No. 22-10312

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

ELIZABETH A. HOLMES,

Defendant-Appellant.

BRIEF FOR THE UNITED STATES AS APPELLEE

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
NO. 18-CR-00258-EJD-1

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August 17, 2023

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BRIEF FOR THE UNITED STATES AS APPELLEE

Defendant-Appellant Elizabeth Holmes and her co-defendant, Ramesh "Sunny" Balwani, stand convicted following separate jury trials for their multi-year scheme to defraud investors into believing that their company, Theranos, had a revolutionary market-ready blood-testing device that had been endorsed and adopted at high levels—when in fact that was not true. Holmes and Balwani secured more than $800 million from investor-victims based on these claims, and real patients paid the price as collateral damage. On appeal, Holmes raises several discrete evidentiary challenges and urges error in calculating the loss amount, which the court reasonably estimated at $120 million. Her claims are meritless, but, regardless, unavailing given the overwhelming evidence and independent categories of fraudulent statements Holmes made. This Court should affirm.

JURISDICTION, TIMELINESS, AND BAIL STATUS

The district court (Hon. Edward J. Davila) had jurisdiction under 18 U.S.C. § 3231. This Court has jurisdiction under 28 U.S.C. § 1291. Holmes filed a timely notice of appeal. Fed. R. App. P. 4(b)(1)(A)(i); 55-ER-15907-09; CR-1670, 1720.[1] Holmes has also appealed the restitution order. CR-1763. This Court denied Holmes's motion for bail pending appeal, which raised the same evidentiary claims she presses here, holding that Holmes had not shown that her "appeal raises a 'substantial question' of law or fact that is 'fairly debatable'" nor that favorable resolution would result in "reversal, an order for a new trial on all counts resulting in imprisonment," or a meaningful change to her sentence. Dkt. 52. Holmes's projected release date is December 19, 2032. https://www.bop.gov/inmateloc/ (BOP Register No. 24965-111).

ISSUES PRESENTED

1. Whether the district court abused its discretion by:

   a. permitting a former Theranos laboratory director to testify as a percipient rather than expert witness about what he contemporaneously did—and told Holmes—in 2016.

[1] ER refers to Appellant's Excerpts of Record, AOB to Appellant's Opening Brief, SER to the Government's Supplemental Excerpts of Record, PSR to the Presentence Investigation Report, CR to the district court clerk's record, and Dkt. to this Court's docket.

b. admitting for a limited purpose a small portion of an exhibit from 2016 documenting a regulatory agency's observations of Theranos's laboratory.

c. admitting evidence demonstrating that Theranos voided all patient blood tests reported on its proprietary device when it was required by federal regulation to act after regulatory deficiencies were found.

2. Whether the district court abused its discretion by limiting the scope of Holmes's cross-examination of one witness about his post-Theranos employment, after Holmes had cross-examined the witness for four days.

3. Whether the district court abused its discretion by excluding Balwani's self-serving, non-inculpatory, and uncorroborated prior testimony regarding Theranos's financial model.

4. Whether any evidentiary error was harmless given the overwhelming evidence that Holmes made multiple categories of false statements to investors—most of which stand unchallenged on appeal.

5. Whether the district court properly applied the preponderance of the evidence standard at sentencing to find a loss of $120,146,247, given that Holmes was convicted of a conspiracy that included the relevant underlying conduct.

STATEMENT OF THE CASE

I. FACTUAL BACKGROUND

Holmes's fraud centered on the company she founded, Theranos, and the false statements she made about Theranos's blood testing technology. From 2010 to 2015, Holmes and Balwani secured dozens of investors by falsely claiming that Theranos had manufactured one single, proprietary blood analyzer that could run any blood test that was run by conventional labs, all from a blood sample drawn from a fingerstick rather than a vein, with higher accuracy and less variability than traditional methods. To support these claims, Holmes repeatedly told potential investors that major pharmaceutical companies had validated Theranos's device, and the U.S. military was using it in the battlefield to treat wounded soldiers. Holmes also represented that Theranos was profitable and had an expanding relationship with retail pharmacy company Walgreen Co. ("Walgreens"), through which it provided blood tests to patients. Holmes made these statements to Theranos investors, including PFM HealthCare Master Fund LP ("PFM"), RDV Corporation ("RDV"), and Daniel Mosley, whom the jury convicted Holmes of defrauding.

In truth, Theranos's device could never complete more than 12 types of blood tests, often with less accuracy, less automation, and less consistency than traditional "predicate" machines manufactured by third-parties. Pharmaceutical

companies did not validate Theranos's device, and the military never used it to treat soldiers as claimed. Theranos had minimal revenue and was not profitable. Holmes and Balwani hid these shortcomings by using—without disclosing—third-party machines to fulfill the majority of Theranos's blood test menu offered to patients in Walgreens. Meanwhile, Theranos's relationship with Walgreens was faltering because Theranos too frequently had to resort to traditional venous draws. None of this information was shared with investors.

A. Holmes Used Fraudulent Pharmaceutical-Related Reports to Secure Partnership with Walgreens and Entice Investors

Holmes founded Theranos in 2003 and was Chief Executive Officer ("CEO") until 2018. 38-ER-10869; *see* 25-ER-6924. Holmes secured early investments with promises to deliver a revolutionary device the size of a small printer that could run blood tests from a fingerstick blood sample. *See* 29-ER-8054-68; 32-ER-9014-19.

Holmes attempted to partner with pharmaceutical companies but, by 2009, the minimal work Theranos did with these companies was dwindling because the companies found Theranos's claims about its device's capabilities untrustworthy or insufficiently supported. *See*, *e.g.*, 28-ER-7997-8015 (Pfizer found Theranos report "not believable" and told Holmes Pfizer had no foreseeable use for Theranos's device); 31-ER-8649-65 (Schering-Plough was "dissatisfied" with Theranos report and found Holmes "cagey"); *see also* 22-ER-6035-48 (Celgene

dropping Theranos to "stick with the gold standard"); 50-ER-14469-70 (Theranos's revenue from pharmaceutical companies ceased in 2011). As a result, Theranos was on the brink of collapse. Theranos was barely making payroll until Balwani, Holmes's romantic partner (from 2004 to 2016), agreed to guarantee a multimillion-dollar line of credit. 16-ER-4306-21, 4446; CR-1166. Shortly thereafter, Balwani joined Theranos as President and Chief Operating Officer. 39-ER-11082.

In 2010, Holmes pivoted to partnering with retail chains, Walgreens and Safeway. Holmes promised Walgreens and Safeway a "mini-lab" device that could run any blood test from a fingerstick for less than the traditional cost of established providers of blood-testing services. 24-ER-6691-707; 25-ER-6919-33. Despite Theranos's financial struggles, in mid-2010, Holmes told Safeway that Theranos was cash-flow neutral and was projected to earn $223 million in revenue in 2011, $464 million in 2012, and $934 million in 2013. 24-ER-6699-714.

