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12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA
14 SAN JOSE DIVISION

15 UNITED STATES OF AMERICA,)	Case No. 18-CR-00258 EJD
)	
16 Plaintiff,)	UNITED STATES' CORRECTED OPPOSITION
)	TO DEFENDANT HOLMES'S MOTION TO
17 v.)	EXCLUDE ANECDOTAL TEST RESULTS
)	
18 ELIZABETH HOLMES and RAMESH)	Date: March 23, 2021
"SUNNY" BALWANI,)	Time: 10:00 a.m.
19 Defendants.)	Court: Hon. Edward J. Davila
)	
20)	

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1 **INTRODUCTION**

2 “Data is a powerful thing because it speaks for itself.”

3 -Elizabeth Holmes, Cleveland Clinic, October 26, 2015

4 Theranos’s blood tests were dangerously unreliable. Consider the quality control (QC) data for a
5 handful of commonly-run assays run on the Theranos analyzer in March 2014.¹ (Decl. of Robert Leach
6 (“Leach Decl.”), Exh. 58, at 2.) For these five blood tests, the overall QC failure rate for that month was
7 25.6%. (*Id.*) For TT3 blood tests (a critical test that assesses thyroid function), the failure rate was
8 51.3%. (*Id.*) In other words, Theranos’s TT3 blood test results were so inaccurate, it was essentially a
9 coin toss whether the patient was getting the right result. The data was devastating.

10 The data for the millions of patient tests Defendant Elizabeth Holmes references in her motion
11 was stored on a specially-developed SQL database called the Laboratory Information System (LIS).
12 This database collected, among other things, all patient test results and all QC data. The database even
13 flagged blood test results that might require immediate medical attention, and communicated this to the
14 patient’s physician. Laboratory specialists documented problems with blood tests in this database and
15 updated the system when there were validation errors with a patient’s test. For the three years that
16 Theranos tested patients’ blood, all of the data associated with these tests was stored in the LIS.

17 On or about August 31, 2018—three months after a federal grand jury issued a subpoena
18 requesting a working copy of this database—the LIS was destroyed. The government has never been
19 provided with the complete records contained in the LIS, nor been given the tools, which were available
20 within the database, to search for such critical evidence as all Theranos blood tests with validation
21 errors. The data disappeared. Defendant should be barred from arguing the government’s case is
22 anecdotal when Theranos (and others) destroyed this data.

23 Moreover, despite this loss, Defendant’s arguments fail. The government’s case is hardly
24 “anecdotal.” The reliability and accuracy problems in Theranos’s clinical lab were well-documented

25
26 _____
27 ¹ Quality control tests are run on blood testing equipment before patient sample are run to ensure
28 that the equipment is performing accurately on known, pre-tested samples. Since there is no way to tell
whether a specific patient blood test is accurate on its own, the QC tests provide assurance in a clinical
laboratory setting that the analyzers and tests can be relied on for actual patients. These measures are
critical to performing patient blood tests safely.

1 when the Centers for Medicare & Medicaid Services (CMS) investigated the lab, discovered the
 2 accuracy and reliability problems, and determined Theranos could not safely administer its tests on
 3 patients. Whistleblowers will also testify about Theranos’s accuracy and reliability problems. And
 4 patients themselves experienced these problems, receiving incorrect results that affected their treatment
 5 and deprived them of the benefit of the purportedly reliable blood tests for which they had paid.
 6 Evidence at trial is always presented through the individual stories of witnesses. Where this testimony
 7 describes Defendant’s criminal conduct—as the patient testimony does here—it is absolutely relevant
 8 and probative of the fraud. There is no basis for exclusion.

