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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES, Defendant.	Case No. 18-CR-00258 EJD UNITED STATES' SUPPLEMENTAL BRIEF REGARDING ADMISSION OF CMS REPORT (TRIAL EXHIBIT 4621), TESTIMONY OF DR. KINGSHUK DAS, AND EVIDENCE REGARDING VOIDING OF THERANOS TEST RESULTS Date: November 9, 2021 Time: 8:00 a.m. Court: Hon. Edward J. Davila

The government seeks admission of certain evidence and testimony all of which have been the subject of prior motions practice and oral argument before the Court, namely: (1) admitting the entirety of the Centers for Medicare and Medicaid Services' ("CMS") January 25, 2016 letter to Theranos's former lab director, Dr. Sunil Dhawan, and the attached Form CMS-2567, Statement of Deficiencies, for the Theranos Newark clinical laboratory (collectively, "January 2016 CMS Report"), as captured in Trial Exhibit 4621 (*available at* ECF No. 898-3); (2) admitting percipient testimony of Dr. Kingshuk Das, as previously discussed; and (3) admitting evidence regarding Theranos's ultimate voiding of all tests run on its proprietary blood analyzer device in or about March 2016 (during the alleged conspiracy to defraud patients, as alleged in Count Two). The government has read the relevant orders by the Court and asserts these three evidentiary topics are admissible pursuant to those orders. *See* ECF Nos. 798 (Order re: Motions *in Limine* ("MIL Order")), 989 (Order re: Pre-trial Motions ("MIL 2 Order")).

BACKGROUND

The Third Superseding Indictment ("TSI") alleges that Defendant Elizabeth Holmes and co-Defendant Ramesh "Sunny" Balwani devised a scheme to defraud patients between approximately 2013—when Theranos began providing lab testing services to patients through certain Walgreens stores in Palo Alto and Arizona—and 2016—when Theranos elected to shutter its lab following interactions with CMS. ECF No. 469 ¶¶ 14–18. Specifically, the TSI alleges that from 2013 to 2016, the entire time Theranos was providing testing services to patients, Theranos represented to doctors and patients that Theranos could provide accurate, fast, reliable, and cheap blood tests and test results at the same time that Defendants knew that Theranos was not, in fact, capable of consistently producing accurate and reliable results. *Id.* Based on an order from the Court, the government provided a Bill of Particulars and ultimately incorporated those 25 assays into the TSI for the patient-related counts. *Id.* ¶ 16.

The evidence and testimony the government seeks to admit explains why Theranos's clinical testing of patients ceased in 2016—it was not a voluntary decision by Defendant as she would like the jury to believe. Beginning in September 2015, CMS conducted an in-person inspection of Theranos's Newark, California laboratory and observed that Theranos's blood analyzer repeatedly failed quality control checks and repeatedly produced values outside of ranges *Theranos* deemed acceptable—yet Theranos continued to report patient results. *See* ECF No. 875 at 5–10. These findings were ultimately

memorialized in the January 2016 CMS Report. *Id.* In response to these negative CMS findings, Defendants hired Dr. Kingshuk Das around December 2015 as Theranos's Newark Lab Director, in part to respond to questions from CMS and realign the lab with relevant regulations. *See* ECF No. 727-2 (memorandum of interview of Dr. Das on February 1, 2021). Dr. Das was hired to investigate and report on CMS's findings—presumably with the hope of finding a path forward—but, by spring 2016, Dr. Das "concluded [CMS inspectors] were '100%' correct with their deficiency findings." ECF No. 846-2 (memorandum of interview of Dr. Das on June 7, 2021). Dr. Das told Defendant that Theranos was required by CLIA regulations to void all of the test results produced by Theranos's blood analyzer due to accuracy and reliability concerns—but Defendant "push[ed] back" and told Dr. Das this was "not a device issue[.]" *See* ECF Nos. 727-2, 846-2. Dr. Das is expected to testify that he had regular meetings with Defendant to inform her of the issues with Theranos's blood analyzer, but the "conversations did not go well." ECF No. 727-2. Ultimately, Dr. Das prevailed; Theranos in March 2016 voided all patient test results on its proprietary analyzer from 2014 and 2015 (within the charged period) and, later that year in October 2016, Defendant Holmes shuttered Theranos's Newark lab altogether. ECF Nos. 588 at 16, 588-6, 673 at 5. Thus, the evidence the government seeks to admit is directly connected to the allegations in the TSI.