In April 2010, Holmes emailed Walgreens reports with favorable conclusions about Theranos's device. 2-SER-298-352. She emblazoned the reports with logos of prominent pharmaceutical companies. *Id.* Holmes described the documents as "three independent due diligence reports on Theranos systems" that were "from GlaxoSmithKline, Pfizer, and Schering-Plough after their own technical validation and experience with Theranos Systems in the field." *Id.*; *see*

25-ER-6939-52 (Walgreens understood that Pfizer had either authored or approved the report).

However, Pfizer and Schering-Plough did not validate Theranos's device, endorse the conclusions in the reports that Walgreens received, or authorize Theranos to affix their logos to the reports. 28-ER-7997-8015; 31-ER-8649-65. Holmes admitted at trial that she personally added the pharmaceutical logos to reports Theranos wrote and enhanced the conclusions shortly before sending them to Walgreens. 39-ER-11038-39; 41-ER-11703-37. The following compares the original report and the one Holmes doctored:

CONFIDENTIAL

Theranos Angiogenesis Study:

Report Prepared for Dr. Aidan Power
Pfizer, Inc.

4-SER-798.

CONFIDENTIAL

Theranos Angiogenesis Study Report

Pfizer, Inc.

2-SER-305.

Holmes also told Safeway and other investors that Theranos's device had been "comprehensively validated" "by ten of the fifteen largest pharmaceutical companies," when that was not true. *See*, *e.g.*, 24-ER-6735; 35-ER-10056-57.

Walgreens and Safeway both partnered with and invested in Theranos. 24-ER-6717-6739; 25-ER-7003-06.

As late as 2014, Holmes continued to send the falsified reports to investors, including RDV and Mosley, who testified that the reports were material to their investment decisions. 29-ER-8275-94 (RDV); 31-ER-8717-45 (Mosley stating that "[t]he most extensive evidence supplied regarding the reliability of the Theranos technology and its application is a study report prepared by Pfizer"); *see* 4-SER-649 (Holmes texted Balwani in 2013 that she was planning to include "the Pfizer report" in materials for investors); CR-1338.

B. Holmes Lied About the Military's Use of Theranos's Device

In 2013 and 2014, Holmes repeatedly told investors, including PFM and RDV, that the U.S. military was using Theranos's device on medevac helicopters, "in the battlefield," and to treat soldiers in Afghanistan and Iraq. 35-ER-10010-16; *see*, *e.g.*, 24-ER-6744-48; 25-ER-7017; 29-ER-8126-30, 8273-74; 30-ER-8605-11; 32-ER-9062-64. The jury also heard two recordings of Holmes directly making these claims. 29-ER-8116-30; 37-ER-10558-62; 1-SER-41-42.

In truth, General James Mattis and former Theranos employee Daniel Edlin confirmed that the military never used Theranos's device to treat soldiers in the battlefield, never sent a device to the Middle East, never transported (much less used) the device on a medevac helicopter, and never moved out of initial testing phases with any branch of the military. 19-ER-5224-64, 5326-28 (Mattis was in a military leadership position overseeing U.S. operations in the Middle East until March 2013 and thereafter joined Theranos's board of directors until resigning in late 2016); 27-ER-7659-62; 28-ER-7878-98 (Edlin explained that, while a small number of Theranos devices were shipped within the United States to a military base for preliminary evaluation, those devices were not capable of running the blood tests that the military required). Edlin also confirmed that Theranos's device briefly flew around on a helicopter (not a medevac) in Africa (*id.*), but that is not what Holmes told investors.

C. By Fall 2013, Theranos Was Running Out of Money, But Holmes Projected Hundreds of Millions in Revenue

By the fall of 2013, Theranos again was out of money. Theranos earned approximately $500,000 in revenue in 2011 and zero revenue in 2012 and 2013. 16-ER-4326, 4375-84. Holmes knew this: Theranos's highest-ranking financial officer reported directly to Holmes and provided her with weekly updates on Theranos's finances. 16-ER-4306-21, 4406, 4446. In November 2013, Balwani emphasized to Holmes that Theranos was down to approximately $15 million in

cash (while spending up to $2 million per week). 16-ER-4405-08; 4-SER-651-53. Nevertheless, Holmes told PFM in December 2013 that Theranos had historically earned over $200 million from projects with the military and pharmaceutical companies, when, in reality, Theranos had only earned approximately $290,000 from any military-associated entity, and approximately $9.6 million from pharmaceutical companies. *Compare* 35-ER-10014-16, *with* 16-ER-4396-404, *and* 50-ER-14469-70.

Theranos's revenue did not improve—earning just $150,000 in 2014. 16-ER-4393. Yet Holmes continued to provide substantially inflated financial projections to investors like RDV and Mosley—three-quarters through 2014—predicting $140 million in 2014 revenue and nearly $1 billion in 2015. 29-ER-8258-65, 8294-300; 30-ER-8593-600; 31-ER-8709-31; 46-ER-13157; *see* 35-ER-10014-16, 10030-42, 10074-82.

D. Holmes Rushed the Launch of an Unproven Product with Walgreens in September 2013

By mid-2013, Holmes risked losing Theranos's retail partners. Theranos's partnership with Safeway was waning because Holmes was unable to deliver what she had promised in 2010: one miniature device to run blood testing. 24-ER-6790-98. Holmes promised Walgreens that Theranos would be ready to launch and begin testing patients by September 2013—and Walgreens made its next payment contingent upon the launch. 25-ER-6998-7124; 45-ER-13085; 4-SER-

774-83. Walgreens, based on assurances from Holmes, believed "the vast majority of [blood] tests would be done on a Theranos machine" rather than a third-party device. 25-ER-7000-05; 34-ER-9602-09; *see also* 24-ER-6723-28.

That summer, Theranos could not get any version of its proprietary device ready for market. One long-time Theranos scientist, Surekha Gangakhedkar, described consistent problems with multiple iterations of Theranos's device—the Edison, 3.0, 3.5, 4.0, and minilab[2]—and Holmes's decision to continue with the launch despite knowing about these issues. 18-ER-4879-916; 2-SER-353. Holmes pressured the scientists to quickly validate blood tests ("assays") for clinical ("patient") use on Theranos's device to meet the promised launch date. *See id.*; 20-ER-5424-30.