9 STATEMENT OF FACTS

10 I. The Destruction of the LIS, the “Most Comprehensive” Repository of Patient Data

11 A. Background on the LIS

12 Theranos hired an outside company called IncRev Corp. to develop and maintain the software
 13 that comprised the LIS database.² This company was owned and run by Shekar Chandrasekaran, a long-
 14 time friend of Defendant Ramesh Balwani. Chandrasekaran reported directly to Balwani. Over the
 15 period of IncRev Corp.’s contract with Theranos from 2011–May 2018, Theranos paid the company
 16 over \$10 million. In fact, in 2017, when Theranos was trying to cut costs—and after the LIS database
 17 had ceased collecting and processing any additional blood tests—IncRev Corp. continued to bill the
 18 company at a rate of \$159,000/month.³ (*Id.*, Exh. 59 (statement of worked signed by Defendant on
 19 April 4, 2017, setting IncRev Corp. billing rate at \$159,000/month); Exh. 60 (March 2017 Billing
 20 Statement).) According to one Theranos whistleblower, Chandrasekaran engaged in self-dealing,
 21 increasing the budget and work allocated to his own company when he was promoted in 2016 to head
 22 Theranos’s IT department. (*Id.*, Exh. 61.)

23 A senior Theranos official described the LIS database as “the most comprehensive . . . company
 24 repository of clinical information – patient contact info, doctor contact info, test data and results, etc.”
 25 (*Id.*, Exh. 62.) The LIS contained all patient test results from approximately the time of Theranos’s

26
 27 ² The government expects witness testimony and evidence at trial will prove the facts outlined in
 this section.

28 ³ IncRev Corp.’s billing records for Theranos do not specify the tasks or specific work performed
 by IncRev Corp. employees. (*See, e.g.*, Leach Decl., Exh. 60.)

1 commercial launch in October 2013, through July 30, 2016. It also stored all the associated data that
2 was generated in the clinical lab, including the QC test results. The database flagged patient test results
3 that required immediate medical attention, as well as information updates from Clinical Laboratory
4 Scientists who reviewed patient test results for errors. Monthly QC reports were run from the LIS to
5 update lab clinicians in Arizona on how various assays were performing.

6 But, perhaps even more critically, the LIS database contained immense functionality. The
7 database was custom made and those who possessed “backdoor” access to the SQL database could
8 query the database to produce sophisticated results that explained what the data showed about
9 Theranos’s capabilities. For example, a litigation consultant hired by Theranos to respond to ongoing
10 regulatory and government inquiries explained it was possible to query the database in near-real time for
11 any and all blood test results with validation errors. Those queries could be further narrowed by test
12 result, by type of analyzer, etc. In other words, a few clicks on the keyboard could reveal how many
13 errors were flagged for Theranos’s hCG tests, or PSA tests, or HIV tests—to cite just a few assays that a
14 patient would rely on for medically significant information. The LIS was where the metaphorical bodies
15 were buried.

16 **B. Theranos Plans to “Dump” the “Bespoke” LIS Database on the Government**

17 On June 4, 2018, a federal grand jury issued a subpoena requesting a softcopy or proxy of the
18 LIS database, along with any proprietary software required to access and search the database. (*Id.*, Exh.
19 63.) The government also requested the entirety of all blood test lab reports maintained in the LIS. (*Id.*)
20 The government provided this request to the law firm Wilmer Cutler Pickering Hale and Dorr LLP
21 (WilmerHale), which represented Theranos.

22 WilmerHale had retained two litigation consulting services to assist with discovery production in
23 responding to various litigation requests on behalf of Theranos. Price Waterhouse Coopers (PWC)
24 assisted in decrypting company files and compiling those files into an e-discovery database. FTI
25 Consulting assisted in running “backdoor” queries in the LIS database to respond to litigation requests
26 from WilmerHale and Theranos. Neither of these companies, though, appears to have assisted Theranos
27 in producing a working copy of the LIS database. Instead, a WilmerHale attorney advised a senior
28 Theranos official that the “better strategy” was to “just dump the entire bespoke database on the

1 Government.”⁴ (*Id.*, Exh. 64.) Accordingly, a plan developed over the next month to ask Theranos IT
2 contractors, Michael Chung and Eric Caddenhead, to copy a backup version of the LIS database onto a
3 hard drive to give to the government. Copies would also be provided to the firms representing
4 Defendant and Balwani in this criminal case, Williams & Connolly LLP and Davis Wright Tremaine
5 LLP, respectively.

6 The backup copy of the database that Theranos planned to provide the government and the
7 defense law firms, however, would never have allowed the government to reconstruct the LIS. At a
8 basic level, the copy was missing the binaries⁵ and source code⁶ that would be necessary to put the
9 database back together. But these missing pieces were likely not enough either. The only people
10 capable of reconstructing the database, given the complexity of the bespoke system, were
11 Chandrasekaran and the IncRev Corp. employees who had created the software.