In addition, the evidence and testimony the government seeks to admit is an appropriate response given that Defendant has repeatedly put her actions and state of mind in 2016 at issue during the trial thus far. In the first few minutes of her opening statement, Defendant vividly described her packing her car in 2018 and leaving the Newark laboratory on her last day—suggesting a guilty person would not have stuck it out. 09/8/2021 Hearing Transcript ("9/8 Tr.") at 560:1–23. Despite Defendant texting her co-Defendant Balwani at the time of the CMS inspection that she was "praying continually" as he informed her that the inspection was "going bad so far" (10/14/2021 Hearing Transcript ("10/14 Tr.") at 3738:5–3739:15), Defendant's counsel pointed to her conduct in 2016 after receiving the final CMS findings during opening statements. *See* 9/8 Tr. at 609:10–613:6. Defendant has since sought to admit—and admitted occasionally over the government's objections—evidence during this 2016 timeframe to show her state of mind following the January 2016 CMS Report and the critical October 2015 *Wall Street Journal* article. *See*, *e.g.*, 09/22/2021 Hearing Transcript ("9/22 Tr.") at 1648:4–

1655:10 (admitting Exhibits 10512 and 7653 (attached to this filing as Exhibits 1 and 2, respectively) over objection relating to positive feedback Defendant received in 2016). Indeed, Defendant has repeatedly introduced evidence of her discussion of Theranos's technology during the American Association of Clinical Chemistry ("AACC") conference in August 2016, which the government should be permitted to rebut with Defendant's voiding of all tests run on Theranos's proprietary analyzer just a few months before and Defendant's shuttering of the lab approximately two months later. *See* 9/22 Tr. at 1645:15–1646:5 (questioning General Mattis about Defendant's statements during the AACC conference); 10/26/2021 Hearing Transcript ("10/26 Tr.") at 4828:4–4831:23 (questioning Lisa Peterson about Defendant's presentation at the AACC conference); *see also id.* at 4592:8–4593:20 (arguing AACC video where Defendant defends Theranos's technology is admissible to show her state of mind in August 2016); 09/21/2021 Hearing Transcript at 1426:5–1427:19 (questioning Dr. Audra Zachman about the number of hCG tests Theranos performed for Dr. Zachman's clinic from October 2015 through October 2016—which unbeknownst to the witness would have occurred after Theranos ceased using the Edison for hCG testing).

Defendant has also questioned multiple witnesses on cross examination regarding events occurring after the CMS inspection and Report throughout 2016—purportedly to demonstrate Defendant's state of mind with respect to Theranos's technology in 2016. *See*, *e.g.*, 10/26 Tr. at 4829:10–4831:23 (asking Lisa Peterson about attending AACC conference in August 2016 almost two years after RDV Corporation invested in Theranos); 10/13/2021 Hearing Transcript at 3505:2–3508:19 (asking Wade Miquelon, former CFO of Walgreens, about encouraging and positive emails he sent to Defendant in 2016 when he was no longer employed by Walgreens); 09/17/2021 Hearing Transcript at 1117:4–1120:2 (questioning Erika Cheung about a Theranos patent application from 2016 that the witness noted was filed after she left the company). Defendant has even introduced evidence beyond the charged conspiracy period for the patient counts by questioning witnesses about events in December 2016 and even late 2017, well after Theranos ceased providing blood testing services to patients. *See* 9/22 Tr. at 1646:6–1648:3 (questioning General Mattis about Theranos participating in a comparative study with UCSF in late 2017); 10/20/2021 Hearing Transcript at 4263:22–4266:1 (questioning Edlin regarding Dr. Robertson and whether Theranos created a technology advisory board in December 2016).