[2] Holmes continues to rely on the purported capabilities of the 4.0 or minilab rather than the Edison or 3.0/3.5. AOB-5-7; 38-ER-10991-94; *see* 35-ER-10027. However, multiple witnesses—including Holmes—testified that the minilab and 4.0 were never used to test patient samples and never worked—even as late as 2016 when Theranos ceased testing patients. 17-ER-4490-96 (Cheung); 18-ER-4858-82 (Gangakhedkar); 20-ER-5415 (Rosendorff); 27-ER-7535 (Edlin); 34-ER-9645-46 (Das); 40-ER-11580 (Holmes); *see* 38-ER-10855-66 (defense witness admitting that in 2016 he "would not have made" statement that "Theranos was presently capable of testing about 200 assays on a Theranos device"—namely the minilab—"[b]ecause it would not have been accurate even in 2016"). To the extent she claims that Ian Gibbons informed her in 2010 that 4.0 could run any test (AOB-6-7), his contemporaneous presentations explicitly discussed future capabilities. *See*, *e.g.*, 48-ER-13762-64 ("4.0 will be capable"); 53-ER-15519. Finally, Holmes claims Johns Hopkins evaluated Theranos's device (AOB-9), but the institution never "validate[d]" "the box" and instead relied on information that Theranos provided. 24-ER-6834-36; 25-ER-7053-56.

By the September 2013 launch date, Theranos had not validated a single assay for patient use on any version of its device. *Id.*; 47-ER-13682; 2-SER-354-55, 396-98. Multiple scientists felt compelled to resign before the launch because unreliable devices were going to be used to test real patients. 18-ER-4879-916. In response to these concerns, Holmes said that "she ha[d] a promise to deliver to the customer [Walgreens], she d[id]n't have much of a choice but to go ahead with the launch." 18-ER-4910-16; *see* 4-SER-774-83; *see also* 20-ER-5411-35 (Holmes "was very nervous . . . and upset" but not surprised before launch).

Externally, Holmes told a different story, reinforcing the belief that Theranos was using its own miniaturized device. For example, Holmes reviewed and approved a *Wall Street Journal* piece, contemporaneous with the Walgreens launch, claiming Theranos devices "automate and miniaturize more than 1,000 laboratory tests" and that "Theranos's processes are faster, cheaper and more accurate than the conventional methods and require only microscopic blood volumes, not vial[s]." 2-SER-356-65; *see also* 45-ER-13120 (joint Theranos-Walgreens press release making similar claims). Theranos's website boasted "[n]o big needles" and "[j]ust a tiny sample" with a misleading caveat that "[o]ccasionally, a venipuncture may be required based on the lab order, but this is uncommon," with Holmes ignoring attorneys who advised her that such claims needed substantiation. 53-ER-15507-13; 2-SER-399-425.

In December 2013, Holmes shared the September 2013 *Journal* piece and press release with current investors and offered them the opportunity to invest again before a new fundraising round. 29-ER-8073-131; 31-ER-8702, 8731-33; 32-ER-9017-50; 34-ER-9703-17; 35-ER-10048-49; 2-SER-360-61. These investors understood Theranos's device to be more mature and the company's financial situation to be more stable than when they originally invested in 2006. 29-ER-8070-80; 32-ER-9013-64, 9171-74; 34-ER-9670-9717.

E. Holmes Concealed Theranos's Pivot to Third-Party Devices

Theranos used third-party, commercially-available blood analyzers to fulfill the vast majority of the blood tests offered to patients at Walgreens, but Holmes lied about that fact to Walgreens and investors. *Compare* 17-ER-4490-504, *and* 20-ER-5411-35, *with* 25-ER-6983, 7000-05, *and* 26-ER-7197-216. For example, in August 2013, Holmes gave a misleading demonstration to Walgreens executives by leading them to believe that their blood was being tested on a Theranos device displayed to them, when in reality it was tested on a third-party machine. 26-ER-7298-300; 27-ER-7533-46; *see also* 25-ER-6991-92; 28-ER-7899-906. Similarly, PFM's managing partner received a vein draw instead of a fingerstick at Walgreens, but Balwani and Holmes falsely assured him that the test was still run on Theranos's device. 35-ER-10086-88; 36-ER-10273-75; 2-SER-374-76.

When Theranos did use its device, it was beset with problems. Erika Cheung testified about her daily role testing patient samples on the Edison in Theranos's laboratory from October 2013 until April 2014, including how quality control failed at alarming rates, and how Theranos did the vast majority of its patient testing on unmodified third-party machines. 17-ER-4479-536, 4648-62. Tyler Shultz, another employee and the grandson of a prominent Theranos board member, appealed directly to Holmes with similar concerns about Theranos's device. 40-ER-11546-57 (discussing 2-SER-377-82; 4-SER-758-72).[3]

Other insiders described the limitations and recurring issues with Theranos's device, including Dr. Adam Rosendorff, who oversaw Theranos's clinical lab as laboratory director from April 2013 until November 2014. 20-ER-5404-05. Rosendorff testified that the Edison was only ever designed to run a handful of tests and never clinically ran more than 12 types of tests; that the minilab was never used to test patients; and that Theranos used mostly third-party machines to test patient samples. 20-ER-5411-35. Rosendorff described his increasing concerns about patient-testing on Theranos's device and how he raised those concerns to Holmes and Balwani—only to conclude that management cared "more about PR and fundraising than about patient care[.]" 20-ER-5404-05, 5457-530;

[3] Holmes also deceived regulators in 2013 by directing them on a path that included only third-party machines. 17-ER-4635-44; 46-ER-13387; 2-SER-369.

see also 2-SER-385-86 (Holmes's brother escalating concerns). Contemporaneous documents demonstrated that Holmes knew of the problems with Theranos's device and recommended switching to "traditional methods[.]" 2-SER-366-68; *see* 17-ER-4535-40, 4664-72; 18-ER-4902-13.

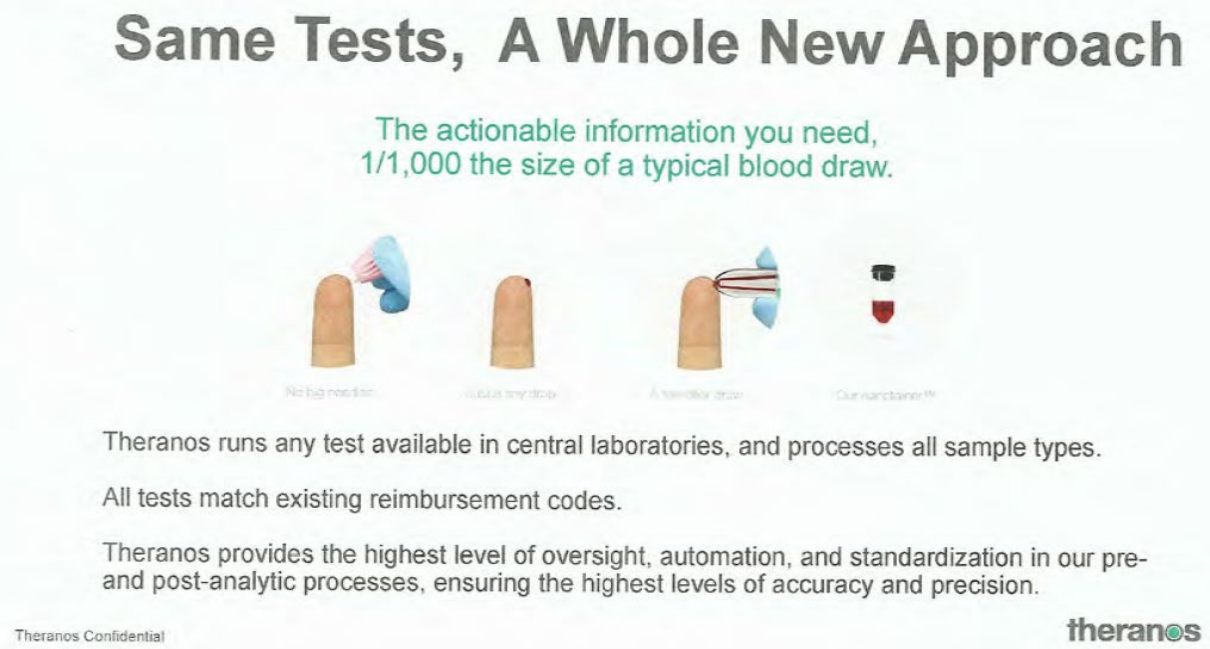
Theranos never used its heralded device for more than 12 types of blood tests and ceased using it altogether by July 2015. 47-ER-13682.