12 Yet, attorneys for Theranos represented to the government in an email that the only proprietary
13 software the government would need to restore the database was “Microsoft SQL Server Enterprise
14 License on Windows Server 2012R2,” and “SQL Server Management Studio 2014 Management Studio
15 or any other standard software to query SQL Server database.” (*Id.*, Exh. 65.) Meanwhile, Theranos
16 employees acknowledged internally that the backup copy that was being provided to the government
17 would likely be lacking the “layers of applications and data” that were part of the LIS. (*Id.*, Exh. 66.)
18 Theranos’s VP of Operations acknowledged in an email to in-house counsel, “if we are just handing
19 over a database I’m not sure it will meet the needs.” (*Id.*)

20 **C. The Password for Restoring the Backup Copy of the LIS Cannot be Found**

21 On June 6, 2018—two days after the government’s request—a senior Theranos official,
22 Caddenhead, and Sekhar Variam, an employee of IncRev Corp., among others, held a conference call
23 regarding “LIS data base discussion – response to request.” (*Id.*, Exh. 67.) Later that day, Variam
24

25 ⁴ A “bespoke database” means a tailor-made application. In other words, the software
26 comprising the LIS database had been specially created to meet the company’s needs.

27 ⁵ “Binaries” are a type of computer code that allow a program to be installed.

28 ⁶ “Source code” is the source of a computer program. It contains declarations, instructions,
functions, loops, and other statements, which act as instructions for the program or database on how to
function.

1 emailed the group to explain where Caddenhead could find the backup copy of the LIS and the
2 instructions for “restoring the database” to a different server. (*Id.*) Variam also explained that there was
3 an additional “Password for Restore” that would be needed to restore the private key for the database.
4 (*Id.*) (A “key” file is the file that enables a SQL database to be reconfigured.) Variam stated that this
5 password should be in a document that Theranos’s former head of IT, Antti Korhonen, had been
6 provided in September 2016. (*Id.*) Thus, two days after receiving the government’s request for the LIS,
7 Theranos representatives had been advised that a “password for restore” would be necessary to make use
8 of any backup copy of the LIS database.

9 As Chung and Caddenhead worked to copy the backup of the LIS onto the three hard drives
10 intended for the government, Williams & Connolly, and Davis Wright Tremaine, they also attempted to
11 track down the “password for restore.” Caddenhead, who had previously worked with Korhonen,
12 reached out to him via email. (*Id.*, Exh. 68.) But they were never able to get the password from
13 Korhonen. (In fact, Korhonen later tried to track down the password himself to no avail.) On August
14 10, 2018, Chung emailed Theranos’s VP of Operations to remind him that “there may be a need for an
15 additional password,” and copied the text from Variam’s June 6 email. (*Id.*, Exh. 69.)

16 Variam’s email, explaining that the backup copy required a “password for restore,” was also
17 forwarded to Theranos’s in-house counsel, Xan White, and attorneys for WilmerHale, including
18 Attorney 1 and Attorney 2. On August 8, 2018, White followed up with Attorney 1 and Attorney 2, as
19 well as other WilmerHale attorneys, to let them know that the three copies would be ready by the end of
20 the week, but there “may be one password only Antti knows.” (*Id.*, Exh. 70.) White explained that IT
21 was still working on getting the password. (*Id.*)

22 By mid-August, Theranos had sent the three hard drives with the backup copy of the LIS to
23 WilmerHale, but the “password for restore” was still missing.