In sum, Defendant has repeatedly introduced evidence of her 2016 conduct under the theory that convening a scientific board, presenting at a scientific conference, or submitting herself to questioning by investors and the public undercuts an intent to deceive regarding the accuracy and reliability of Theranos's tests.

ARGUMENT

The government submits that the evidence and testimony it seeks to admit is directly relevant to prove allegations against Defendant in the TSI—specifically with respect to the conspiracy to defraud Theranos's patients from 2013 to 2016—and is necessary to rebut the presently misleading impression Defendant has introduced at trial that her state of mind in 2016 was solely that the technology worked when she was being told a different story internally by Dr. Das and through the January 2016 CMS Report and subsequent interactions with CMS. Indeed, Theranos's decision in March 2016 to void all test results on its proprietary device from 2014 and 2015 as a result of the CMS Report and findings, and Dr. Das's internal review of those findings, demonstrates Defendant's knowledge of the severity of the inaccuracy and unreliability problems with Theranos's blood analyzer during the charged period.

I. CMS Findings

The government hereby provides notice to the Court and Defendant that it intends to seek admission of the entirety of the January 2016 CMS Report (and letter) as explicitly permitted by the Court's MIL Order. MIL Order, ECF No. 798 at 16–20. As the Court recently observed with respect to an issue raised by Defendant that the Court had granted in its MIL Order, to reverse course now in the midst of trial would "do violence to the Court's order in the MIL motion." 11/03/2021 Hearing Transcript at 5211:8–12.

The January 2016 CMS Report has been the subject of several filings to date. ECF Nos. 574, 588, 659, 675, 717, 726, 798, 897, 906, 989, 1086. The government initially moved *in limine* to seek admission of the January 2016 CMS Report, and Defendant moved *in limine* to blanketly exclude "Evidence of CMS Survey Findings and Sanctions," which included the January 2016 CMS Report (and letter). ECF Nos. 574, 588 at 15–17, 659, 675, 717, 726. The Court denied Defendant's motion and granted the government's motion, finding the CMS survey findings and sanctions relevant, "more probative than prejudicial," and not hearsay. ECF No. 798 at 16–20. The Court noted that Defendant

took particular issue with references to "CMS's finding of 'immediate jeopardy'" but held the phrase did not raise unfair prejudice concerns. *Id.* at 19. Nevertheless, a few weeks before trial began, Defendant moved the Court to reconsider its finding on the January 2016 CMS Report—based again on relevance and hearsay grounds—and asserted that the Court's prior ruling did not encompass the CMS letter accompanying Form CMS-2567. ECF Nos. 897, 906. The Court disagreed, holding that "no new arguments have been presented to justify the breadth of the redactions requested" by Defendant and "reject[ing] Holmes's assertions that the cover letter is 'new' and not covered in the MIL Order." MIL 2 Order, ECF No. 898 at 7–8 & n.1. When the government provided notice of its intent to seek admission of a different CMS-related document, Defendant again submitted a filing stating her intent to object on the same grounds of relevance, unfair prejudice, and hearsay. ECF No. 1086.