Externally, Holmes used the media to tout Theranos's device as one without limitations. In June 2014, Holmes posed for the cover of *Fortune* magazine. 46-ER-13215-23. She falsely told the reporter that Theranos did "not buy any analyzers from third parties," which was published in the accompanying article. 46-ER-13220; *see* 37-ER-10571-85; 1-SER-26-71. Holmes subsequently shared the *Fortune* article with investors despite knowing the truth. *See* 29-ER-8255-58, 8291-92; 31-ER-8721-33; 2-SER-383-84.

In December 2013 and January 2014, Holmes and Balwani met with investor-victim PFM. Holmes told PFM that Theranos's device "could do all – over a thousand CPT codes with their technology" and that Theranos's "technology was actually better than conventional laboratory equipment[.]" 35-ER-10005-16. Holmes showed PFM the "minilab," described it as a comprehensive "laboratory shrunk down into a [small] box," and claimed the minilab was the device Theranos was using to test patients. 35-ER-10026-39. She

also told PFM "that they made their own analyzers as opposed to using third parties[.]" 35-ER-10060-65. PFM sent two pages of due diligence questions to Holmes and Balwani in early January 2014, intending to ensure "there was no ambiguity" and "no confusion about what the technology was capable of doing"—"[t]he answer was that there were no limitations." 35-ER-10025-39; 2-SER-370-73. Holmes and Balwani made similar claims to other investors throughout 2014 and 2015, including to RDV and Mosley, who both invested in October 2014. *See*, *e.g.*, 29-ER-8266-85; 31-ER-8714-21; 32-ER-8995-99.

Holmes also approved written materials for investors in 2014 and 2015 that repeated these false statements. *See*, *e.g.*, 27-ER-7555-59, 7601-09 (materials sent to investor-victim Rupert Murdoch); 29-ER-8277-94 (RDV); 31-ER-8695-739 (Mosley); 35-ER-10039 (PFM). An example slide follows:



46-ER-13404; 3-SER-473; *see also* 47-ER-13455 (describing "800+ test menu" on "minilab and 4s" device).

Theranos received hundreds of millions of dollars in investments between late 2013 and early 2015. *See* 16-ER-4392; 2-SER-439-44.

Investors repeatedly testified that they would have been shocked to learn that Theranos was using third-party machines—not Theranos's device as pitched—to run patient blood samples and that Theranos's device could never run more than 12 tests. *See*, *e.g.*, 26-ER-7198-99, 7208, 7216; 29-ER-8274-77, 8304-08; 31-ER-8714-21; 32-ER-8998-99, 9058-62; 34-ER-9720-22; 35-ER-10026-48, 10072-74; *see also* 24-ER-6727-28, 6798; 25-ER-6983, 7000-05; 37-ER-10571-85. Holmes told investors that the minilab was being used to test patients when it was not. *Compare* 29-ER-8281, *and* 35-ER-10027, *with* 40-ER-11580.

F. Theranos Provided Inaccurate Blood Testing Services to Patients

Meanwhile, Theranos provided lab testing services to patients in Walgreens stores from 2013 to 2016. 13-ER-3526-40. Despite promising patients "the highest levels of accuracy," Theranos repeatedly sent erroneous results to patients, including results run on Theranos's Edison device. *See*, *e.g.*, 20-ER-5457-530, 5642; 47-ER-13662-706; 48-ER-13757-60; 2-SER-385-95, 426-35. One woman received results indicating she was going to have a miscarriage when she was carrying a healthy baby. 19-ER-5076-145. Another received results indicating

that he had late-stage prostate cancer when he did not. 37-ER-10460-521. Another was informed (incorrectly) that she had HIV. 36-ER-10372-87.

By November 2014, Rosendorff resigned from Theranos because he was "really uncomfortable with what [was] happening" in the company and felt "pressured to vouch for results" in which he was not confident. 20-ER-5405, 5642-49; 21-ER-5652-63; 23-ER-6480; 2-SER-436-38. Rosendorff took steps to preserve evidence and considered how best to reveal what was happening within Theranos. 20-ER-5536-38.

Internally, Holmes and Balwani texted each other about Theranos's dark reality: "[the] lab is a fucking disaster zone" and "fundamentally we need to stop fighting fires by not creating them[.]" 4-SER-657-65. After Rosendorff resigned, Theranos hired Balwani's dermatologist, Dr. Sunil Dhawan, as lab director. 26-ER-7314-26. Dhawan visited the laboratory twice and spent roughly ten hours total working for Theranos that year. *Id.*

G. Holmes Falsely Claimed that Theranos's Relationship with Walgreens Was Expanding When It Was Shrinking

Walgreens originally partnered with Theranos in part because Walgreens believed that it could offer customers the "innovation" of lab tests from "a few drops of blood with a fingerstick" on Theranos's device—as Holmes promised. 26-ER-7198-202, 7300-06. To that end, after the launch, Walgreens tracked metrics such as the percentage of vein draws versus fingerstick. 26-ER-7190-224.

In regular meetings throughout 2014, Theranos kept promising Walgreens that vein draws would be used for less than 10% of patients—but in fact never got below 40%. *Id.*; *see* 25-ER-6991-7124. As a result, by August 2014, Walgreens grew frustrated and decreased its 2015 goal for stores with Theranos testing from 500 to 200. 26-ER-7209-12; 46-ER-13167. Balwani forwarded Holmes Walgreens's statement that further expansion was unlikely until vein draws were "in the 10% range[.]" 4-SER-773.