24 //

1 **D. Backup Copy Provided to the Government But Not to Defense Firms**

2 On August 27, 2018, an attorney for WilmerHale (Attorney 1) provided a transmittal letter to the
3 government, explaining that Theranos was producing an encrypted hard drive containing a copy of
4 Theranos' LIS database in its native format. (*Id.*, Exh. 71.) WilmerHale provided a password for the
5 hard drive, but did not explain that another password was required for the "key" file needed to restore
6 the database. (*Id.*) All subsequent efforts by the government to access the data on this hard drive have
7 failed. The government retained a computer forensic expert to assist in retrieving this data, who found
8 that the "key" file on the hard drive, required to reconfigure the SQL database, is itself encrypted by a
9 distinct password (not the one provided with the transmittal letter to open the hard drive), and cannot be
10 opened. (*Id.*, Exh. 72.) Without the key file, the data files contained on the hard drive cannot be
11 reconfigured into a SQL server and remain inaccessible. (*Id.*)

12 The other two hard drives containing the backup copies of the LIS—originally intended for
13 Williams & Connolly and Davis Wright Tremaine—apparently were never provided to the defense
14 firms. Instead, Davis Wright Tremaine hired Chandrasekaran in mid-August as a litigation consultant to
15 work with Theranos, Caddenhead, and Chung, purportedly to obtain a copy of the LIS database for
16 Balwani's defense team.

17 **E. Theranos Shuts Down the Newark Facility Hosting the LIS Database, Permanently
18 Destroying All the Data**

19 Theranos planned to break its lease and move out of its Newark facility on August 31, 2018. The
20 Newark facility housed many of the company's remaining servers, including the servers that comprised
21 the LIS database. As Chung and his IT firm prepared to assist Theranos with the move, he warned
22 Theranos representatives that once the LIS hardware and servers were taken apart, it would be almost
23 impossible to recreate the database. That was because the database ran off of hundreds of devices with
24 thousands of connections. Chung estimated there was a zero percent chance of successfully recovering
25 the information from this infrastructure once it was disassembled.

26 On August 28, 2018, three days before the Newark shutdown, a senior Theranos official emailed
27 WilmerHale Attorney 1, Chung, Caddenhead, and Chandrasekaran, and asked to convene a conference
28 call to discuss "what we still need from LIS and what we need to do to get it, given that the system will

1 be put into storage this Friday and may thereafter be very difficult to resuscitate.” (*Id.*, Exh. 73.)
2 During the call, the group discussed the encryption of the LIS backup copy, among other things, and the
3 imminent shut down of the Newark facility.

4 Thus, by August 28, 2018, senior Theranos managers, Attorney 1, and Chandrasekaran
5 understood or had been advised that (1) the LIS database, which was about to be taken down, would be
6 “very difficult to resuscitate” after Friday, August 31, 2018; and (2) that the “password for restore”
7 necessary to make use of copies of the database had not been located. Attorney 1 later acknowledged in
8 an email that she understood a second password was necessary to make use of the copies of the database
9 that had been made.

10 Even though the government had been provided its copy of the LIS database only the day before
11 (August 27, 2018), no one informed the government that this copy was “double encrypted” and therefore
12 inaccessible.

13 The hardware comprising the LIS database began coming down on August 30, 2018, and by
14 August 31, 2018, the database had been completely shut down. (*Id.*, Exh. 74.) Up until the time that the
15 hardware came apart, the LIS database was running and Theranos employees were able to run queries on
16 it. Afterwards, the data was gone.

17 **F. Chandrasekaran Does Not Halt the Destruction of the LIS Database**

18 Even though Chandrasekaran knew the LIS hardware would be coming apart on Friday, August
19 31, 2018, and even though he was on an email chain in which the “all clear” was given to take apart the
20 hardware, he waited until two days later, September 2, 2018, to email a senior Theranos official with a
21 list of items he would need from the database in order to reconstruct the LIS. The Theranos official
22 forwarded the request to Chung, who pointed out that the database had been “torn down” on Friday.
23 (*Id.*, Exh. 75.) Chandrasekaran followed up several times, and referenced Variam’s June 6 email with
24 the information on the “password for restore.” (*Id.*, Exh. 76.)

25 The government anticipates that Chung will testify that he had no idea what Chandrasekaran’s
26 role was during this time, but he was *not* under the impression that Chandrasekaran was trying to obtain
27 a working copy of the LIS database. Chandrasekaran’s emails on September 2, 2018, support this

28 //

1 conclusion: it does not appear from the timing of Chandrasekaran's requests that he, in fact, intended to
2 successfully copy the database before it shutdown.