The government hereby provides advance notice of its intent to seek admission of the January 2016 CMS Report (and accompanying letter) and asserts that the Court has considered and rejected Defendant's arguments numerous times and there is thus no barrier to admission of Trial Exhibit 4621. The development of evidence at trial thus far underscores the relevance of the January 2016 CMS Report. For example, several of defense counsel's cross examinations of former Theranos employee witnesses have focused on Theranos's CLIA certification, policies in place within the lab (a.k.a. "SOPs"), and assay validation reports. *See*, *e.g.*, 09/28/2021 Hearing Transcript, 09/29/2021 Hearing Transcript, 10/01/2021 Hearing Transcript, 10/05/2021 Hearing Transcript (cross examination of Dr. Adam Rosendorff). And co-Defendant Balwani asked then-lab director Dr. Sunil Dhawan to sign approximately 300 SOPs the week before the CMS inspection in September 2015. 10/14 Tr. at 3727:21–3732:2. But the CMS Report found the lab deficient and lacking documentation or instituted policies in many of these same areas. Based on the survey, CMS found Theranos failed to comply with five conditions required for CLIA certification, as well as numerous CLIA standards. And, among other things, in the Form CMS-2567, CMS found Theranos failed to ensure that quality control ("QC") was acceptable for the Theranos blood analyzer (TPS or Edison 3.0/3.5) *before* using the analyzer for reporting patient test results, failed to verify accuracy, precision, and/or reportable reference range for numerous assays, and failed to verify the performance specifications and conduct of a third-party device it was using. *See* ECF No. 588 at 15–16 & 898-3.

While Defendant claimed at the motion *in limine* stage that the CMS Report was irrelevant because it did not demonstrate she was aware of these problems at the time of patient testing (*see* MIL Order, ECF No. 798 at 18–19), the trial testimony of former Theranos employees to date has shown otherwise. *See*, *e.g.*, 09/24/2021 Hearing Transcript at 1725:8–1732:14 (Dr. Adam Rosendorff testifying that he described issues in lab to Defendant leading up to Walgreens launch and admitting Exhibit 1049); 09/15/2021 Hearing Transcript at 973:1–980:25 (Erika Cheung testifying about Defendant's knowledge of issues in the lab and admitting Exhibit 1660 for notice to Defendant). In addition, Defendant objected at the motion *in limine* stage to the "immediate jeopardy" language in the CMS Letter, but she has since acquiesced to the introduction of such evidence through her own rule of completeness arguments to the "Today Show" video clip in April 2016 (Exhibit 3152). 10/26 Tr. at 4584:2–4596:24, 4702:4–4708:24 (admitting the entirety of Exhibit 3152 as requested by Defendant, and Exhibit 3152 recounts CMS's finding of "immediate jeopardy" against Theranos). Thus, as the Court previously found, the January 2016 CMS Report is more probative than prejudicial because it shows "Holmes's state of mind, knowledge, and intent regarding her representations to investors regarding the accuracy and reliability of Theranos' technology." *Id.*

Based on evidence introduced thus far in the trial, the Court should also reject any assertions by Defendant that the January 2016 CMS Report contains inadmissible hearsay within hearsay merely because CMS inspectors incorporated information conveyed by Theranos laboratory employees. *Cf.* ECF No. 897 at 8. The Court previously indicated that admission of such portions would depend on whether the government demonstrated a sufficient agency relationship between the Theranos employee and Defendant Holmes. ECF No. 798 at 20 n.6, 94–97. The government produced the email attached as Exhibit 3 (Bates CMS-USAO-001391) to Defendant, identifying which Theranos employees the CMS inspectors interviewed in connection with its report. Specifically, CMS inspectors interviewed Theranos's two General Supervisors (Hoda Alamdar and Gurbir Sidhu), Technical Supervisor (Godfried Masinde), Quality Assurance and Quality Control Manager (Langley Gee), Director of Assay Systems (Dr. Suraj Saksena), and Theranos's Senior Vice President (Dr. Daniel Young). *See* Exhibit 3. These were all employees listed—along with their qualifications—in the introductory presentation that Theranos presented to CMS when they arrived for their inspection. *See* Exhibit 4 (Admitted Trial