Holmes and Balwani knew Theranos's relationship with Walgreens was shrinking rather than expanding—texting each other "we can't scale with wag [Walgreens.]" 4-SER-657. Nevertheless, Holmes continued to provide investors, including RDV and Mosley, with financial projections assuming that Theranos would be in 900 Walgreens locations in 2015—rather than the 200 then-projected. 29-ER-8260-67, 8291; 31-ER-8750-51; 46-ER-13157.

H. Holmes Retaliated and Minimized as the Truth Was Revealed by Media and Regulatory Agencies

In spring 2015, Holmes and Balwani learned that *Wall Street Journal* reporter John Carreyrou was investigating Theranos and assumed he "[wa]s looking to write something negative." 4-SER-683-750. They tried to interfere by coordinating a fingerstick (rather than vein draw) test for him and to ascertain his sources. *Id.* By May 2015, Balwani identified "Tyler [Shultz,] Erika [Cheung,] and Adam [Rosendorff,]" to which Holmes responded, "I know." *Id.* Holmes

attempted to silence those individuals with threats of lawsuits. 17-ER-4670-77; 40-ER-11529-69; 4-SER-709-20; CR-1005. Holmes even attempted to quash the story before it was published. 40-ER-11564-68. Holmes admitted that she was "aggressive" in her efforts and claimed she regretted her conduct. 40-ER-11408, 11529-69.

Contemporaneously, Balwani privately lamented to Holmes that Theranos was overexposed, lacked "solid substance[,]" and "should think about sharing we have a large reference lab" (*i.e.*, not using Theranos's device) because "[t]his will shock people[.]" 4-SER-687, 693, 697; *see also* 4-SER-679-735.

Theranos also drew regulatory scrutiny. The Food and Drug Administration ("FDA")—the agency that approves medical devices—and Centers for Medicare and Medicaid Services ("CMS")—the agency that oversees blood testing laboratories—inspected Theranos unannounced in August and September 2015. 1-ER-199-222. Privately, Holmes and Balwani boasted that they could "run circles around others and fda" and that—even though Theranos had ceased using its device and fingerstick collection method—"people will talk about our fingerstick[w]ithout us talking about it." 4-SER-726-41, 751-52. When inspections were going badly, they conceded the inspection was "[g]oing bad so far" and exhorted each other to "[p]ray." *Id.* During its inspection, CMS found deficiencies that presented "immediate jeopardy" to patient health and that

Theranos continued to report patient results after quality-control failures. 47-ER-13683-702 (admitted portion). CMS memorialized its observations in a 121-page report and 4-page cover letter sent to Theranos on January 25, 2016 (hereinafter, "CMS Report"). 1-SER-111-235 (full CMS Report); *see* 1-SER-92-98. Holmes conceded at trial that the CMS Report vindicated the quality control issues that Cheung and Shultz had raised to Holmes back in early 2014. 40-ER-11537-61.

On October 15, 2015, the *Journal* published Carreyrou's article exposing the severe limitations of Theranos's device and the company's reliance on third-party machines to do the bulk of its testing, among other things.[4] *See* 4-SER-743 (Balwani texted Holmes: "Jc [John Carreyrou] article is out"). Multiple witnesses described this article as pivotal in their understanding of the capabilities of Theranos's device. 19-ER-5278-95; 28-ER-7915-16; 30-ER-8370-31, 8574, 8607.

Nevertheless, Holmes fought to keep up the façade. Holmes stated on live television: "Every test that we offer in our laboratory can run on our proprietary device[.]" 1-SER-81; *see* 29-ER-8309-12; *but see* 47-ER-13682 (no tests offered on Theranos's device then). Balwani privately expressed concern about Holmes's public statements, texting that he was "[w]orried about your 'all fingersticks on our technology' comment." 4-SER-745, 750. Holmes suggested further deception of

[4] John Carreyrou, *Hot Startup Theranos Has Struggled With its Blood-Test Technology*, Wall St. J., Oct. 15, 2015, https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901.

Walgreens when Walgreens was "posturing to walk away" because of "[l]ack of transparency" and finding "out thru [sic] media and not thru [sic] us." 4-SER-743-49. Balwani responded: "Bad idea. At this point they know. So need to be transparent." *Id.*

In December 2015, Holmes hired Dr. Kingshuk Das as Theranos's lab director, reporting directly to her. 33-ER-9406-23. Das had previously served as the equivalent of a laboratory director at UCLA. *Id.* As part of his Theranos job responsibilities, Das reviewed the CMS Report, determined how to respond, and determined how it impacted the lab he was running. *Id.* Das developed concerns with Theranos's Edison device and communicated those concerns to Holmes. 33-ER-9420-86. For example, Das told Holmes that the Edison was erroneously producing prostate results for females that "should only be detected in males." 33-ER-9448. In response, Holmes offered implausible explanations. 33-ER-9449.

As lab director, Das prepared a document—that Holmes approved—called a "Patient Impact Assessment" to respond to CMS. 33-ER-9450-60; *see* 8-ER-1983-2020 (full assessment); 47-ER-13707-08 (admitted portion). The self-assessment found that the Edison had "poor [quality control] performance throughout" and problems across all assays tested over multiple time periods. *Id.* Das told Holmes in 2016 that the problems with Theranos's device identified in the CMS Report were a "representative sample" of the greater number of actual issues. 33-ER-

9449-60, 9479-82; 34-ER-9651-53. Indeed, Das found in his internal review that there were multiple instances where Theranos reported patient results in 2014 and 2015 *after* Theranos's device had failed quality control. 33-ER-9469-83. Similarly, the self-assessment found that the magnitude of the problem with patient results was unknown. *Id.*; *see* 33-ER-9458. Theranos ultimately provided the self-assessment to CMS, but only after Holmes fought to characterize the issues as caused by shoddy lab practices rather than fundamental problems with the Edison device itself. 34-ER-9654-57. Das never recommended to Holmes that patient testing resume on any Theranos-manufactured device because he found the Edison "unsuitable for clinical use." 33-ER-9460, 9485-85.

In March 2016, Theranos voided all 50,000 to 60,000 patient test results from 2014 and 2015 that Theranos's device had produced—an action Das testified was required by federal regulation. 33-ER-9450-60, 9485; 47-ER-13708; *see* 1-ER-222-27.

Despite the internal reality, Holmes continued to obfuscate. She met with RDV in April 2016 and minimized the press coverage and CMS's concerns. 29-ER-8313-20; *see also* 1-SER-85-90. Throughout 2016, Theranos employees came to realize "that the company was [not] capable of standing behind the claims it had been making about the technology [given] the company made several attempts to

prove its technology, but they were all unsuccessful[.]" 28-ER-7915-16; *see* 20-ER-5362.

Theranos shuttered its clinical lab in late 2016, agreed in 2017 not to reopen it for at least two years, and ultimately dissolved as a company in 2018. *See* 1-ER-220-22; 11-ER-2860; 1-SER-240-41.