3 **II. CMS Inspection Reveals Theranos's Blood Tests Were Not Reliable**

4 Beginning in September 2015, CMS inspectors conducted an in-person survey of Theranos's
5 Newark laboratory, examining documents provided by Theranos and interviewing Theranos personnel,
6 including Defendant.⁷ The surveyors observed that Theranos's blood analyzer repeatedly failed quality
7 control checks (yet Theranos continued to report patient results). They noted that Theranos's blood
8 analyzer repeatedly produced values outside of ranges Theranos deemed acceptable (yet they continued
9 to report patient results). With respect to Vitamin D, they noted quality control results for analyzers
10 were showing coefficients of variation between 18.7% and 63.6% during certain periods in 2014 (yet
11 they continued to report patient results). The deficiencies noted by the surveyors were so severe CMS
12 determined they posed immediate jeopardy to patient health and safety.

13 **III. Patient Testimony Will Show Theranos Fraudulently Sold Them Unreliable Blood Tests**

14 The government anticipates presenting testimony from approximately 11 patient witnesses at
15 trial. These patients will describe how they used Theranos for specific blood tests, took those blood
16 tests intending to rely on them, but then discovered that their results were not accurate. (*See* United
17 States' Opp. to Mot. to Exclude Customer Impact Evidence at 4–5, 7–8.)

18 The evidence will show, for example, that Theranos struggled with the accuracy of its hCG
19 (human chorionic gonadotrophin) test—used by doctors to determine whether a patient is pregnant—and
20 that Defendant was well aware of these problems. One patient, who had been trying unsuccessfully to
21 have a child for a long time, became pregnant only to receive a Theranos blood test during the early
22 stages of her pregnancy indicating that she was miscarrying. After being forced to live through the
23 heartbreak caused by that news, she obtained a test result from a conventional lab showing that,
24 thankfully, her pregnancy was still viable. Another patient received a Theranos test result indicating that
25 she was not pregnant. In reality, she was currently experiencing an ectopic pregnancy that would have
26 threatened her life had a test from another lab not revealed its presence. In each case, the patient's
27

28 ⁷ The CMS inspection and report are described in greater detail in the government's Opposition to Defendant's Motion *In Limine* to Exclude Evidence of CMS Survey Findings and Sanctions.

1 experience of these effects—and her subsequent blood tests—revealed that she had been defrauded: she
2 had purchased a test on which she could not rely.

3 Another patient, who was a breast cancer survivor on estrogen-blocking drugs, received a
4 Theranos test showing her estrogen levels were much higher than would be expected given her treatment
5 course. She immediately thought that the test results must either be wrong or her cancer had returned
6 and a tumor was growing somewhere in her body. Her OBGYN provider called her later that day, also
7 convinced there was something wrong with the Theranos test result. Her oncologist then wanted her to
8 come in to have a new blood test performed. Her subsequent test through Sonora Quest showed her
9 estrogen levels at the predictable level given her treatment and her oncologist told her “everything
10 looked good.” The patient’s testimony will show how Theranos’s misrepresentations caused her to
11 purchase a test on which she could not rely.

12 ARGUMENT

13 I. Defendant Should be Barred from Arguing the Government’s Evidence is “Anecdotal”

14 The LIS database was destroyed while it was under subpoena by a federal grand jury. The data
15 contained therein, including all of Theranos’s patient blood test results from October 2013 to July 2016,
16 was lost. Meanwhile, Theranos, through its counsel WilmerHale, provided the government an
17 inaccessible and useless copy of the LIS, failing to explain that the password for restoring this copy had
18 never been found.

19 Throughout this time, the law firms representing Defendant and Balwani communicated with
20 WilmerHale and Theranos on topics relating to the LIS and, specifically, the government’s ongoing
21 criminal investigation.⁸ For example, according to a privilege log provided by WilmerHale, at 1:10 a.m.
22 on August 29, 2018, a Theranos executive emailed WilmerHale Attorney 1, and copied attorneys for
23 Williams & Connolly and Davis Wright Tremaine. The email concerned, “information necessary to
24 obtain legal advice regarding DOJ investigation and prepared in anticipation of litigation.” (Leach Decl.
25 ¶ 59.) At 1:33 a.m., a David Wright Tremaine attorney responded, copying an attorney for Williams &
26

27
28 ⁸ In fact, WilmerHale has asserted in its privilege log that a “common interest work product”
privilege existed between WilmerHale, Williams & Connolly, and Davis Wright Tremaine during this
time. The government disputes that such a privilege applies here.

1 Connolly. (*Id.*) The following day, August 29, 2018, the Davis Wright Tremaine attorney emailed
 2 again, also concerning, “legal advice regarding DOJ investigation.” (*Id.*) On September 5, 2018, an
 3 attorney from Davis Wright Tremaine emailed an attorney for WilmerHale, copying a Williams &
 4 Connolly attorney and a senior Theranos official. (*Id.*)

5 At some point, it was decided that Williams & Connolly and Davis Wright Tremaine would *not*
 6 receive the same useless copy of the LIS database provided to the government. Instead, Balwani hired
 7 Chandrasekaran—a long-time friend and fact-witness in the criminal case against him—to coordinate
 8 with Theranos managers, Attorney 1, and others about the LIS database in August 2018. Yet, despite
 9 Chandrasekaran’s expertise in the bespoke LIS system and its software, no preserved copy of the
 10 database was ever provided to the government. From August 30-31, 2018—while Balwani’s litigation
 11 consultant stood by and did nothing—the hardware comprising the LIS was pulled apart and the data
 12 was lost.

13 Defendant now intends to argue at trial that the government’s case is “anecdotal”—whatever that
 14 means—because the government has not conducted a statistical analysis of the (purportedly) millions of
 15 patient blood test records in the LIS which Theranos (along with others) destroyed. This should not be
 16 permitted. Nor should Defendant’s lawyers be permitted to assert that, “as far as we are aware, of the 7-
 17 10 million test results generated by Theranos, not one caused any physical harm.” (*See* Motion to
 18 Exclude Customer Impact Evidence, Dkt. #562, at 1.) This assertion has no basis in fact. Worse than
 19 that, though, Defendant’s self-serving speculation is enabled by Theranos’s own destruction of the
 20 database. It would be unjust for Defendant to now benefit from this destruction by advancing such
 21 baseless claims in front of the jury.⁹

22 **II. Theranos’s Blood-Testing Problems Were Well-Documented**

23 Defendant’s motion also fails because she is incorrect about the scope of the evidence showing
 24 widespread accuracy and reliability problems with Theranos’s blood tests. Contrary to her claims, these

26 ⁹ Moreover, the government will admit evidence demonstrating Theranos’s destruction of the
 27 LIS under Federal Rule of Evidence 404(b). *See United States v. Mendez-Ortiz*, 810 F.2d 76, 79 (6th
 28 Cir. 1986) (“Though not listed in Rule 404(b), spoliation evidence . . . is admissible to show
 consciousness of guilt.”). The government provided detailed notice of this in its Rule 404(b) notice and
 Defendant has *not* moved to exclude this evidence.

1 problems were well-documented. The government’s case is hardly “anecdotal.”

2 For example, one of the CMS surveyors, Sara Bennett, is expected to testify that Theranos was
3 *not* following its own QC procedures in conducting blood tests on patient samples during the time of
4 CMS’s inspections from September through November 2015. She will explain that “[i]f the QC is
5 problematic, there is no way to assess whether the patient data is accurate and reliable. If the laboratory
6 runs the controls and they are unacceptable, then they should not be running patients after that.” *Id.* at 6.
7 As explained above, reliable and accurate QC procedures are synonymous with reliable and accurate
8 blood testing of patient tests. This is because the QC tests are run on known samples, whereas the
9 patient samples have no comparisons. When QC samples show an analyzer’s blood tests are repeatedly
10 failing to report a result within an acceptable range of error, as Bennett will explain, this means that a
11 lab cannot provide accurate and reliable blood tests to patients. Bennett will explain that this is exactly
12 what happened in Theranos’s lab: “CMS found . . . that QC results on [Theranos’s] device had been out
13 of range multiple times, yet Theranos was still reporting patient results during that time. Theranos’s
14 solution was to simply adjust the mean.” *Id.* at 7. “Theranos continued to report patient values despite
15 having these QC problems.” *Id.*

16 CMS’s final report cited numerous lab standards Theranos was failing to meet and, as a result,
17 the report concluded Theranos’s lab “pose[d] immediate jeopardy to patient health and safety.” (*See*
18 *United States’ Opp. to Mot. to Exclude CMS Survey* at 4–5.) CMS also documented instances where:
19 (1) Theranos ran patient tests after failing QC (Dkt. #581-1 at 43–46); (2) QC results for multiple assays,
20 for weeks on end, were at least two standard deviations from the mean (*id.* at 45–46); (3) QC results for
21 multiple assays had coefficients of variation as high as 63.8% (*id.* at 55–56); (4) the overall percentage
22 of QC samples on all tests on all devices was at or in excess of 20% (*id.* at 57–58); and (5) accuracy,
23 precision, reportable range, and allowable bias for multiple assays did not meet even Theranos’s criteria
24 (*id.* at 80–81). The evidence will show the accuracy and reliability problems with Theranos’s blood
25 tests were widespread.

26 Similarly, the inspection by the Food and Drug Administration (FDA) revealed that Theranos’s
27 own design validation plan for its “nanotainer” showed four assays (bicarbonate, calcium, glucose, and
28 potassium) failing the plan’s accuracy criteria. (*See United States’ Opp. to Exclude FDA Inspection* at

1 5–6.) In other words, Theranos’s nanotainer—the device used to collect patient blood for testing—was
 2 so inaccurate that patients using these devices could not rely on the results from their blood tests. Again,
 3 this evidence shows the widespread flaws in Theranos’s blood testing—flaws that put patients’ health
 4 and safety at risk and denied them the benefit of what they had paid for: reliable and accurate blood
 5 tests.

6 **III. Patient Testimony About their Own Inaccurate Test Results is Probative and Admissible**

7 Defendant’s motion makes the extraordinary argument that the testimony of individual victims of
 8 a fraud cannot be used to prove that fraud.¹⁰ (See Mot. at 4.) Defendant analogizes victim witness
 9 testimony about their own experiences of receiving bad test results to the scientific opinions offered by
 10 experts and the requirements for class certification in civil cases. (*Id.*) These comparisons are
 11 nonsensical. Defendant cites *no* case requiring a limitation on victim witness testimony based on such
 12 requirements. In fact, this argument runs contrary to the basic framework of a criminal trial: that
 13 witnesses may testify to their own experiences in order to prove facts that support a conviction. Fraud
 14 cases are no different. See, e.g., *United States v. Copple*, 24 F.3d 535, 545 (3d Cir. 1994) (evidence
 15 about the victims’ losses and Copple’s refusal to make good those losses was relevant to show Copple’s
 16 specific intent to defraud).

17 Here, patients will describe their own experiences receiving inaccurate blood tests from
 18 Theranos. These experiences were harrowing and illustrate why Defendant’s misrepresentations about
 19 Theranos’s capabilities were material: patients and providers actually relied on these claims for critical
 20 health information. The anticipated patient and provider testimony describing patients’ inaccurate blood
 21 tests will (1) help demonstrate the fraud, *i.e.*, show that patients did not get what they paid for; (2) show
 22 that Defendant’s misrepresentations about the accuracy and reliability of Theranos’s blood test were

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 25
 26 ¹⁰ Defendant’s motion—similar to several of her other motions *in limine*—is not at all clear
 27 about what specific evidence and testimony she seeks to exclude. Is her position that *all* patient
 28 testimony about their inaccurate blood tests is “anecdotal” and therefore should be excluded? As
 discussed above, this is an extraordinary claim in a case where the government has alleged a fraud
 perpetrated on patient victims. Because Defendant makes no effort to specify which patient tests she
 seeks to exclude, the Court may also deny her motion as too vague. See *United States v. Head*, No. 08-
 CR-116 KJM, 2013 WL 5739095, at *4 (E.D. Cal. Oct. 22, 2013).

1 material; and (3) reveal Defendant’s fraudulent intent. (See United States’ Opp. to Mot. to Exclude
2 Customer Impact Evidence at 7–9.) Accordingly, this evidence is relevant and admissible.

3 **CONCLUSION**

4 For the foregoing reasons, the Court should deny Defendants Motion *In Limine* to Exclude
5 Anecdotal Test Results, Dkt. #563.

6 DATED: January 8, 2021

Respectfully submitted,

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