Exhibit 4528 at PowerPoint slide pages 8, 12–18). The testimony of Dr. Sunil Dhawan demonstrated that these individuals held senior positions in Theranos's lab, and these were the individuals Dr. Dhawan relied upon when he signed documents on behalf of Theranos as Lab Director in Fall 2015. *See*, *e.g.*, 10/14/2021 Hearing Transcript ("10/14 Tr.") at 3735:11–3739:15; 10/15/2021 Hearing Transcript ("10/15 Tr.") at 3795:10–3797:25, 3806:3–3809:13, 3820:9–3825:1. In addition, text messages between Defendant Holmes and co-Defendant Balwani at the time of the CMS inspection demonstrate that both Defendants were focused on the CMS inspection and supports the inference that they chose these Theranos employees to speak with authority on behalf of them and the company. *See* 10/15 Tr. at 3736:25–3739:15; *see also* ECF No. 798 at 25–27 (finding Defendant Holmes sufficiently connected to Theranos's September 2015 communications with CMS). Thus, any information communicated to CMS by these senior lab employees was within the scope of their relationship while it existed and non-hearsay under Federal Rule of Evidence 801(d)(2)(D).

The government submits the entirety of the CMS Report (Exhibit 4621) is admissible, as the Court found several months ago in its MIL Order.

II. Testimony of Dr. Kingshuk Das

For similar reasons, Dr. Das should be permitted to testify based on his percipient knowledge of completing the tasks that Defendant hired him to do, pursuant to the limitations the Court outlined in the weeks leading up to trial. *See* MIL 2 Order, ECF No. 989 at 3–4.

As with the CMS Report, the parties and the Court extensively discussed pretrial Dr. Das's expected testimony. *See* ECF Nos. 892, 906, 912, 926, 989. Defendant argued that a substantial portion of Dr. Das's testimony would qualify as expert testimony—as it had at the MIL stage with respect to Dr. Adam Rosendorff—and the government asserted that the majority (if not all) of Dr. Das's expected testimony would be percipient testimony. *See id.* The Court largely agreed with the government that, based on the government's representations at the August 20, 2021 hearing, "the Court is persuaded that Dr. Das may proceed as a percipient witness." MIL 2 Order, ECF No. 989 at 4. The Court warned, however, that discussion of "the Six Sigma analysis [ ] would move Dr. Das's testimony from percipient to expert." *Id.* The Court's ruling in its MIL 2 Order matches the discussion at the hearing, where the Court expressed reservation about the Six Sigma analysis, but noted it was possible for the witness to

testify in a percipient manner and not get into those specifics, providing the following hypothetical: "This is my job, this is what I do, I get the results, I look at the results, . . . I compare it to whatever it is, and that's not my opinion, it's the results, and I'm reporting the results [to my boss]." 08/20/2021 Hearing Transcript at 64:18–80:25 (attached as Exhibit 5). Defendant expressed her view that only 20% of Dr. Das's testimony would qualify as percipient testimony, but the Court disagreed. *Id.* The Court also noted that it provided its thoughts on what testimony—in particular the Six Sigma analysis—would cross the line into expert testimony and the government would proceed into such topics at its own peril. *Id.* at 79:19–80:18.

The government understands the limitations the Court has expressed for Dr. Das's testimony and has crafted its direct examination accordingly. The government has read the Court's relevant MIL 2 Order and the related portions of the transcript and intends to abide by the Court's directions. Thus, the government should be permitted to call Dr. Das to testify about his job, what he was hired by Defendant to do, what he discovered in performing the tasks the Defendant asked him to do (namely, investigate CMS's findings and concerns), and his perspective of the resulting discussion of what he discovered with Defendant. Each of those topics are squarely within his percipient knowledge.

III. Voiding Test Results

The government also submits that the evidence admitted at trial thus far has provided sufficient foundation to address the prerequisites the Court stated in its MIL Order with respect to Theranos's voiding of the test results in March 2016, and any remaining concerns will be addressed by Dr. Das's expected testimony. Defendant moved to exclude evidence relating to Theranos voiding its tests and subsequent settlements the company entered into and, as relevant here, the Court deferred with respect to the evidence relating to voiding of the tests. MIL Order, ECF No. 798 at 30–39. Specifically, the Court found the evidence relevant but "defer[ed] 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." *Id.* at 34–38. The government submits it has met those two requirements.

As stated above, Defendant has repeatedly placed events in 2016 at issue in the case and, of course, the charged conspiracy to defraud patients extends until the Newark lab closed down in October 2016. Defendant claimed at the MIL stage a similar defense she has presented to the jury—that she took CMS's findings seriously and wanted to respond to skepticism stemming from the *Wall Street Journal* article including by attending the AACC. *See id.* at 37; 10/26 Tr. at 4828:4–4831:23. But Lisa Peterson on behalf of investor-victim RDV Corporation has already testified that she heard a different version of events from Defendant in a meeting with Thernaos investors in April 2016, specifically that Defendant "very much downplayed what had been happening in the press" and told Peterson that "CMS was questioning the process, not the accuracy of the tests[.]" 10/26 Tr. at 4709:6–24. The government submits it has sufficiently tied Defendant's decision to void the tests in March 2016 with the charged conduct because it relates both to keeping the investors in the dark regarding how serious the CMS findings were and to the inaccuracy and unreliability of tests Theranos offered to patients in 2014 and 2015. To the extent there remains any doubt, Dr. Das is expected to testify that he received push back from Defendant when he informed her that Theranos was required to void the test results, and to pass the issue off as a quality control systems issue—not an issue with Theranos's proprietary device. *See* ECF No. 893-2 at 3. Similarly, Dr. Das is expected to testify that he was obligated—under the same CLIA regulations that Defendant admitted into evidence during the testimony of Dr. Rosendorff (Trial Exhibit 7603)—to void the tests on behalf of Theranos. *Id.* That Defendant had to be persuaded to this course of action goes directly to the core of Defendant's intent and knowledge. Voiding the tests in March 2016 is tied to the charged conduct and was completely involuntary, and thus the Court should admit related testimony.

And, of course, even if the Court were to find Theranos's voiding of the tests to be a voluntary remedial measure under Rule 407, such a ruling would not preclude any evidence of Theranos's internal analysis leading to voiding of the tests. As the Court noted, "statements by Theranos and Holmes to . . . CMS in the course of its survey and subsequent proceedings are not subject to exclusion[.]" MIL Order, ECF No. 798 at 39; ECF No. 673 at 8–9. As the government argued at the MIL stage, Rule 407 prohibits evidence of voluntary subsequent *measures*, not evidence of a party's *analysis* of its product, even when prompted by regulators. *See*, *e.g.*, *Aguilar v. City of Los Angeles*, 853 F. App'x 92, 95

(9th Cir. 2021) (finding legal error in district court excluding LAPD's internal in-custody death investigation under Rule 407 because they were "retrospective, not remedial"); *Rocky Mountain Helicopters, Inc. v. Bell Helicopters Textron, a Div. of Textron, Inc.*, 805 F.2d 907, 918 (10th Cir. 1986) ("It would strain the spirit of the remedial measure prohibition in Rule 407 to extend its shield to evidence contained in post-event tests or reports.").

In addition, given the Defendant's repeated arguments and suggestions that her actions in 2016 and beyond (convening an advisory board, soliciting input from scientists, attending AACC, etc.) demonstrate a lack of intent to defraud, it would be unfair to deny the government an opportunity to show through her other statements and actions a complete picture of her state of mind in 2016. The government should be permitted to provide the whole picture to the jury and explain why the conspiracy with respect to the scheme to defraud patients ended in 2016 with Defendant voiding all of the tests (as a consequence of CMS's findings in the Report) and shuttering the lab later that year.

CONCLUSION

For these reasons and those stated in the government's prior filings on this topic, the government requests the Court admit Trial Exhibit 4621 in its entirety—over any relevance, Rule 403, or hearsay objections by Defendant—when offered by the government at trial. The government further requests that Dr. Das be permitted to testify as a percipient witness within the guardrails the Court outlined during pre-trial motion practice. Finally, the government requests the Court admit evidence and testimony regarding voiding of tests in March 2016 as it has met the court's prerequisites.

DATED: November 8, 2021

Respectfully submitted,

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