II. PROCEDURAL BACKGROUND

A. Indictment and Pretrial Proceedings

The Third Superseding Indictment ("TSI") charged Holmes and Balwani with conspiracy to commit wire fraud against investors from 2010 to 2015 (Count 1); six wire fraud counts involving certain "C-1 investors" who invested in December 2013 (Counts 3-5) and "C-2 investors" who invested in 2014 (Counts 6-8); conspiracy to commit wire fraud against patients from 2013 to 2016 (Count 2); and four wire fraud counts involving patients (Counts 9-12). 13-ER-3526-40. The TSI alleged—and the government ultimately proved—that Holmes made misrepresentations to investors about: (A) the capabilities of Theranos's device; (B) Theranos's financial health; (C) technology demonstrations; (D) a purportedly expanding relationship with Walgreens; (E) Theranos's work with the U.S. military; (F) the use of third-party devices to test patients; and (G) pharmaceutical companies' purported validation of Theranos. *Id.*

The district court granted in part Holmes's motion to dismiss aspects of the patient counts, but otherwise denied her nine pretrial motions to dismiss. CR-330, 552. The court granted Balwani's severance motion. CR-977.

Holmes filed over 250 pages of motions *in limine*. *See* 55-ER-15958-61 (docket entries). The court held a three-day hearing and issued a comprehensive 100-page order addressing each. 1-ER-190-289; *see* 9-ER-2346-533; 10-ER-2536-833; 11-ER-2836-54. Holmes renews two on appeal. 1-ER-205-09, 219-27.

Holmes moved to suppress several categories of evidence, alleging that the government failed to preserve a Theranos database—the Laboratory Information System (LIS)—which Holmes claimed contained all Theranos patient test results and quality control data. 1-SER-236-53; *see* 56-ER-16141-58. The grand jury had issued a subpoena to Theranos—while Holmes chaired its board of directors—seeking a functioning copy of the LIS, but the government received an inaccessible copy. *Id.* Theranos decommissioned the LIS four days later, making it impossible to retrieve the original data. *Id.* The court held a hearing and denied the suppression motion, finding that the "exculpatory value [of LIS was] speculative" and "[i]t was the deliberate actions of these third parties"—including Theranos's lawyers—"that resulted in the loss of the LIS database and its contents, not the Government's actions." *Id.*; *see* 13-ER-3541-620. The parties extensively litigated the so-called "missing" LIS database. *See* CR-682, 780, 846, 862, 1181,

1319, 1426, 1432, 1440, 1454, 1457, 1577, 1586, 1592. Holmes ultimately disavowed a trial defense blaming the government for the decommissioned database. 1-SER-2-3; *see* 5-ER-1191 n.3.

Holmes moved to strike the government's allegedly late disclosure of Das as an expert witness and to preclude him from testifying at trial. 9-ER-2236. Holmes filed three additional pretrial motions. CR-895-900. The court held a hearing and denied or deferred ruling on each. 8-ER-2204-12; 13-ER-3443-525.

B. Trial

Beginning on August 31, 2021, Holmes's trial spanned 46 trial days, during which over 900 exhibits were admitted and 32 witnesses testified. Dkt. 27. Holmes testified and called two additional witnesses, including a board member who joined Theranos in 2016 and a summary witness. 38-ER-10757-868. Throughout trial, Holmes lodged a stream of motions raising evidentiary challenges, one of which resulted in the exclusion of testimony by patient-victim B.B. (leading to dismissal of Count 9). *See* CR-1000, 1019, 1023, 1028, 1077, 1086, 1098, 1103, 1116, 1126, 1134, 1140, 1146, 1163, 1165, 1180, 1191. Ultimately, the jury found Holmes guilty of four investor-related counts, including the investor-related conspiracy from 2010 to 2015 (Count 1) and wire fraud relating to investor-victims PFM (Count 6), RDV (Count 7), and Mosley (Count 8). 6-ER-1471-73. The jury did not reach a verdict on the wire fraud

counts related to three C-1 investors (Counts 3-5), and it acquitted on the patient-related counts (Counts 2, 10-12). *Id.*[5]

C. Post-Trial Proceedings

Holmes moved for judgment of acquittal and belatedly filed three motions for a new trial, each of which the district court denied after hearings. 5-ER-1179-254, 1341-45. At sentencing, the district court determined that at least ten investor-victims lost $120,146,247, yielding a U.S. Sentencing Guidelines range of 135 to 168 months of imprisonment, and sentenced Holmes to the low-end. *See* 1-ER-2-166.

SUMMARY OF ARGUMENT

The district court did not abuse its discretion in its evidentiary decisions. First, Holmes challenges three evidentiary rulings that occurred during the direct examination of one witness, Dr. Kingshuk Das, and the nature of his testimony—testimony that spanned three hours out of 46 trial days. AOB-27-53. The court did not err under Federal Rule of Evidence 702 by admitting two pages of the Patient Impact Assessment—an internal document Theranos prepared to respond to CMS—nor by permitting Das to testify about observations he made while running Theranos's lab, preparing the company's response to CMS, and keeping Holmes

[5] Subsequently, Balwani was found guilty on all twelve counts in a comparably lengthy trial and sentenced to 155 months' imprisonment. CR-1507, 1730. The Court denied his motion for bail pending appeal. *See* Dkt. 44-2.

informed of his work in 2016. Das testified as a percipient witness and, regardless, any error was harmless: Das would have qualified as an expert because the government timely disclosed him as a potential expert, Holmes has never challenged his qualifications, and the purportedly "missing" database underlying his "opinions" is a red herring (Das disavowed its significance).

Holmes's other evidentiary challenges respecting Das fare no better. The district court did not err in admitting as relevant and not unduly prejudicial the CMS Report (for a limited purpose) and Theranos's voiding of all Edison tests. Holmes's defense at trial was that she believed Theranos's device worked as promised, even after she had directly been told the contrary by Das, CMS, and others. Because Holmes put her 2016 state of mind at issue, the court properly admitted evidence demonstrating that Holmes knew Theranos's device was not producing accurate patient results—evidence necessary to provide a fully accurate history to the jury. Furthermore, because Theranos was required by regulation both to ameliorate the deficiencies CMS identified and to issue corrected reports of erroneous results, Theranos's decision to void all Edison tests was not a voluntary remedial measure excludable under Federal Rule of Evidence 407.

Second, the district court did not abuse its discretion in limiting, after four days, Holmes's cross-examination of Rosendorff within one narrow and irrelevant area of inquiry regarding his post-Theranos employment.

Third, the court did not abuse its discretion in excluding Balwani's self-serving, non-inculpatory, and uncorroborated hearsay.

Even if the court erred, either individually or cumulatively, any error was harmless given the overwhelming evidence of multiple categories of falsehoods wholly independent of the evidentiary rulings Holmes now challenges, which relate to just two of those categories. Both sides barely referenced in closing argument the evidence Holmes now challenges as erroneously admitted, and—even then—mostly in connection with the patient-related counts of which she was acquitted. Fundamentally, Theranos's device never worked, yet Holmes either entirely fabricated or grossly exaggerated endorsements from pharmaceutical companies, the military, Walgreens, and others in order to deceive and cheat investors. The two witnesses and handful of challenged evidentiary rulings relate to, at most, ancillary points immaterial to the jury's verdict.

Finally, the district court did not err in applying the preponderance of the evidence standard at sentencing for calculating loss, given that Holmes was convicted of a conspiracy that encompassed the relevant conduct. The investor losses charged in the indictment on the counts of conviction alone exceed the loss the court used for sentencing. Regardless, the government could have met its burden under any standard.

ARGUMENT

I. THE DISTRICT COURT PROPERLY ADMITTED EVIDENCE FROM 2016 DURING DAS'S TESTIMONY

A. Standard of Review

This Court reviews challenges to evidentiary rulings, including whether to permit witnesses to testify as lay rather than expert witnesses, for abuse of discretion. *United States v. Perez*, 962 F.3d 420, 434-35 (9th Cir. 2020).[6] A district court abuses its discretion when its decision is "(1) illogical, (2) implausible, or (3) without support in inferences that may be drawn from the facts in the record." *United States v. Hinkson*, 585 F.3d 1247, 1262 (9th Cir. 2009) (*en banc*) (quotation omitted).

This Court reviews unobjected-to trial testimony for plain error. *United States v. Lopez*, 762 F.3d 852, 859 (9th Cir. 2014). Plain error requires: "(1) error; (2) that is plain; (3) that affects substantial rights;" and (4) "seriously affects the fairness, integrity, or public reputation of judicial proceedings[.]" *Perez*, 962 F.3d at 434-35 (quotation omitted).

[6] Holmes asserts *de novo* review applies under *United States v. Durham,* 464 F.3d 976, 981 (9th Cir. 2006), AOB-26, 36, but that runs counter to the general rule that this Court reviews evidentiary rulings for abuse of discretion. *See*, *e.g.*, *United States v. Torres*, 794 F.3d 1053, 1059 (9th Cir. 2015). Regardless, for the reasons that follow, the district court did not err under any standard.

B. The District Court Properly Permitted Das to Testify as a Percipient Witness

Holmes first argues that the district court erred in permitting Das to testify as a percipient witness and provide lay opinions under Federal Rule of Evidence 701. AOB-27-41. She claims that the government was thereby permitted to present untested expert testimony about the Patient Impact Assessment and the limitations of Theranos's device without meeting the prerequisites of Federal Rule of Evidence 702 and Federal Rule of Criminal Procedure 16. *Id.* This argument fails because Das was a percipient witness who described his observations from his 2016 Theranos employment and testified about the information he conveyed to Holmes based on data he had access to while employed at Theranos. Merely because those events involved medical technology does not transform his recollections of what he did and observed into expert testimony. In any event, Das would have been qualified as an expert if necessary, rendering any error harmless under *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246-47 (9th Cir. 1997).

1. Das Testified as a Percipient, Not Expert, Witness

As a threshold matter, the Court should review this claim for plain error because Holmes did not object to Das's statement that he found the Edison "unsuitable for clinical use." 33-ER-9450-60; *see United States v. Gadson*, 763 F.3d 1189, 1206-14 (9th Cir. 2014); *Lopez*, 762 F.3d at 859, 863-66. This was not for lack of opportunity. Holmes repeatedly objected on other topics before and

during Das's testimony under Rule 702, but failed to object to the above statement. *See* 33-ER-9300-48, 9433-50; *see also* 1-ER-220-22; 8-ER-2117-33. Because Holmes did not object to the testimony she now challenges, this Court should review for plain error.

Under Rule 701, a witness not testifying as an expert may offer testimony in the form of an opinion if it is: "(a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Under Rule 702, a "witness who is qualified as an expert by knowledge, skill, experience, training, or education, may testify" if a district court determines his testimony to be "both relevant and reliable." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) (citation omitted).

"[W]hether evidence is more properly offered by an expert or a lay witness depends on the basis of the opinion, not its subject matter." *Perez*, 962 F.3d at 436 (quotation omitted); *see*, *e.g.*, *Lopez*, 762 F.3d at 863-65 (testimony violated Rule 701 because agent did not personally witness deportation); *Durham,* 464 F.3d at 982-83 (witness familiar with marijuana could testify substance appeared to be marijuana). "The gatekeeping inquiry [as to whether opinion is expert or lay] is always case-specific." *United States v. Holguin*, 51 F.4th 841, 857 (9th Cir. 2022).

Rule 701 encompasses the principle that "[a] lay witness's opinion testimony necessarily draws on the witness's own understanding, including a wealth of personal information, experience, and education, that cannot be placed before the jury." *Gadson*, 763 F.3d at 1208. In *Gadson*, this Court "examine[d] the scope of Rule 701" and noted that the promulgators rejected the notion that witnesses should be required "to limit their testimony just to the facts they perceived and avoid opinions or inferences based on those facts"—in part because that distinction "proved to be unworkable in practice." *Id.* at 1206 (quotations omitted). Furthermore, the promulgators rejected the notion that lay opinion would mislead juries given that "the natural characteristics of the adversarial system will generally lead to an acceptable result, and any weaknesses in the lay witness's testimony can be emphasized through cross-examination and argument." *Id.* (quotation omitted).[7]

Here, the "Patient Impact Assessment, and Das'[s] opinions that flowed from it" (AOB-38-39) were not expert testimony. The Patient Impact Assessment was an internal Theranos document that Das prepared and Holmes approved to respond to CMS. 33-ER-9450-60; *see* 8-ER-1983-2020. Holmes acknowledged

[7] Holmes relies on several Second Circuit cases interpreting Rule 701, AOB-38-39, but this Court held in *Gadson* that the Second Circuit is part of a minority of circuits that "construe[s] Rule 701 much more narrowly" than this Court. *Id.* at 1208. Thus, those cases are inapposite.

this during argument below—asserting it was "a compilation of patient impact assessments that are compiled by Theranos with Das's involvement[.]" 33-ER-9339; *see* 34-ER-9543-45, 9575-80, 9658-61. The document itself indicates that it speaks for Theranos: "the laboratory has concluded that there is a possible patient impact for every test reported from [Theranos's device]." 47-ER-13708. Before its finalization, Holmes pushed back on Das's reasoning, claimed that Theranos's device was not the issue, and attempted to sell that narrative to CMS, investors, and the public. 34-ER-9654-57; *see also* 33-ER-9448, 9458-60; 34-ER-9574-75. Holmes helped shape the final document. *Id.*

The Patient Impact Assessment was thus a company-prepared document. Such records, even if they arguably contain expert opinions, may be admitted without expressly meeting the requirements of Rule 702. *SEC v. Jasper*, 678 F.3d 1116, 1124 (9th Cir. 2012) (rejecting challenge under Rules 701 and 702 where company-prepared document was admitted as a business record indicating trustworthiness). This is because the "dangers" of permitting inadmissible hearsay or speculation under the guise of Rule 701 are not present in such scenarios—like this one. *Gadson*, 763 F.3d at 1208-09; *cf. United States v. Lloyd*, 807 F.3d 1128, 1154-55 (9th Cir. 2015) (testimony based on hearsay and speculation violated Rule 701 and should have been presented under Rule 702). The Patient Impact Assessment demonstrated Holmes's knowledge that Theranos's device was not

reliable—Rule 702 has no role in precluding such evidence.

Furthermore, Das testified as a percipient witness and, at most, expressed permissible lay opinions under Rule 701, not expert testimony. The government's direct examination focused on Das's firsthand observations during the job he was hired to do and what he communicated to Holmes in real time (*i.e.*, early 2016). 33-ER-9420-86; 34-ER-9647-57. Holmes hired Das to run the lab, assess the findings in the CMS Report, review Theranos's available information, and report back to her—all of which he did contemporaneously to the charged conduct underlying the patient counts. *Id.*; *see* 11-ER-3055-133; 12-ER-3136-50 (Theranos's response to CMS signed by Das).[8]

In urging otherwise, Holmes categorizes Das's testimony as retrospective and comprehensive (AOB-38-39, 48), but that was what Holmes hired Das to do. And rather than preparing a report in anticipation of litigation, Das prepared the Patient Impact Assessment in 2016 on behalf of Theranos and explained why he ultimately discontinued use of any Theranos-manufactured device for testing patients—because he concluded it was "unsuitable for clinical use." 33-ER-9450-60. This is testimony about what was happening at Theranos in 2016 from someone at Theranos. This is not expert testimony.

[8] The most technical topics Das discussed—such as the six Sigma metric, the Westgard rules, and total allowable error—were all elicited by Holmes during cross-examination. 34-ER-9560-71, 9639.

Holmes chose to commit extensive fraud while running a company that offered blood testing services through its clinical lab. The fact that her company operated in a technical field should not mean that insiders who witnessed the criminal conduct need to qualify as experts before they can testify about what they contemporaneously observed. To hold otherwise would preclude direct contemporaneous observations of criminal conduct absent every insider's qualification under *Daubert*. The rules and cases do not require that result. *See Jasper*, 678 F.3d at 1124 (admission of annual financial statement was not error simply because allegedly expert accounting judgments were involved). Just as a company's top accountant might prepare a spreadsheet to explain the company's dire financial status to executives or take the lead in preparing the company's response to regulators, Das took the lead in responding to CMS and testified about what he contemporaneously found and explained to Holmes in 2016—at the same time Holmes was covering up Theranos's failure.

To the extent any of Das's testimony was lay opinion, it was akin to testimony that this Court has upheld as properly admitted under Rule 701 because it was "predicated upon concrete facts within [his] own observation and recollection." *United States v. Garrido*, 596 F.3d 613, 616-17 (9th Cir. 2010) (quotation omitted) (witness who observed gun could testify without qualifying as weapons expert). For example, a person familiar with a narcotic can testify as a

lay person that a substance appears to be that narcotic. *Durham*, 464 F.3d at 982-83. Similarly, a case agent familiar with an investigation or an organization may help decode recorded conversations—even if he or she was not an original participant on the call. *See Perez*, 962 F.3d at 434-39; *Gadson*, 763 F.3d at 1206-14. The same rationale applies here.

In short, the district court did not err under Rules 701 or 702, let alone abuse its discretion or plainly err, in permitting Das to testify as a percipient witness about the Patient Impact Assessment and to his recollection of events in 2016.

2. Das Could Have Given Expert Testimony at Trial

Holmes's reliance on *Figueroa-Lopez* to argue that Das testified as an expert, AOB-37, ignores the case's actual holding: the error was deemed harmless because the witness could have qualified as an expert. 125 F.3d at 1246-47. The same is true here.[9] Holmes has never challenged Das's expert qualifications. Indeed, Holmes held Das up at trial as an expert whom she had hired to fix problems. At her request, the court admitted Das's resume as of when he was hired at Theranos. 33-ER-9517-24; *see* 33-ER-9406-11; 4-SER-784-91. During closing, she argued that she had learned of the issues with Theranos's device only from the CMS Report and that Das "sound[ed] like a defense witness" given that

[9] For the same reasons described below, Holmes cannot meet plain error's third and fourth prongs. *See Perez*, 962 F.3d at 434-35.

he and others had been "part of a reform effort" with Holmes's support. 44-ER-12789-91. Even if some of Das's testimony strayed into Rule 702 territory, it was harmless because he could have been qualified as an expert.

Trying to avoid this inevitable conclusion, Holmes argues that any Rule 702 testimony would have been inadmissible because of the government's purportedly untimely disclosure of Das and the "missing" data underlying Das's "opinions" from 2016. AOB-40-41. As a threshold matter, this Court need not address either argument unless it finds that some portion of Das's unobjected-to testimony should have been deemed expert testimony *sua sponte* by the district court.

Regardless, both arguments fail. First, the unavailability of the LIS database is not a basis to exclude Das's testimony. Putting aside the "speculative" exculpatory value of the database and the fact that the government did not cause its absence (*see supra* pp.25-26), Das rejected the notion that all data he relied upon in 2016 came from that database. 34-ER-9559-71. Rather, Das relied on multiple sources of information to determine the Edison was unsuitable—most importantly validation reports accessible at trial (and offered for admission by Holmes). *See* 33-ER-9420-21, 9458-59; 34-ER-9559-71; 51-ER-14625-900 (admitted validation reports). Specifically, Das testified that he would not have signed the validation reports permitting patient testing on Theranos's device at all—rendering moot the accessibility of a database to subsequently house those results. 34-ER-9559-71; *cf.*

44-ER-12789–91 (Holmes's closing argument emphasizing discrepancy between Rosendorff's signing validation reports and Das's testimony that he never would have done so).

Moreover, Das explained pretrial that he had left all information from LIS that he used to form his recommendations firmly in Theranos's control when he left the company. 8-ER-2228-29. Holmes failed to show Theranos's available records were an inadequate substitute for LIS. And Holmes challenged Das's observations contemporaneously, as did another former Theranos employee, Daniel Young, whom Holmes chose not to call. 33-ER-9448-60; 34-ER-9574-80, 9654-57.

Second, the government made a timely disclosure of Das in July 2021 pursuant to Rule 16. Rule 16 then required only the proposed witness's qualifications and opinions, and the bases and reasons for those opinions, which this Court recently noted was "not intended to create unreasonable procedural hurdles." *United States v. