id.* The government makes no allegation about Ms.

Holmes' role in these actions."

Holmes 565 Mot.at 3–4.

It is well settled that "guilt" is an "individual and personal" matter, and thus vicarious liability "has no place in the criminal law as our Rules of Evidence recognize." *United States v. Cadden*, No. 14-10363-RGS, 2018 WL 2108243, at *6 (D. Mass. May 7, 2018); *see also Lady J. Lingerie, Inc. v. City of Jacksonville*, 176 F.3d 1358, 1367 (11th Cir. 1999) ("[D]ue process prohibits the state from imprisoning a person without proof of some form of personal blameworthiness more than [an agency relationship]."). A defendant may be liable for the actions of another in only limited circumstances, such as where there is conspiracy liability. *United States v. Tarallo*, 380 F.3d 1174, 1184 (9th Cir. 2004), *amended*, 413 F.3d 928 (9th Cir. 2005). Evidence of "guilt by association" is improper. *See United States v. Dunn*, 640 F.2d 987, 989 (9th Cir. 1981) (vacating conviction where government "concentrated on the criminal convictions of other members of [defendant's] family" and impeached witness through "the crimes of her brother").

Here, the Government does not specifically address the so-called bad acts, with one exception. Instead, the Government focuses on actions that it alleges Holmes took herself. For example, the Government intends to call witnesses at trial to testify about Holmes's role in assembling and approving materials that went to potential and actual investors in the company. These materials contain the numerous allegedly false and misleading statements about Theranos' technology, including the number of tests it could perform and the level of accuracy it could achieve. The Government also intends to present testimony from investors regarding their conversations with Holmes and the ways she misled them about the regulatory status of Theranos and the military's purported use of the company's analyzer. Holmes also repeated to members of the media the allegedly false statements she delivered to potential investors.

The Government also intends to present evidence of Holmes's role in responding to customer inquiries. For example, the Government intends to present evidence that in August 2014, Holmes directed Theranos employees regarding how to respond to customer inquiries about withheld test results. Specifically, Theranos representatives were to respond that "CO2 results

1 were not reported due to temporary unavailability of this test for this sample” and note that the
2 company was growing as fast as it could. Gov’t Opp’n to Holmes 565 Mot. (“Gov’t 565 Opp’n”),
3 Dkt. No. 662, at 3. In February 2015, Holmes allegedly approved a script for Theranos
4 representatives to use when explaining changes to its Complete Metabolic Panel (CMP) tests to
5 customers.

6 The problem with the Government’s argument is Holmes’s motion is not directed to
7 evidence of her role in preparing materials for investors, her presentations to investors, or to her
8 personal engagement with the media. Nor is Holmes’s motion directed to evidence of her role in
9 responding to customer inquiries. And indeed, evidence of Holmes’s direct participation in these
10 activities is relevant to the alleged fraud. *See, e.g., United States v. Blitz*, 151 F.3d 1002, 1006
11 (9th Cir. 1998) (evidence of personal contact with prospective victims was sufficient to sustain
12 conviction for knowing participation in fraudulent scheme); *United States v. Lothian*, 976 F.2d
13 1257, 1267–68 (9th Cir 1992) (evidence that defendant made misrepresentations to customers
14 about company was sufficient to prove fraud); *United States v. Peters*, 962 F.2d 1410, 1414 (9th
15 Cir. 1992) (upholding conviction for fraud because appellant knew of complaints from victims
16 about money they were promised, continued to do administrative tasks, and deposited fraudulently
17 acquired checks). Rather, Holmes seeks to exclude “bad acts” that she contends the Government
18 has not connected to her.

19 The only other evidence the Government proffers to connect Holmes to the “bad acts” is
20 her status as founder and CEO of Theranos. The Government contends that Holmes was involved
21 in virtually every aspect of the company and that she possessed final authority over decisions on
22 virtually any issue facing the company. In other words, Holmes exerted “influence” over all facets
23 of the company’s operations. Gov’t 565 Opp’n at 3. For example, the Government contends that
24 as CEO, Holmes was the primary contact for David Boies, and therefore “[i]t is implausible that
25 Defendant did not play a significant role in influencing Boies’s actions during that time period.”
26 *Id.* at 5.

1 The Government’s proffered evidence is not enough to connect Holmes to Boies. To do so
 2 would invite the jury to potentially find Holmes vicariously liable for the actions of others based
 3 on nothing more than her “influence.” The only case the Government cites in support of this
 4 “influence” theory is *United States v. Ciccone*, 219 F.3d 1078, 1083–85 (9th Cir. 2000). But the
 5 Government’s attempt to analogize this case to *Ciccone* is strained. In *Ciccone*, the owner of a
 6 telemarketing company designed a “pitch” for his solicitors to use in order to persuade people to
 7 send money to his company. *Id.* at 1080. On appeal, the defendant argued that there was
 8 insufficient evidence to permit a jury to convict because he did not call the victims; his solicitors
 9 did. *Id.* at 1084. The Ninth Circuit rejected that argument because there was evidence in the
 10 record that he did make some calls himself, and even if he did not himself make the calls, “[t]he
 11 defendant need not personally have mailed the letter or made the telephone call; the offense may
 12 be established where one acts with the knowledge that the prohibited actions will follow in the
 13 ordinary course of business or where the prohibited acts can reasonably be foreseen.” *Id.* at 184
 14 (quoting *Lothian*, 976 F.2d at 1262). *Ciccone* in no way suggests that the defendant was convicted
 15 based on evidence of his “influence” over his company. The Government may attempt to hold
 16 Holmes liable for her own acts, as in *Ciccone*. But it cannot attribute the acts of others to her
 17 without evidence that causally connects her with those actions. *Lady J. Lingerie*, 176 F.3d at
 18 1367; *see also United States v. Rank*, 805 F.2d 1037, at *4 (6th Cir. 1986) (“declin[ing] to adopt
 19 the government’s theory, akin to a respondeat superior basis for criminal liability” for president
 20 and CEO of a company in a mail fraud case).

21 Perhaps in implicit recognition of the need for evidence of a causal connection between
 22 Holmes and the so-called “bad acts,” the Government represents that it is likely that further trial
 23 preparation will lead to former Theranos employees who “will have additional information about
 24 the control Defendant had over employee’s knowledge of key facts and their responses to
 25 questions other posed about the company.” Gov’t 565 Opp’n at 5. Because pretrial preparation is
 26 ongoing, the Court is not inclined to issue a pretrial order precluding evidence of all “bad acts.”
 27 Nevertheless, it is incumbent upon the Government to come forward with proof of a sufficient

connection between Holmes and each “bad act” so that the Court may assess the relevance and potential prejudice of each “bad act.” Fed. R. Evid. 104(b) (“When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist.”). Further, Rule 104(c)(3) requires a hearing out of the presence of the jury to consider whether the Government has presented sufficient evidence of a connection to justify admissibility of any particular bad act, to avoid Rule 403 issues. Fed. R. Evid. 104(c)(3) (“The court must conduct any hearing on a preliminary question so that the jury cannot hear it if . . . (3) justice so requires.”); *see also United States v. Evans*, 728 F.3d 953, 957 (9th Cir. 2013) (describing a Rule 104 pretrial hearing for such a purpose in the proceedings below). This approach will “insure[] that the jury will not be tainted by hearing prejudicial evidence—or learning of its existence—until the [Government] has demonstrated that it will be able to provide an adequate foundation for admission.” *United States v. Branch*, 970 F.2d 1368, 1371 (4th Cir. 1992).

Holmes’s motion is **DEFERRED** pending the Government’s establishment of the necessary foundation for the evidence it seeks to introduce.

J. Holmes’s MIL to Exclude Evidence of Theranos’ Trade Secrets Practices (Dkt. No. 566)

Holmes next moves to preclude the Government from introducing evidence of Theranos’ trade secrets practices. Holmes’s Mot. in Limine to Exclude Evidence of Theranos’ Trade Secrets Practices Under Rules 401-404 (“Holmes 566 Mot.”), Dkt. No. 566. The motion primarily concerns three categories of evidence about Holmes playing a role in: (1) fostering a culture of secrecy and forcing employees and others to sign non-disclosure agreements; (2) restricting access to laboratory areas within Theranos; and (3) threatening or intimidating employees or former employees. *See Saharia Decl.*, Ex. 1, Dkt. No. 580 at 4–6. The Government states evidence related to these categories “tends to show consciousness of guilt and tends to show a belief that transparency would expose the falsity of what [Holmes] claimed to investors, patients, and others.” *See id.*, Ex. 3, Dkt. No. 580-2 at 55, 57, 63. Moreover, the Government stated at the

1 hearing that it “wants to offer this evidence to say that these were practices at Theranos to prevent
2 the discovery of the fraud.” May 6, 2020 Hr’g Tr., Dkt. No. 794, at 46:24–47:1.

3 Holmes argues that these actions largely reflect common measures that California law
4 requires companies like Theranos to adopt to protect their trade secrets. According to Holmes,
5 evidence concerning Theranos’ trade secrets practices has no probative value and will confuse,
6 mislead, and prejudice the jury because the noticed categories of evidence merely depict a
7 company protecting its trade secrets. Holmes also argues that these categories of evidence are
8 inadmissible character evidence under Rule 404(b) because they are too different and unrelated to
9 the charged offense.

10 The Court first addresses Holmes’s Rule 404(b) argument. Although Holmes correctly
11 notes that evidence of another act is admissible evidence of intent only if the other act is “similar
12 to the offense charged,” a review of the three categories suggests that this evidence should not be
13 considered “acts” for purposes of Rule 404(b). *United States v. Mayans*, 17 F.3d 1174, 1181 (9th
14 Cir. 1994). The Ninth Circuit has held that “evidence should not be considered ‘other crimes’ or
15 ‘other act’ evidence within the meaning of Rule 404(b) if ‘the evidence concerning the ‘other’ act
16 and the evidence concerning the crime charged are inextricably intertwined.’” *United States v.*
17 *Dorsey*, 677 F.3d 944, 951 (9th Cir. 2012) (quoting *United States v. Soliman*, 813 F.2d 277, 279
18 (9th Cir. 1987)). This doctrine applies when the acts in question are so interwoven with the
19 charged offense that they should not be treated as other crimes or acts for purposes of Rule 404(b).
20 There are generally two categories of cases in which the Ninth Circuit has concluded that “other
21 act” evidence is inextricably intertwined with the charged crime and therefore need not meet the
22 requirements of Rule 404(b). *Vizcarra-Martinez*, 66 F.3d at 1012. First, evidence constituting a
23 part of the transaction that serves as the basis for the criminal charge is admissible. *Id.* Second,
24 “other act” evidence may be admissible if necessary to permit the prosecutor to offer a coherent
25 and comprehensible story regarding the commission of the crime. *Id.* at 1012–13. “[I]t is
26 obviously necessary in certain cases for the government to explain either the circumstances under
27 which particular evidence was obtained or the events surrounding the commission of the crime.”

1 *Id.*

2 Under these authorities, even if the identified categories of evidence dealing with trade
3 secrets practices at issue were not part of the crime charged, they are not subject to exclusion
4 because they allow the Government to offer a coherent and comprehensible story regarding the
5 commission of the charged crime. The Government seeks to introduce this evidence to show that
6 these practices at Theranos were intended to prevent the discovery of the alleged fraud. These acts
7 relate to the alleged scheme to defraud as a whole.

8 Moreover, much of the evidence discussed in these categories is evidence that can be
9 introduced not as Rule 404(b) evidence but as factual evidence. In particular, former employees
10 of Theranos may testify largely about their observations and experiences while working at the
11 company. Their personal experiences and observations related to some of the trade secrets
12 practices Theranos implemented is not inadmissible character evidence for this purpose.

13 The Court finds that Rule 403 does not prohibit the admission of this evidence. The
14 evidence the Government anticipates it will introduce is highly probative of a specific element of
15 the charged offense—namely, Holmes’s alleged scheme to defraud and the steps she took to
16 continue the scheme. Holmes argues that presentation of evidence concerning Theranos’ trade
17 secrets practices would create a series of mini-trials as she would be unduly forced to introduce
18 expert testimony to try to establish that Theranos’ trade secrets practices were not improper. This
19 disagreement about particular trade secrets practices and when and how they were employed is a
20 factual dispute. Additionally, although evidence related to threatening or intimidating employees
21 or former employees of Theranos may be prejudicial, the evidence is relevant as to how Holmes
22 was operating the company and therefore does not rise to the level of unfair prejudice. Finally, the
23 Court does note that for some of these practices, it will be incumbent upon the Government to
24 come forward with a sufficient connection between Holmes and Theranos’ implementation of
25 particular trade secrets practices, including threatening and intimidating employees or former
26 employees of the company.

1 For these reasons, Holmes's motion to exclude evidence of Theranos' trade secrets
2 practices is **DENIED** at this time. Holmes may raise pertinent objections at trial if the
3 Government has not established a sufficient connection between Holmes and Theranos' trade
4 secrets practices.

5 **K. Holmes's MIL to Exclude Certain Evidence and Argument Regarding Third-**
6 **Party Testing Platforms (Dkt. No. 576)**

7 In this motion Holmes moves to exclude evidence and argument that Theranos "tampered
8 with" and "concealed" commercially available third-party diagnostic testing platforms. Holmes's
9 Mot. in Limine to Exclude Certain Evidence and Argument Regarding Third-Party Testing
10 Platforms Under Rules 401-403, 404(b), and 702 ("Holmes 576 Mot."), Dkt. No. 576. Holmes,
11 however, is not arguing that the Government should be precluded from introducing evidence
12 related to the modifications or the tests run on the modified testing platforms. Rather, Holmes
13 argues the Government should be precluded from insinuating there was anything improper about
14 such modifications or that the modifications violated the manufacturer's specifications or from
15 presenting any evidence of the same. *Id.* at 4. Additionally, Holmes asserts the Government
16 should be precluded from suggesting that the measures Theranos implemented to protect these
17 trade secrets were improper or an attempt to "conceal" information. *Id.*

18 The Government responded in its opposition and at the hearing that it does not intend to
19 introduce testimony or argument that Theranos' modifications of third-party analyzers violated
20 industry standards or manufacturer agreements, or that those modifications were wrong or
21 unethical in and of themselves. Gov't Opp'n to Holmes's 576 Mot. ("Holmes 576 Opp'n"), Dkt.
22 No. 666, at 2; May 6, 2021 Hr'g Tr., Dkt. No. 794 at 65:9-12. Still, while the Government will be
23 able to present evidence related to modifications Theranos made to third-party testing platforms,
24 the use of the phrase "tampered" goes beyond the scope of proposed witness testimony and
25 opinions related to third-party testing platform modifications. The Government has not presented
26 any opinions from qualified experts under Rule 702 to establish whether and to what extent certain
27 modifications to third-party testing platforms may be considered "tampering."

Thus, while the Government can introduce evidence related to the modifications or the tests run on third-party platforms, it will not be able to frame its evidence and argument in a way to suggest the third-party platforms were “tampered” with until and unless that has been proven by appropriate evidence.

Holmes also argues the Government should be precluded from introducing evidence about what was or was not “concealed” or shared with manufacturers of the third-party testing platforms. Holmes contends there is no probative value to this evidence, and it will only serve to unfairly prejudice her for conduct related to protecting trade secrets. For similar reasons discussed in Holmes motion to exclude evidence about Theranos’ trade secrets practices, the Court finds this type of fact evidence to be probative and not so unfairly prejudicial it outweighs the probative value. Theranos’ use of third-party platforms and what Holmes and Theranos disclosed about its use correlates to key events at issue in this case. The Court, therefore, finds evidence relating to what Theranos disclosed and did not disclose about modifications to third-party platforms is relevant and not unfairly prejudicial.

Accordingly, the Court **GRANTS IN PART** and **DENIES IN PART** Holmes’s motion to exclude certain evidence and argument regarding third-party testing platforms.

L. Holmes’s MIL to Exclude Evidence of Alleged Blaming and Vilifying of Competing Companies and Journalists (Dkt. No. 577)

The Government intends to present evidence under Rule 404(b) that Defendants blamed or vilified competing companies and journalists. *See* Holmes’s Mot. in Limine to Exclude Evidence of Alleged Blaming and Vilifying of Competing Companies and Journalists Under Rules 401-403 and 404 (“Holmes 577 Mot.”), Dkt. No. 577. Specifically, the Government identifies five acts that it intends to introduce at trial:

- 1) A Theranos employee will testify that Holmes and Balwani led a group of employees in a chant of “Fuck you, Sonora Quest,” with the implication that competitors such as Sonora Quest and Quest were “behind the questioning of Theranos.” Saharia Decl., Ex. 3 at 59.

- 2) A Walgreens employee will testify that Holmes stated that “Theranos’ competitors were sending people into Walgreens to order esoteric blood tests in order to throw off the blood draw percentages.” *Id.* at 61.
- 3) Another Walgreens employee will testify that “Balwani advised Walgreens that the reasons for the high number of venous blood draws included the cartridges not being ready for tests that were being ordered, LabCorp and Quest sending people in to order tests which required venous blood draws, and doctors ordering esoteric tests.” *Id.* at 61–62.
- 4) A Theranos employee will testify that he learned at “an all-hands meeting” of an impending WSJ article by John Carreyrou. At that meeting, “the attendees were told the article made several allegations that were false, and that this story was being pushed by LabCorp and Quest.” *Id.* at 62.
- 5) A Theranos employee will testify that Holmes and Balwani led a group of employees in a chant of “Fuck you, Carreyrou.” *Id.* at 59.

Holmes argues that this evidence is irrelevant under Rules 401, 402 and 404, and that if the Government intends to introduce this evidence under Rule 404(b) as false statements, the Government has not complied with its obligation to identify evidence of falsity under Criminal Local Rule 16-1(c)(3). Holmes 577 Mot. at 3–4; Holmes Reply Br. in Supp. of Holmes’s 577 Mot. (“Holmes 577 Reply”), Dkt. No. 720, at 1–4.

The Government concedes that the evidence concerning “Fuck you” chants is “somewhat inflammatory,” but argues that Holmes’s “extreme response to media criticism” is probative of her “*mens rea* and consciousness of guilt.” Gov’t Opp’n to Holmes 577 Mot. (“Gov’t 577 Opp’n”), Dkt. No. 678, at 3–4. With respect to the statements Defendants made to Walgreens employees and the all-hands meeting concerning the impending WSJ article, the Government contends such statements are admissible “to provide ‘a coherent and comprehensible story regarding the commission of the crime’” and that they are probative of Holmes’s intent, knowledge, and consciousness of guilt. *Id.* at 4–5 (quoting *United States v. DeGeorge*, 380 F.3d 1203, 1220 (9th Cir. 2004)).

The Court agrees with Holmes that the chants have little probative value as to whether Theranos’ technology was accurate or reliable, or whether Holmes made false statements to investors or customers. Fed. R. Evid. 401, 402. Whatever minimal probative value this evidence

offers is outweighed by the potential for prejudice. Fed. R. Evid. 403.

As to the statements made at the all-hands meeting regarding the WSJ article and the statements Defendants made to Walgreens employees, the Court finds significant the Government's inability to point to any evidence in its Rule 404(b) disclosure showing that those statements were false. The Government says only that "[t]he evidence at trial *will* show that these are misrepresentations, made to Walgreens in an attempt to explain why Theranos was failing to do what it claimed it could do" and that "[t]hese misrepresentations are therefore inextricably intertwined with the alleged investor fraud and should be admitted." Gov't 577 Opp'n at 4 (emphasis original). The Government does not explain what evidence will prove falsity, and the Court therefore cannot say at this time whether the statements should be excluded. The Court declines the Government's invitation to allow the Government to escape its Criminal Local Rule 16-1(c)(3) obligations by admitting the statements as part of an overall narrative, particularly when the Government has not adequately explained why statements about potential sabotage by Theranos competitors tends to shed any light on investor fraud.

Accordingly, the Court **GRANTS** Holmes's motion as to the chants, but **DEFERS** ruling on the statements to Walgreens employees and the all-hands meeting statements.

M. Holmes's MIL to Exclude Evidence of Alleged Violations of Industry Standards and Government Regulations (Dkt. No. 569)

In this motion, Holmes seeks to exclude evidence regarding Theranos' purported "[v]iolations of industry standards and government regulations or rules regarding research and development procedures, medical devices and clinical laboratory practices." Holmes's Mot. in Limine to Exclude Evidence of Alleged Violation of Industry Standards and Government Regulations Under Rules 401-403 ("Holmes 569 Mot."), Dkt. No. 569, at 1–2 (citing Saharia Decl., Ex. 1, Dkt. No. 580 at 7). The Government's 404(b) notice states, "[i]n furtherance of their scheme to defraud, Defendants disregarded and failed to conform to industry standards as well as government regulations or rules regarding research and development procedures, medical devices and clinical laboratory standards." Saharia Decl., Ex. 1, Dkt. No. 580 at 7. Specifically, Holmes

1 seeks to exclude any testimony offered suggesting that Theranos violated any industry standard or
2 federal regulation. *See* May 4, 2021 Hr’g Tr., Dkt. No. 792, at 170:14-18.

3 Holmes, for example, points to the Government’s intent to introduce as part of Dr.
4 Rosendorff’s testimony, evidence that after Theranos began using the Theranos blood analyzer
5 (“Edison 3.5”) in the CLIA lab in November 2013, Dr. Rosendorff advised Balwani by email: “we
6 are currently not compl[iant] in terms of CLIA law.” *See* Leach Opp’ns Decl., Ex. 45, Dkt. No.
7 681-9. Dr. Rosendorff also highlighted how Theranos had not established the upper end of
8 reportable reference ranges for tests. *Id.* Holmes has identified four subcategories of evidence
9 disclosed by the Government she believes are at issue in this motion and should not be introduced
10 to suggest Theranos violated industry standards or federal regulations : (1) research and
11 development validation studies; (2) clinical trials; (3) CMS and CDPH reports and
12 correspondence; (4) Theranos’ control over its laboratory. Holmes 569 Mot. at 4–5. To support
13 her request, Holmes argues that (1) the Government’s evidence of alleged violations of industry
14 standards and government regulations requires impermissible legal opinions and (2) alleged
15 violations of industry standards and government regulations are irrelevant and prejudicial.

16 **1. The Government’s evidence of alleged violations of industry standards and**
17 **federal regulations does not require impermissible legal opinions**

18 Holmes is correct that experts may interpret and analyze factual evidence but may not
19 testify about the law. *See S.E.C. v. Capital Consultant, LLC*, 397 F.3d 733, 749 (9th Cir. 2005).
20 Indeed, testimony that is “couched . . . in the form of a legal conclusion—ostensibly based on
21 what appears to be [the witness’] own survey of state laws . . . is improper and must be excluded.”
22 *Lukov v. Schindler Elevator Corp.*, No. 5:11–cv–00201 EJD, 2012 WL 2428251, at *2 (N.D. Cal.
23 June 26, 2012).

24 Here, however, the Government is not seeking to introduce impermissible legal opinions
25 related to important legal questions for the case. Instead, The Government want to introduce
26 evidence, like Dr. Rosendorff’s statements about CLIA regulations and industry standards,
27 because they are relevant to central issues regarding notice to Holmes and her state of mind.

Specifically, the Government seeks to use Dr. Rosendorff's statements about Theranos' compliance with industry standards and federal regulations to introduce into evidence how Holmes responded when these issues were brought to her attention by Theranos' laboratory director. Gov't Opp'n to Holmes 569 Mot. ("Gov't 569 Opp'n"), Dkt. No. 670, at 5–6. Citing *United States v. Graf*, 610 F.3d 1148, 1164 (9th Cir. 2010), the Government argues this purpose is consistent with Ninth Circuit case law. In *Graf*, the court affirmed admission of statements relating to legal conclusions communicated to a defendant because the evidence was relevant to the defendant's state of mind. 610 F.3d at 1164.

Accordingly, while the Government cannot offer evidence detailing violations of industry standards or government regulations solely to support an element of the charged offense, the Court will allow statements made to Holmes which concerned perceived violations of industry standards and government regulations to be admitted. A curative instruction will be given to the jury dictating that this evidence is being offered only to show notice was given to Holmes and her state of mind. The evidence will not be introduced for the purpose of establishing that Theranos' laboratory practices violated industry standards or government regulations.

2. Evidence of alleged violations of industry standards and federal regulations is relevant and not unduly prejudicial

Because the Government asserts that evidence relating to alleged violations of industry standards and government regulations relates to Holmes's knowledge and response to certain laboratory conditions, Holmes's Rules 401 and 403 arguments lack merit. Each of the subcategories identified by Holmes concern aspects of Theranos' laboratory practices, and are probative because of the notice given to Holmes about different aspects of the lab and her state of mind after she was given notice. The TSI pointedly puts this evidence at issue. The Court's curative instruction to the jury also helps to eliminate the risk of undue prejudice.

Accordingly, the Court **DENIES** Holmes's motion to exclude evidence of alleged violations of industry standards and government regulations.

N. Holmes's MIL to Exclude Theranos Customer Service Spreadsheets (Dkt. No. 570)

Holmes moves on hearsay, prejudice, and improper character evidence grounds to preclude the Government from introducing Theranos' customer-service spreadsheets, which purportedly contain summaries of various customer-service communications. Holmes's Mot. in Limine to Exclude Theranos' Customer-Service Spreadsheets Under Rules 401-404 and 801-803 ("Holmes 570 Mot."), Dkt. No. 570. The Government intends to offer these spreadsheets to demonstrate that Holmes "knew that Theranos' tests . . . suffered from accuracy problems that rendered them unreliable and not suitable for informing clinical treatment decisions." Saharia Decl., Ex. 1, Dkt. No. 580 at 2; *id.*, Ex. 3, Dkt. No. 580-2.

The Government opposes this motion, rejecting Holmes's argument that the customer-service spreadsheets are hearsay (and their contents double hearsay). According to the Government, the customer-service spreadsheets are admissible as business records and probative of Holmes's intent to defraud because they help show that Holmes had notice of "shortcomings" with the technology she was marketing to patients. Gov't Opp'n to Holmes's 570 Mot. ("Gov't 570 Opp'n"), Dkt. No. 665, at 1. Holmes argues the Government has not established she reviewed, was familiar with, or even had access to the spreadsheets. Holmes 570 Mot. at 6. In addition, Holmes argues the Court should preclude the Government from introducing the customer-service spreadsheets at trial pursuant to Rule 403. *Id.* at 7. In contrast, the Government argues Holmes is prematurely seeking to have the Court sustain objections to the purported business records before the Government has had the opportunity to obtain certificates of business records or call custodians at trial to meet the Federal Rule of Evidence 803(6) standard and lay foundation for how Holmes was kept informed of customer complaints. Gov't 570 Opp'n at 3-5.

Under Rule 803(6), business records fall within an exception to the hearsay rule. For a document to be considered a business record, the following criteria must be satisfied: "(A) the record was made at or near the time by--or from information transmitted by--someone with knowledge; (B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit; (C) making the record was a regular

1 practice of that activity; (D) all these conditions are shown by the testimony of the custodian or
2 another qualified witness, or by certification that complies with Rule 902(11) or (12) or with a
3 statute permitting certification; and (E) the opponent does not show that the source of information
4 or the method or circumstances of preparation indicate a lack of trustworthiness.” Fed. R. Evid.
5 803(6).

6 The Court cannot rule on the business records issue until trial. The Government states it
7 intends to introduce the proper custodians and certificates and lay foundation connecting these
8 spreadsheets to Holmes at trial. Gov’t 570 Opp’n at 3–5. The Court does find, however, that the
9 contents of the spreadsheets, i.e., the purported summaries of customer communications, can be
10 introduced to show notice. Such evidence would not run afoul of Rule 801(c) because it would
11 not be offered for the truth of the matter asserted that there were “shortcomings” with Theranos’
12 technology. *See White v. Ford Motor Co.*, 312 F.3d 998, 1009 (9th Cir. 2002) (upholding the use
13 of customer reports to show notice without concluding that the reports were admissible for their
14 truth); *see also United States v. Moseley*, 890 F.3d 9, 13 (2d Cir. 2020) (evidence of “complaints
15 which were called to a defendant’s attention” are “relevant to the issue of the defendant’s intent.”).

16 Although specific customer complaints included in the spreadsheets that focus on
17 Theranos’ testing cannot be considered to prove the truth of the matter asserted, complaints about
18 Theranos’ technology can be admissible to show Theranos received such complaints. Moreover,
19 this evidence could help establish Holmes state of mind or knowledge related to specific
20 allegations in the TSI.

21 With respect to Holmes’s Rule 403 objection, her knowledge or notice is an essential
22 element of the alleged scheme to defraud. However, introduction into evidence of the specific
23 details of the customer complaints that address Theranos’ tests would be a waste of time, could
24 confuse and mislead the jury, and be prejudicial to Holmes. Accordingly, the Court would only
25 allow the Government to present evidence that customer complaints focusing on Theranos’ tests
26 exist but will not be allowed to introduce the specific details of the complaints. The Court would
27 also give the jury a limiting instruction that such evidence is admissible only for the purpose of

1 establishing Holmes's notice of those complaints and cannot be used to establish there were actual
2 issues with Theranos' technology or for any other purpose.

3 Accordingly, the Court declines to issue an order broadly precluding the customer-service
4 spreadsheets or evidence that those summaries of customer communications about Theranos'
5 testing technology exists and **DEFERS** ruling until trial.

6 **O. Holmes's MIL to Exclude Certain Rule 404(b) Evidence for Lack of Expert**
7 **Support (Dkt. No. 564)**

8 Holmes next moves to exclude three subcategories of evidence disclosed in the
9 Government's Rule 404(b) notice dealing with aspects of Theranos' laboratory practices: (1)
10 multiplexing test results and disregarding outliers to mask inconsistency; (2) improperly setting
11 and altering reference ranges; and (3) withholding important information from doctors and
12 patients. *See generally* Holmes's Mot. in Limine to Exclude Certain Rule 404(b) Evidence For
13 Lack of Expert Support Under Rules 401-403 and 701-702 ("Holmes 564 Mot."), Dkt. No. 564.

14 Holmes argues the Government cannot prove that Theranos' laboratory practices violated
15 industry standards or were otherwise improper in part because these are issues "based on
16 scientific, technical, other specialized knowledge," that require expert testimony. Fed. R. Evid.
17 701. Holmes adds that the Government has disclosed no such expert testimony and that no expert
18 will be able to opine that these aspects of Theranos' laboratory practices rendered Theranos' tests
19 inaccurate or unreliable. Thus, this evidence is irrelevant, any connection between this evidence
20 and Holmes's intent is speculative, and the Court should exclude it under Rules 401-403 and 701-
21 702.

22 Although included in the Government's Rule 404(b) notice, the Court recognizes the
23 majority of evidence within these three subcategories as fact evidence not necessitating evaluation
24 under Rule 404(b). These subcategories also correlate to key allegations raised in the TSI, or are
25 probative to what Holmes's knew about laboratory practices and not unduly prejudicial.

26 **1. Multiplexing test results and disregarding outliers to mask inconsistency**

27 With respect to the use of "multiplexing," the Government alleges that Theranos "operated

1 its analyzers according to a protocol that included running each individual test [six] times [on a
2 given sample in parallel] and then multiplexing the test results in order to drive the final, reported
3 result.” Saharia Decl., Ex. 1 at 8. When a patient’s sample was inserted into the Theranos device,
4 six pipette tips would simultaneously draw six portions of blood from the larger sample. Each of
5 those six portions would then be tested for the target analyte, i.e., the substance that was being
6 measured. Those six tests would then yield six results. Theranos’ algorithm would then review the
7 set of six numerical values and discard any that were outliers. The remaining values were then
8 averaged, and the combined average value was reported to the patient. According to the
9 Government, “this approach tended to mask consistency problems with Theranos’ tests.” *Id.* In
10 support, the Government relies on statements regarding the efficacy of multiplexing made by
11 Theranos’ former lab director Dr. Adam Rosendorff. For example, Dr. Rosendorff would testify
12 that the multiplexing process he used in real time as Theranos’ laboratory director was “not good
13 laboratory practice,” “not ideal,” and that “it would be better to run the assay a single time using a
14 highly accurate and reliable method, and report that result.” Saharia Decl., Ex. 3 (Sept. 28, 2020
15 Gov’t Suppl. Rule 404(b) Notice); ; *see also id.*, Ex. 5 at 13 (Rosendorff’s belief that “[t]his
16 process was not ideal because it *may* have tended to increase the appearance of precision beyond a
17 lab test’s true performance” (emphasis added)).

18 Holmes argues this evidence would require an expert opinion rooted in sufficient data and
19 a reliable methodology, to prove that Theranos’ multiplexing method actually masked precision
20 problems with Theranos’ tests. *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharms., Inc.*, 509
21 U.S. 579 (1993). The Court does not agree, because an explanation of what multiplexing entailed
22 does not involve the application of any technical algorithms or procedures. Dr. Rosendorff’s
23 background as a laboratory director gives him a sufficient basis on which to present his
24 observations and beliefs about Theranos’ use of multiplexing and his experience employing the
25 method. Moreover, the change in Dr. Rosendorff’s view of the multiplexing method is not a basis
26 to disqualify him from testifying about multiplexing. Holmes is entitled to explore these issues on
27 cross-examination. Accordingly, the Court finds that a blanket exclusion of evidence relating to

Theranos' multiplexing method is not warranted at this time.

2. Improperly setting and altering reference ranges

For reference ranges, the Court also does not believe evidence the Government intends to offer on this topic requires expert analysis. The Government revealed in its 404(b) notice that Dr. Rosendorff may testify that he was involved in setting reference ranges for Theranos tests. Dr. Rosendorff may testify that Theranos launched its clinical testing services in 2013 without conducting a formal reference range study to determine the appropriate reference range values because Theranos was "in a hurry" to launch, and that it would have been preferable to establish reference ranges before the launch. Saharia Decl., Ex. 3 at 71-72. Separately, Dr. Rosendorff may testify that Holmes and Balwani were resistant to the idea of establishing and disclosing reference ranges that were specific for Theranos' capillary blood tests and distinct from the venous sample tests that Theranos ran on third-party devices. *Id.*

This testimony is based on Dr. Rosendorff's percipient observations while at Theranos as well as his judgment and experience as a certified laboratory director. Because the evidence will not be introduced to argue that Theranos' reference ranges were violating industry standards, the introduction of a scientific basis and methodology pursuant to Rule 702 is not needed. Therefore, the Court declines to issue a blanket exclusion of evidence relating to Theranos' reference ranges.

3. Withholding important information from doctors and patients

Lastly, the Government seeks to introduce evidence that Theranos "withheld" from doctors and patients information such as "what type of analyzer had been used for a given test," "the fact that Theranos' tests were not FDA approved," that Theranos "relied on third-party analyzers for many of its tests." Saharia Decl., Ex. 1 at 8. In its supplemental disclosure, the Government explains that Dr. Rosendorff advocated stating on laboratory reports whether the blood was collected by fingerstick or venous draw, but this was ultimately not done. *Id.*, Ex. 3 at 74. Holmes argues this evidence should be excluded because the Government has not disclosed any reliable opinion to establish Theranos did anything improper or that its practices had any impact on the adequacy and reliability of its technology.

For reasons discussed above, the Court finds that evidence regarding information Theranos allegedly withheld from doctors and patients should not be excluded for lack of expert opinion. The evidence presented is fact evidence about information Theranos disclosed and did not disclose to investors and patients. Although the Court notes Holmes's argument that the Government cannot use this evidence to establish Theranos was violating industry standards without proper expert opinion, the jury can consider what decisions Holmes and Theranos made about certain disclosures when evaluating Holmes's intent and the alleged scheme to defraud. Thus, because the evidence will be used as fact evidence, a blanket order at this stage excluding evidence relating to withheld information is not warranted.

Accordingly, the Court **DENIES** Holmes's motion to exclude certain Rule 404(b) evidence for lack of expert support.

P. Holmes's MIL to Exclude Evidence and Argument as to the Purported Inaccuracy or Unreliability of Tests Not Identified in the Bill of Particulars (Dkt. No. 568)

Holmes next moves to preclude the Government from introducing at trial evidence and argument regarding the purported inaccuracy and unreliability of tests not identified in the Government's Bill of Particulars.¹³ *See generally* Holmes's Mot. in Limine to Exclude Evidence and Argument by the Government as to the Purported Inaccuracy or Unreliability of Tests Not Identified in the Bill of Particulars ("Holmes 568 Mot."), Dkt. No. 568. Holmes is not seeking a blanket ruling precluding any mention of other tests offered by Theranos that were not included in the Government's Bill of Particulars. Holmes Reply Br. in Supp. of Holmes's 568 Mot. ("Holmes 568 Reply"), Dkt. No. 711, at 2. Rather, for tests not listed in the Bill of Particulars, Holmes requests that the Court require the Government to provide notice of exhibits and testimony related to these unidentified tests so that any anticipated issues can be raised outside of the presence of the jury.

¹³ The Court took the motion under submission on the papers after the parties did not request oral argument.

Recognizing that Holmes should not be forced to prepare unnecessary defenses for evidence the Government would not raise at trial, the Court ordered the Government to identify “the particular tests that the Government claims Theranos was not capable of consistently producing.” Dkt. No. 330 at 16 (citing *United States v. Bortnovsky*, 820 F.2d 572, 574 (2d. Cir. 1987)). The Government’s March 2020 Bill of Particulars (“the Bill of Particulars”) identified twenty-five tests. Dkt. No. 377 at 25. The TSI also listed the same twenty-five tests. TSI ¶ 16. In June 2020, however, the Government’s initial exhibit list included several exhibits which addressed tests not identified in the Bill of Particulars. Holmes states that the potential evidence addressing additional unlisted tests comes in many different forms including exhibits and potential witness testimony discussing test results data, individual patient results, and reruns of certain tests. Holmes 568 Mot. at 2.

The Government responds that it has no plans to introduce evidence or argument about tests, other than those disclosed in the indictment, for the purpose of “attacking their accuracy and reliability.” Gov’t Opp’n to Holmes 568 Mot. (“Gov’t 568 Opp’n”), Dkt. No. 664, at 2. Nevertheless, the Government argues evidence regarding additional tests is still admissible for purposes unrelated to the accuracy and reliability of those tests. *Id.* The Government explains evidence related to additional unlisted tests could be used to demonstrate the number and types of tests that Theranos offered at a given time and which devices and methods Theranos used to perform those tests. *Id.* at 3. Similarly, the Government contends that evidence referencing additional unlisted tests is relevant to the extent it shows Theranos’ general practices in connection with developing, offering, conducting, and reporting results of its assays. *Id.* at 3. The Court finds that the Government should not be precluded from introducing all evidence related to additional unlisted tests. Indeed, Holmes recognizes that there may be permissible purposes for the introduction of such evidence, which still comport with the Court’s Order directing a Bill of Particulars about the tests that the Government claims Theranos was not capable of consistently producing. Holmes 568 Reply at 2.

Accordingly, Holmes's motion to exclude evidence and argument regarding tests not listed in the Bill of Particulars is **GRANTED**. The Government is precluded from introducing any evidence or argument regarding the purported inaccuracy and unreliability of tests not identified in the Government's Bill of Particulars. The Government may still introduce evidence or testimony about tests not listed in the Bill of Particulars for purposes unrelated to the accuracy and reliability of those tests. The Government shall provide notice of exhibits or testimony that may involve tests not identified in the Bill of Particulars prior to their introduction so that the parties and Court can address any issues, in the context of specific evidence, outside the presence of the jury.

IV. GOVERNMENT'S MOTIONS IN LIMINE AND RELATED DEFENSE MOTIONS

A. MIL No. 1 to Preclude Defendant from Offering an Improper Defense of Blaming Her Victims and Selective Prosecution

The Government moves to preclude Holmes from offering a defense of blaming her victims for failing to exercise greater diligence in their dealings with Theranos. Gov't Mot. The Government further seeks to preclude Holmes from introducing a related defense regarding the Government's selective prosecution of Holmes and Theranos amongst a range of similar abuses perpetuated by other Silicon Valley startups. Holmes opposes both arguments asserted in the Government's motion. Holmes's Opp'n to Gov't Mots. In Limine ("Holmes Opp'n"), Dkt. No. 659. The Court addresses each argument in turn.

1. Victim blaming

The Government first argues that a fraud victim's naiveté or gullibility is not a defense to criminal charges under federal fraud statutes. According to the Government, excluding this defense is necessary to prevent distraction from the key issues of the case: "Defendant's intent to defraud and the falsity and materiality of her statements." Gov't Mot. at 1. However, Holmes argues such preclusion is overbroad because it will forestall the introduction of evidence on these very points. Holmes Opp'n at 2. Specifically, Holmes contends that evidence of circumstances surrounding a victim's engagement with Theranos directly relate to the element of "materiality" and could potentially be used for impeachment purposes.

1 “Materiality of falsehood” is an essential element of wire fraud. *Neder v. United States*,
 2 527 U.S. 1, 25 (1999). The test to determine materiality is whether the statement “has a natural
 3 tendency to influence, or was capable of influencing, the decision of the decision-making body to
 4 which it was addressed.” *United States v. Peterson*, 538 F.3d 1064, 1072 (9th Cir. 2008) (quoting
 5 *Kungys v. United States*, 485 U.S. 759, 770 (1988)). This is an objective test. *Id.*

6 It is well settled that a victim’s negligence is not a defense to wire fraud. *United States v.*
 7 *Lindsey*, 850 F.3d 1009, 1015 (9th Cir. 2017). Unlike common law fraud, reliance upon the
 8 defendant’s misrepresentations has no place in criminal fraud cases. *Neder*, 527 U.S. at 25.
 9 Moreover, “[i]t is immaterial whether only the most gullible would have been deceived by the
 10 defendants’ scheme.” *Ciccone*, 219 F.3d at 1083 (quoting *United States v. Hanley*, 190 F.3d 1017,
 11 1023 (9th Cir. 1999)) (alteration in original). However, evidence of the circumstances
 12 surrounding a victim’s entanglement in the fraudulent scheme may be admissible for other
 13 purposes. Indeed, documents and other information available to the parties can be useful for
 14 determining materiality. *United States v. Bogucki*, No. 18-cr-00021-CRB-1, 2019 WL 1024959,
 15 at *4 (N.D. Cal. Mar. 4, 2019). In *Bogucki*, the court granted defendant’s Rule 29 motion for
 16 acquittal after finding no reasonable jury could find the defendant made materially false
 17 statements. *Id.* at *7. In reaching this decision, the court considered five pieces of evidence,
 18 including call transcripts and PowerPoint presentations. *Id.* at *4-6. While the *Bogucki* court
 19 ultimately found this evidence did not satisfy the materiality requirement, this highlights the
 20 necessity of evaluating the information available to victims in order to determine if the alleged
 21 false statements had the capacity to mislead. Relatedly, as Holmes notes, a victim’s knowledge of
 22 the fraud could serve as relevant impeachment evidence. *United States v. Yang*, No. 16-cr-00334-
 23 LHK, 2019 WL 5536213, at *3 (N.D. Cal. Oct. 25, 2019). The Court agrees that the way “victims
 24 reacted to alleged misrepresentations . . . is highly relevant to their credibility.” 659 Opp’n at 2.

25 Based on the foregoing, the Court **GRANTS** the Government’s motion to the extent
 26 Holmes attempts to utilize victim blaming as a defense. However, the Court **DENIES** the
 27 Government’s motion with respect to precluding Holmes from introducing admissible

1 impeachment evidence and other admissible evidence bearing on materiality. The Court will
2 review and hear from the parties as to any specific evidence sought to be introduced prior to its
3 presentation during the trial.

4 **2. Selective prosecution**

5 The Government seeks to further preclude Holmes from introducing a defense focused “on
6 the culture of Silicon Valley startups.” Gov’t Mot. at 3. In particular, the Government asks to
7 exclude potential evidence regarding other startup founders engaging in similar exaggerated and
8 “dramatic promises to generate . . . capital.” *Id.* While not entirely clear, the Government appears
9 to assert these claims amount to an improper selective prosecution defense. This request is
10 overbroad.

11 A selective prosecution claim is an “assertion that the prosecutor has brought the charge
12 for reasons forbidden by the Constitution.” *United States v. Armstrong*, 517 U.S. 456, 463 (1996).
13 To establish a prima facie showing of selective prosecution, a defendant must establish:

14 (1) that, while others similarly situated have not generally been
15 proceeded against because of conduct of the types forming the basis
16 of the charge against him, he has been singled out for prosecution,
17 and (2) that the government’s discriminatory selection of him for
18 prosecution has been invidious or in bad faith, i.e., based upon such
impermissible considerations as race, religion, or the desire to
prevent his exercise of constitutional rights.

19 *United States v. DiStefano*, 129 F. Supp. 2d 342, 347 (S.D.N.Y. 2001).

20 At the hearing, the Government indicated its concerns that Holmes would argue that her
21 conduct was in line with Silicon Valley startup culture and thus she was singled out for
22 prosecution where other entrepreneurs were not. Holmes disavowed advancement of a selective
23 prosecution argument at trial, and the Court takes her at her word.

24 The Government further expressed concern that Holmes would comment on the culture of
25 Silicon Valley startups, including aggressive marketing or exaggeration. The Court recognizes
26 that evidence in this case will undoubtably touch on the nature of startup companies, including
27 financing, funding, industry protocols, and other issues common to the technology industry in

1 Silicon Valley. The Court will permit general fair comment on the marketing of new ventures,
2 including statements concerning investment and the nature of the firm, product, or technology.

3 **B. MIL No. 2 to Preclude the Defense from Referencing Punishment in Front of**
4 **The Jury**

5 The Government moves to preclude any reference by the defense to Holmes's alleged or
6 potential punishment during any trial stage (including jury selection, opening statements,
7 examination of witnesses, and summation). The Government seeks to preclude these references to
8 punishment as irrelevant and/or unfairly prejudicial under Federal Rules of Evidence 401, 402,
9 and 403. The Government provides examples of both overt and subtle references to punishment
10 that it seeks to preclude during trial. An overt example of a reference to punishment could be
11 "[t]he defendant is facing a prison term if convicted." Gov't Mot. at 4. In contrast, the
12 Government's examples of subtler references to punishment include statements such as "the
13 Defendant is facing a lot of time," "the case has serious consequences for the Defendant," "the
14 Defendant's liberty is at stake in this trial," or "your decision will have consequences for a long
15 time to come." *Id.* The Government maintains that once a jury is exposed to statements regarding
16 Holmes's potential punishment or other such consequences, this information cannot be forgotten
17 nor can the circumstances be remedied by a curative instruction.

18 Holmes acknowledges that would be inappropriate for her to reference any potential
19 imprisonment before the jury. However, she disagrees with the Government's motion to the
20 extent it seeks to prohibit the "subtler" references to punishment that the Government has
21 identified, such as "the case has serious consequences for the Defendant" or "the Defendant's
22 liberty is at stake in this trial." Holmes Opp'n at 5; Gov't Mot. at 4.

23 Both sides are correct. "It has long been the law that it is inappropriate for a jury to
24 consider or be informed of the consequences of their verdict." *United States v. Frank*, 956 F.2d
25 872, 879 (9th Cir. 1992). Any commentary to the jury on a defendant's potential penalty or
26 punishment "draw[s] the attention of the jury away from their chief function as the sole judges of
27 the facts, opens the door to compromise verdicts, and confuses the issues to be decided." *United*

1 *States v. Olano*, 62 F.3d 1180, 1202 (9th Cir. 1995); *see also Shannon v. United States*, 512 U.S.
2 573, 579 (1994); *Zal v. Steppe*, 968 F.2d 924, 930 (9th Cir. 1992) (stating that any verdict “must
3 be based on the law and evidence, not on jury nullification as urged by either litigant”).

4 However, “[s]ubtle references such as the one mentioned above are not really referencing
5 punishment.” *United States v. Williams*, No. 3:13-cr-00764-WHO-1, 2017 WL 4310712, at *8
6 (N.D. Cal. Sept. 28, 2017). In *Williams*, the court’s primary focus was whether the defense should
7 be allowed to reference the punishment of cooperating witnesses for impeachment purposes,
8 which is not a question before this Court. Nevertheless, *Williams* is instructive in its ruling that
9 “defendants are precluded from referencing the particulars of any past or potential punishment in
10 an attempt to elicit the sympathies of the jury.” *Williams*, 2017 WL 4310712, at *8. Further, the
11 *Williams* court reasoned that some subtler references to punishment, such as stating that “this case
12 has serious consequences for the defendant,” are “not really about punishment.” *Id.*

13 During the hearing the Court discussed the issue with counsel and granted the
14 Government’s motion from the bench. The Court recognized, however, that comments of counsel
15 about the serious task the jurors will undertake with this case and the opportunity to remind them
16 of their oath to serve are appropriate. The Court indicated it would allow Holmes to make careful,
17 cautious, and appropriate comments when talking about the nature of the case to the jury.

18 The Government’s MIL No. 2 to preclude the defense from referencing punishment in
19 front of the jury is **GRANTED**.

20 **C. MIL No. 3 to Preclude an Improper Advice-Of-Counsel Defense**

21 The Government moves to preclude Holmes from asserting “an improper advice-of-
22 counsel defense.” Mot. at 5. More specifically, the Government seeks to preclude both (1)
23 testimony suggesting that attorneys made statements to Holmes or that she relied upon such
24 statements to negate intent; and (2) a formal advice-of-counsel defense and the associated jury
25 instruction. *Id.*

26 An advice-of-counsel defense “is not regarded as a separate and distinct defense but rather
27 as a circumstance indicating good faith which the trier of fact is entitled to consider on the issue of

1 fraudulent intent.” *Bisno v. United States*, 299 F.2d 711, 719 (9th Cir. 1961). In order for Holmes
2 “[t]o qualify for an advice of counsel instruction, the defendant must show that there was full
3 disclosure to his attorney of all material facts, and that he relied in good faith on the specific
4 course of conduct recommended by the attorney.” *United States v. Ibarra-Alcarez*, 830 F.2d 968,
5 973 (9th Cir. 1987). Furthermore, when a defendant presents an advice-of-counsel defense, she
6 waives her previous attorney-client privilege as to the communications at issue. *See Hunt v.*
7 *Blackburn*, 128 U.S. 464, 470 (1888); *see generally Bittaker v. Woodford*, 331 F.3d 715, 718 (9th
8 Cir. 2003).

9 Here, the Government indicates that Holmes has provided no notice to the Government of
10 any intent to assert an advice-of-counsel defense and that Holmes has not waived any attorney-
11 client privilege as a prerequisite to asserting such a defense. Gov’t Mot. at 5. As such, the
12 Government argues, it is appropriate to preclude her from asserting an advice-of-counsel defense
13 at this stage. *Id.* Even in the absence of a properly asserted advice-of-counsel defense, the
14 Government is concerned that Holmes may attempt to elicit testimony from her attorneys that
15 suggest that they made certain statements to her upon which she detrimentally relied. *Id.*
16 Regardless, the overarching focus of the Government’s motion is to preclude any defense efforts
17 to elicit statements by attorneys, made to the Holmes or other Theranos employees, as evidence
18 negating Holmes’s allegedly fraudulent intent. *Id.* at 5–6.

19 Holmes contends that barring an advice-of-counsel defense long before proposed jury
20 instructions are due and before the Government presents its case-in-chief is premature. Holmes
21 Opp’n at 6. She also suggests that much of Theranos’ dealings with its many attorneys will likely
22 be highly relevant to the Government’s case and thus it would be improper to preclude all
23 testimony by Holmes or others concerning statements attorneys made to them. *Id.* Holmes
24 additionally notes that the Government has indicated its intent to introduce evidence of certain
25 nonprivileged attorney-client communications, and therefore it would be inappropriate to preclude
26 Holmes from commenting on statements her attorneys may have made to her. *Id.* In response, the
27 Government states that it is concerned only with statements made by attorneys used as evidence to

negate intent. United States' Reply in Support of its Mots. In Limine ("Gov't Reply") at 3, Dkt. No. 726.

The Court finds that ruling on this motion would be premature at this juncture. Holmes will have an opportunity to defend herself against the Government's allegations with appropriate legal theories and within the confines of the law. Prior to invoking an advice-of-counsel defense, however, Holmes must establish the foundational prerequisites for the advice-of-counsel defense, namely: (1) waiver of the applicable attorney-client privilege, (2) demonstrating that there was a full disclosure to her attorney of all material facts, (3) and that she relied in good faith on the specific course of conduct the attorney recommended.

For the reasons stated above and at the hearing, the Government's MIL No. 3 is **DEFERRED.**

D. MIL No. 4 to Preclude a Defense Argument That the Government's Charging Decisions Were Influenced by Coordination with Journalists or Competitors

The Government seeks to preclude Holmes from arguing that its charging decisions were influenced by "coordination" with journalists or competitors. Gov't Mot. at 6. In particular, the Government seeks to preclude any argument that its investigation or charging decisions were unduly influenced by the input of other lab testing companies, such as Quest or LabCorp, or journalists, such as John Carreyrou. First, the Government argues that there is no factual basis for such an argument because it did not actually coordinate with any lab testing companies or journalists. Specifically, the Government represents that no attorney or agent on the prosecution team has ever had a substantive conversation with Quest, LabCorp, or Mr. Carreyrou in connection with this case. Second, the Government argues that any evidence regarding its charging decisions is irrelevant under Federal Rule of Evidence 402.

In response, Holmes contends the Government's investigatory process is relevant and should be presented to the jury. According to Holmes, "'media attention' related to Mr. Carreyrou's back-channel communications with CMS about Theranos caused CMS to use different procedures for surveying Theranos than it normally would have used." Holmes Opp'n at

8 (citing Saharia Decl., Ex. 34 at 3). The FDA’s interview report with CMS employee Sarah Bennett recounted Ms. Bennett’s explanation:

Normally, re-certification surveys are conducted by the state agency, but because of the media attention associated with Theranos, the decision was made to send [CMS employee Gary] Yamamoto and Bennett. John Carreyoru [sic] (a reporter for the Wall Street Journal) had been in contact with CMS about an article he was writing on Theranos. Carreyoru [sic] talked to Dyer about the article. He has never spoken with Bennett. The CMS regional office conducts federal jurisdictional surveys. . . . Bennett was a natural to ask to do the survey because she has survey experience, and she had done it twice before.

Id. at 3. Relying exclusively on Bennett’s explanation above, Holmes contends that “[t]he existence of secret communications between Carreyrou and government investigators undoubtedly bears on the ‘quality of the investigation’ on which the government developed its case.” Holmes Opp’n at 8.

Evidence regarding the Government’s investigation may be relevant and admissible at trial. *United States v. Sager*, 227 F.3d 1138, 1145 (9th Cir. 2000). For example, “[d]etails of the investigatory process potentially affect[] [the investigating agent’s] credibility and, perhaps more importantly, the weight to be given to evidence produced by his investigation.” *Id.*; see also *United States v. Howell*, 231 F.3d 615, 625 (9th Cir. 2000) (explaining utility of evidence that “raises[s] the opportunity to attack the thoroughness, and even good faith, of the investigation”).

Here, the Government does not seek exclusion of evidence regarding the investigatory process. Instead, the Government seeks only to exclude a defense argument that its charging decisions were influenced by “coordination” with journalists or competitors. The only evidence of “coordination” Holmes proffers is Bennett’s interview with the FDA. Bennett’s interview, however, is not evidence of “coordination” with journalists or competitors. Instead, Bennett explains that a reporter contacted CMS, and that the decision was made to have two CMS employees conduct the certification survey rather than the state agency. In the absence of evidence of actual coordination, neither *Sager* nor *Howell* support Holmes’s position. In *Sager*, the defense sought to question the Postal Inspector about “aspects of his investigation” into

possible fraudulent charges on a credit card issued to Trevor Post (“Post”). *Sager*, 227 F.3d at 1143. The trial judge interrupted defense counsel and questioned the relevance of the cross-examination and eventually instructed the jury: “What I am telling you is that you are not here to grade his investigation. You are here to grade the product of that investigation, that is, the evidence.” *Id.* The Ninth Circuit held that the trial court committed error, reasoning that “[t]o tell the jury that it may assess the product of an investigation, but that it may not analyze the quality of the investigation that produced the product, illogically removes from the jury potentially relevant information.” *Id.* at 1145. In the present case, however, precluding Holmes from arguing that there was no “coordination” based on Bennett’s interview with the FDA will not remove from the jury potentially relevant information.

In *Howell*, the defendant claimed that the prosecutor’s failed to inform the defense of material mistakes in two police reports. *Howell*, 231 F.3d at 623–24. On appeal, the *Howell* court rejected the government’s contention that it had no duty to disclose the mistake to the defense. *Id.* at 625. Here, in contrast, the Government is not seeking to exclude evidence of any mistake in the investigation.

The Government’s MIL No. 4 to exclude the defense’s argument that the charging decisions were influenced by “coordination” with journalists or competitors is **GRANTED**. Nothing in this Order is intended to preclude Holmes from presenting evidence or argument regarding the details, thoroughness, or good faith of the criminal investigation.

E. MIL No. 5 to Preclude Defendant From Presenting an Improper Good Faith Defense

The Government next moves to preclude Holmes from “presenting an improper good faith defense.” Gov’t Mot. at 7–8. In its motion, the Government notes the following:

[Holmes] might attempt to present evidence or argument that she should be acquitted because she acted in good faith. Defendant might claim, despite her deception of investors, that she always intended to make those victims’ investments profitable, such that the victims would suffer no loss when all was said and done.

Id. at 7. The Government argues that “[this] argument—and any argument along those lines—

1 should be barred, as they do not constitute recognized legal defenses to charges and are therefore
 2 improper and irrelevant.” *Id.* (citing *United States v. Benny*, 786 F.2d 1410, 1417 (9th Cir. 1986)
 3 (“While an honest, good-faith belief in the truth of the misrepresentations may negate intent to
 4 defraud, a good-faith belief that the victim will be repaid and will sustain no loss is no defense at
 5 all”); *United States v. Hickey*, 580 F.3d 922, 931 (9th Cir. 2009)).

6 In opposition, Holmes states that “[t]he law of this Circuit draws a distinction between a
 7 good-faith belief in the truth of a misrepresentation (which can negate fraudulent intent) and a
 8 good-faith belief that a knowingly fraudulent scheme will eventually lead to a favorable outcome
 9 for the victim.” Holmes Opp’n at 8 (comparing *United States v. Ghilarducci*, 220 F. App’x 496,
 10 501 (9th Cir. 2007) (as an example of the former), with *Tijani v. Holder*, 628 F.3d 1071, 1077 (9th
 11 Cir. 2010) (as an example of the latter)). Holmes argues the Government’s request “would be
 12 overly broad and would conflate the two [different kinds of] good-faith arguments.” *Id.* at 9.
 13 Holmes cites to *United States v. Barreiro*, where the court denied a similar motion to preclude the
 14 defendants’ good-faith defense argument, stating that “[the defendants] [were] entitled to argue
 15 that they lacked intent to defraud because they believed, in good faith, that any alleged
 16 misrepresentations were true and that [the alleged scheme] was a legitimate business.” No. 13-
 17 CR-00636-LHK, 2015 WL 7734139, at *1 (N.D. Cal. Dec. 1, 2015) (citation omitted).

18 The Government states it is not attempting to preclude Holmes from arguing that she had a
 19 good-faith belief that her alleged misrepresentations were true. *See* Gov’t Reply at 5–6 (“An
 20 argument that [Holmes] thought she was telling the truth is obviously permissible. . . . The
 21 [G]overnment fully expects that [Holmes] will deny intentionally misleading victims regarding the
 22 achievements of Theranos”).

23 The Court agrees with the Government (and with Holmes) that a defendant may not
 24 provide as a defense the argument that the defendant knowingly made false misrepresentations but
 25 nevertheless had a good-faith belief that the defendant’s victims would be repaid or otherwise
 26 suffer no harm. *See Benny*, 786 F.2d at 1417. *Barreiro* is inapposite because in that case the court
 27 denied a motion to preclude the argument that “[the defendants] thought that they were acting

1 lawfully.” *Barreiro*, 2015 WL 7734139, at *1. Here, the Government’s motion is not as broad,
2 and seeks to preclude only the argument that Holmes knowingly made misrepresentations but had
3 a good-faith belief that her alleged victims would be repaid or otherwise suffer no harm.

4 For the reasons above, the Court **GRANTS** the Government’s MIL No. 5 to preclude
5 Holmes from presenting an improper good faith defense outside of Ninth Circuit precedent.

6 **F. MIL No. 6 to Admit CMS’s January 26, 2016 Form CMS-2567, Statement of**
7 **Deficiencies**

8 The Government seeks to admit CMS Form CMS-2567, dated January 26, 2016, which
9 lists the deficiencies observed during CMS’s September 2015 recertification and survey of
10 Theranos’ Newark laboratory. Gov’t Mot. at 8–10. As described above concerning Holmes’s
11 MIL to exclude evidence of the CMS survey findings, the Court GRANTS the Government’s MIL
12 No. 6 to admit the CMS January 2, 2016 Form CMS-2567, Statement of Deficiencies. *See supra*
13 Section III.C.

14 **G. MIL No. 7 to Admit Text Messages Between Holmes and Balwani Offered by**
15 **The Government**

16 The SEC conducted a parallel investigation into Theranos. On September 6, 2016, the
17 SEC issued a subpoena to Theranos requesting production of communications between Holmes
18 and Balwani beginning January 1, 2010. Nov. 20, 2020 Decl. of AUSA Robert S. Leach in
19 Support of United States’ Mots. in Limine (“Leach Decl.”), Dkt. No. 588-1, Ex. F. On July 7,
20 2017, an attorney from Wilmer Cutler Pickering Hale and Dorr LLP (“WilmerHale”), who
21 represented Theranos at the time, produced to the SEC a document Bates-numbered TS1036239
22 through TS1036827 (the “SEC Spreadsheet”), which he represented to be “a spreadsheet
23 containing business-related text messages, iMessages, and Skype exchanges between Elizabeth
24 Holmes and Sunny Balwani.” *Id.*, Ex. G. On July 11 and 13, 2017, Holmes testified under oath
25 before the SEC. During her testimony, the SEC Spreadsheet was marked as an exhibit and the
26 following exchange occurred:

27 Q Exhibit 221 purports to be an Excel file that includes a number

of rows of font. The starting Bates number is TS-1036239. Have you seen Exhibit 221 before?

A I think I've seen some of the content in it. I've never seen it like this.

Q Does this – I'll represent to you that these are – this is the file that Theranos provided to the SEC pursuant to subpoena which is supposed to reflect the text messages between you and Mr. Balwani on your Theranos-issued cell phone.

A Yep.

Q Do you have any reason to believe that this isn't a true collection of those text messages from your work cell phone?

A No.

Id., Ex. H (“SEC Testimony”) at ECF p. 13 (SEC Testimony 376:4-19). Subsequently, a second WilmerHale attorney submitted to the SEC a declaration under penalty of perjury certifying records of regularly conducted activity, which stated: “I certify that the document produced at TS-1036239 through TS-1036827 is a spreadsheet containing Theranos business-related text messages, iMessages, and Skype exchanges between Ms. Holmes and Mr. Balwani. These messages and exchanges were sourced from images taken of Ms. Holmes’[s] business phones, as well as messaging applications on Ms. Holmes’ computer.” Leach Decl., Ex. I.

On November 7, 2017, in response to a grand jury subpoena, WilmerHale produced to the FBI a document Bates-numbered THER-2566547 through THER-2567135 (the “DOJ Spreadsheet”), which WilmerHale represented to be “a spreadsheet reflecting text messages sent to and from Elizabeth Holmes and Ramesh Balwani as collected from Elizabeth Holmes’s Company-issued devices. These text messages were originally produced at TS-1036239 through TS-1036827 and are being reproduced today with revised redactions pursuant to the guidelines discussed on our October 2, 2017 call with Mr. Schenk and Mr. Bostic.” *Id.*, Ex. K. The DOJ Spreadsheet generally has fewer redactions from the SEC Spreadsheet.

The Government now seeks an order admitting portions of the SEC and DOJ Spreadsheets containing certain text messages between Holmes and Balwani. The Government references six specific excerpts and requests that the Court admit “any similar ones offered by the government”

as well. Gov't Mot. at 11–14. At the May 6, 2021 hearing, the Government clarified that it was not seeking a blanket order admitting the entirety of both spreadsheets but anticipates introducing additional excerpts as they become relevant at trial. Holmes objects to admission of the excerpted spreadsheets on the grounds that neither their relevance nor their authenticity can be determined at this stage. Holmes Opp'n at 13.

1. Relevance

The Government seeks to introduce six excerpts from between November 2013 and October 2015. These dates correlate to key events at Theranos within the charging period, about which the Government plans to introduce other evidence. For example, the Government seeks to introduce an excerpt from November 19, 2014, which was around the time Theranos' former lab director, Dr. Adam Rosendorff, expressed his misgivings about the company and was eventually terminated. *See* Gov't 575 Opp'n at 3–4 (explaining that Dr. Rosendorff told Holmes on November 14, 2014 that he felt “really uncomfortable with . . . what is happening right now in this company . . . I am feeling pressured to vouch for results that I cannot be confident in.”). In the text exchange days later, Mr. Balwani wrote a number of texts to Holmes generally relating to the “lab” and leadership of the lab (e.g., “Need to focus on op. Getting hurt in market”; “Lab . . . need[s] director level people”; “We need[t]he lab and call center fixed”; and “New lab dirs., lab manager like Tracy”). Holmes expressed agreement (e.g., “Fundamentally we need to stop fighting fires by not creating them . . . Need to fix root cause here . . . Yes . . . Exactly”). Likewise, the November 28, 2014 texts (including Mr. Balwani's statement that the “Normandy lab is a fucking disaster zone”) were close in time to Dr. Rosendorff's departure. Given the temporal proximity of the messages to the events involving Dr. Rosendorff, and the centrality of those events to the Government's case, the Court finds this excerpt relevant.

Each of the remaining excerpts are similarly correlated to key events at issue in this case, or else are on their face plainly relevant to Holmes's knowledge. Holmes did not raise specific relevance objections to any particular excerpts at the hearing. The Court, therefore, finds that the excerpts provided are relevant to show, at a minimum, Holmes's knowledge.

2. Authenticity

“To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.” Fed. R. Evid. 901(a); *see United States v. Aldaco-Lopez*, 956 F.2d 1168 (9th Cir. 1992). The Government need only make a prima facie showing of authenticity “so that a reasonable juror could find in favor of authenticity or identification.” *United States v. Blackwood*, 878 F.2d 1200, 1202 (9th Cir. 1989) (per curiam) (quoting *United States v. Black*, 767 F.2d 1334, 1342 (9th Cir. 1985), *cert. denied*, 474 U.S. 1022 (1985) (quoting 5 J. Weinstein & M. Merger, *Weinstein’s Evidence*, ¶ 901(a) [01] at 901–16 to –17 (1983)).

The Government argues that there is sufficient evidence to support a finding that the spreadsheets are in fact compilations of messages between Holmes and Balwani from Holmes’s Theranos-issued devices because (1) it was Holmes’s counsel that produced the spreadsheets to the SEC and DOJ, attesting to their authenticity; and (2) Holmes did not challenge the authenticity of the spreadsheets at her SEC deposition.

Holmes argues that WilmerHale did not represent Ms. Holmes in her personal capacity, rather, it represented Theranos as corporate counsel. The transcript of Holmes’s SEC deposition testimony shows that there were two sets of outside counsel present at the deposition: counsel from Cooley LLP, who represented “Ms. Holmes in all capacities,” and counsel from WilmerHale, who represented “the company and Ms. Holmes as CEO.” Leach Decl., Ex. H at ECF p. 5 (SEC Testimony at 12:8-13:19). While there is some ambiguity about the extent of WilmerHale’s representation of Theranos and Holmes “as CEO,” the Court is not prepared to interpret WilmerHale’s production of the spreadsheets as an admission from Holmes that they are authentic. Indeed, Holmes indicated in her SEC deposition testimony that she had never seen the spreadsheets before.

Holmes further argues that because WilmerHale did not represent her in a personal capacity, the certifications of the spreadsheets and the cover letters accompanying the productions are inadmissible hearsay and therefore cannot be used to authenticate the spreadsheets. The Court

1 agrees. Because the spreadsheets contain data from multiple devices compiled by attorneys with
 2 the ability to select and redact material at will, the Court finds that the documents require
 3 authentication. Without some admissible evidence explaining how the spreadsheets were
 4 compiled, the Court cannot determine authenticity at this stage. The Court notes, however, that
 5 the burden on the Government to produce such evidence is slight. *United States v. Whitworth*, 856
 6 F.2d 1268, 1282–83 (9th Cir. 1988) (“Evidence is admissible under Rule 901(a) once a prima
 7 facie case has been made on the issue”). Once a prima facie case has been made, “the matter is
 8 committed to the trier of fact to determine the evidence’s credibility and probative force.” *Id.*

9 Accordingly, the Court **DENIES** the Government’s MIL No. 7 without prejudice. The
 10 Government may renew its motion upon its introduction of additional evidence as to authenticity.

11 **H. MIL No. 8 to Admit Statements By Theranos And Theranos Employees And** 12 **Agents Offered by The Government**

13 In MIL No. 8, the Government moves to admit two categories of statements. First, the
 14 Government moves to admit against Holmes “relevant statements by Theranos agents and
 15 employees on matters within the scope of that relationship and while it existed,” asserting that
 16 these statements are admissible under Federal Rule of Evidence 801(d)(2)(D). Gov’t Mot. at 17.
 17 Second, the Government moves to admit against Holmes “statements by Theranos that she
 18 authorized or manifested that she adopted or believed to be true,” namely interrogatory responses
 19 that Theranos made in civil litigation. The Government contends that the interrogatory responses
 20 are admissible under Federal Rule of Evidence 801(d)(2)(B) and (C). *Id.*

21 The Federal Rules of Evidence define hearsay as: “(A) statement, other than one made by
 22 the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the
 23 matter asserted.” Fed. R. Evid. 801(c). Federal Rule of Evidence 801(d)(2) excludes from the
 24 hearsay definition (and thus the rule against hearsay) statements offered against an opposing party
 25 and (A) made by the party in an individual or representative capacity; (B) one the party
 26 manifested that it adopted or believed to be true; (C) made by a person whom the party authorized
 27 to make a statement on the subject; (D) made by the party’s agent or employee on a matter within

1 the scope of that relationship and while it existed; or (E) made by the party's coconspirator during
2 and in furtherance of the conspiracy. Fed R. Evid. 801(d)(2) & 802.

3 Here, the Government relies on Rule 801(d)(2)(D) to seek admission of statements by
4 Theranos agents and employees. In *United States v. Kirk*, 844 F.2d 660 (9th Cir. 1988), the
5 government charged the founder of a time share venture with conspiracy, wire fraud, and other
6 offenses. Defendant Kirk "ran the day-to-day operations" and exercised "control over the time
7 share scheme." *Id.* at 661. On appeal, the defendant argued, among other things, that the district
8 court erred in admitting hearsay testimony of the company's salespeople. The Ninth Circuit
9 concluded that the statements were admissible as nonhearsay statements of agents or employees
10 under Fed. R. Evid. 801(d)(2)(D). *Id.* at 663. Similarly, in *United States v. Gibson*, 690 F.2d 697,
11 699 (9th Cir. 1982), the government brought mail fraud, wire fraud, and other charges against
12 Gibson, the founder, sole shareholder, chairman, and president of Gibson Marketing International,
13 Inc. ("GMI"), which sold franchises and franchise distributorship rights. *Id.* at 697. At trial, the
14 government introduced evidence of statements by GMI employees and salesmen against Gibson.
15 On appeal, the Ninth Circuit found no error in admitting the statements. The Ninth Circuit held
16 that testimony by investors as to statements made by GMI employees were not hearsay, and even
17 if the testimony did fall within the hearsay definition, the testimony was admissible under either
18 Rule 801(d)(2)(D) (statements by an agent) or Rule 801(d)(2)(E) (statements by a co-conspirator).
19 *Id.* at 701.

20 Although *Kirk* and *Gibson* support the Government's position, it is premature for the Court
21 to issue a categorical ruling admitting any and all testimony of Theranos agents and employees on
22 matters within the scope of that relationship and while it existed. Under general agency principles,
23 Theranos employees were not Holmes's agents; they were Theranos' agents. *See Boren v. Sable*,
24 887 F.2d 1032 (10th Cir. 1989) (an employee's "mere occupation of a subordinate position in the
25 corporate chain of command" is sufficient to establish an "agency relationship" for the purpose of
26 admission under Rule 801(d)(2)). The Government does not cite, and this Court is unaware of,
27 any case supporting the admission of the statements of hundreds of employees to a corporate CEO

under Rule 801(d)(2)(D). Moreover, in *United States v. Bonds*, 608 F.3d 495, 504 (9th Cir. 2010), the Ninth Circuit instructed that to determine whether statements are admissible under Rule 801(d)(2)(D), a court must “undertake a fact-based inquiry applying common law principles of agency.” *NLRB v. Friendly Cab Co., Inc.*, 512 F.3d 1090, 1096 (9th Cir. 2008); *see also U.S. v. Agne*, 214 F.3d 47, 54–55 (1st Cir. 2000) (“Whether the statements of a corporate employee may be admitted against a corporate officer depends upon the relationship between the employee and the officer; ‘if the factors which normally make up an agency relationship are present the evidence should not be excluded simply because the statement is offered against a corporate officer, rather than the corporation.’”). Under common law principles of agency, an agent is one who “act[s] on the principal’s behalf and subject to the principal’s control.” *Bonds*, 608 F.3d at 506 (quoting Restatement (Third) Agency § 1.01). “To form an agency relationship, both the principal and the agent must manifest assent to the principal’s right to control the agent. *Id.* The Government has not attempted to make this showing for all of the hundreds of Theranos employees.

As to the interrogatory responses, the Government specifically seeks admission of Theranos’ admissions that: Theranos earned less than \$500,000 from blood testing revenue from 2013 to 2015; that its contracts with the Department of Defense were limited to three agreements producing de minimus revenue; that it modified third-party analyzers in order to process blood tests; that only 12 tests were ever run on a Theranos-manufactured device in its clinical lab; and that Theranos ceased all testing on Theranos-manufactured devices by June 2015. *See Leach Decl.*, Ex. P at 35–38, Ex. Q at 22–24, 36–39, at Ex. R 22–23. These admissions were made by Theranos in a prior civil suit, *Partner Investments v. Theranos*, C.A. No. 12816-VCL. *Id.*, Exs. P, Q, R. The Government contends that the interrogatory responses are admissible under Rule 801(d)(2)(B) and (C) on the theory that Holmes authorized her company’s interrogatory responses and manifested that she adopted or believed them to be true. The Government reasons that “Holmes was a co-defendant in the lawsuit at the time the statements were made and her own interrogatory responses made reference to Theranos’ statements (*see, e.g., Leach Decl.*, Ex. N at 16–18)—compelling the inference that she authorized her company’s statements and manifested

1 that she adopted or believed them to be true.” Gov’t Mot. at 17.

2 The Government has presented some evidence tending to show Holmes authorized
3 Theranos’ interrogatory responses in the *Partner Investments* suit and manifested that she adopted
4 or believed them to be true. Specifically, during her deposition in a separate suit brought by the
5 SEC, Holmes was shown Theranos’ interrogatory responses, and conceded “I certainly was
6 engaged with our legal team on responding to them” and added “I’m sure I talked with our team
7 about them.” Feb. 16, 2021 Decl. of AUSA Robert S. Leach in Supp. of United States’ Reply in
8 Supp. of its Mot. in Limine, Dkt. No. 727, Ex. U at 143; *id.* at 149 (“I worked with our legal teams
9 as we worked to respond to PFM”). Holmes’s involvement in preparing Theranos’ interrogatory
10 responses in the SEC litigation is circumstantial evidence that she was also involved in and
11 authorized preparing Theranos’ responses in the *Partner Investments* litigation. However, this
12 proffered evidence, without more, is insufficient to support admission of the under Rule
13 801(d)(2)(B) and (C).

14 The Government next contends that Holmes’s “coordination with Theranos” and the
15 repeated cross-references to Theranos’ responses in her own interrogatory responses that give rise
16 to the inference that she knew of and approved Theranos’ responses. Gov’t Reply at 13.
17 However, as Holmes points out, she and Theranos were represented by separate counsel in the
18 *Partner Investments* litigation and prepared separate responses to interrogatories. The cross-
19 referencing tends to show some coordination, but is no basis to conclude that Holmes adopted all
20 of Theranos’ responses.

21 The Government also relies on the fact that Theranos’ interrogatory responses were signed
22 by Holmes’s brother and some of the most senior officers of the company whom she supervised.
23 Familial status is not enough to show Holmes authorized her brother’s responses. Furthermore, at
24 present, there is no evidence whatsoever that Holmes authorized her brother or the other senior
25 officers to prepare the company’s interrogatory responses.

26 The Government’s MIL No. 8 is **DEFERRED** pending the Government’s establishment of
27 the necessary foundation for the evidence it seeks to introduce.

I. MIL No. 9 to Exclude Self-Serving Hearsay Statements Made And Offered By Holmes

The Government represents that through its investigation, it “has collected extensive evidence of previous statements by Defendant regarding Theranos’ technology, business relationships, financial health, regulatory status, and other key topics,” which the Government will seek to introduce at trial. Gov’t Mot. at 17. The Government now moves to prevent Holmes from similarly introducing “witness testimony or direct evidence of self-serving statements she has made to the press, to victims, or in her testimony to the SEC.” *Id.* at 18.

Holmes argues that this motion is premature because the Government has not identified any particular statements that it seeks to exclude, and because the admissibility of Holmes’s out-of-court statements will necessarily depend on the purpose for which they are offered at trial. Holmes Opp’n at 19. Holmes also argues that certain of her hearsay statements may be admissible under the common law rule of completeness or Federal Rule of Evidence 106.

Under Federal Rule of Evidence 801(d)(2)(A), an out-of-court statement is admissible if (1) made by the defendant and (2) offered against the defendant. Fed. R. Evid. 801(d)(2)(A); *see also United States v. Pelisamen*, 641 F.3d 399, 410 (9th Cir. 2011) (defendant’s own statements made during television interview admissible over hearsay objection). It is also well-settled that a defendant may not “place [her] exculpatory statements before the jury without subjecting [herself] to cross-examination.” *United States v. Ortega*, 203 F.3d 675, 682 (9th Cir. 2000) (affirming exclusion of defendant’s “non-self-inculpatory” statements as hearsay).

The Court agrees with the Government that Rule 801(d)(2)(A) applies only to party-opponent statements and that under *Ortega*, Holmes is not permitted to introduce exculpatory statements without testifying in court. At the hearing, Holmes represented that she understood and would adhere to this rule. *See* May 6, 2021 Hr’g Tr., Dkt. No. 794, at 4:14-5:2 (“We agree with your honor that *Ortega* implements Rule 801 which prohibits us from introducing Ms. Holmes’[s] statements if they are hearsay . . . of course, we intend to comply with *Ortega*.”).

Accordingly, bearing in mind *Ortega* and other Ninth Circuit precedent, the Court will not rule at this time that all of Holmes’s out-of-court statements are inadmissible hearsay. “The

admissibility of a particular statement depends on the content of the statement and the purpose for which the party seeks to introduce that statement into evidence.” *Yang*, 2019 WL 5536213, at *4. Without additional context, the Court cannot say that a currently unidentified out-of-court statement by Holmes would be hearsay, let alone that an exception to hearsay does not apply. For the same reason, the Court defers addressing Holmes’s arguments regarding the rule of completeness or Federal Rule of Evidence 106 until the Court has before it particular statements and context to consider.

Accordingly, the Court **GRANTS** the Government’s motion (to the extent that Holmes’s out-of-court statements are inadmissible for the reasons stated in Rule 801 and *Ortega*). The Government may object in due course to specific evidence submitted at trial. Holmes shall provide the Government and Court fair warning when she believe the issue is about to arise at trial, so the Court can then address the issue outside the presence of the jury.

J. MIL No. 10 to Admit Relevant Testimony From ‘Non-Paying’ Patient Witnesses (Dkt. No. 588)

Testimony from non-paying patient witnesses concerning their experience with Theranos testing is relevant and admissible for the reasons described above with respect to Holmes’s MIL to exclude anecdotal evidence of test results. *See supra* Section III.H.1. Accordingly, the Court **GRANTS** the Government’s MIL No. 10. Patients, physicians, and other witnesses who may testify about receiving test results will not be permitted to testify about any physical, financial, or emotional harm they may have experienced beyond simply paying for the test.

K. MIL No. 11 to Order Defendant to Produce Reverse *Jencks* Including Any in Camera Proffers

The Government asks the Court to order Holmes to produce witness statements under Rule 26.2(a) of the Federal Rules of Criminal Procedure. During the May 6, 2021 hearing, Holmes represented that the Rule 26.2(a) materials were produced that morning. The Government’s MIL

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No. 11 is **DEEMED MOOT.**

IT IS SO ORDERED.

Dated: May 21, 2021



EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California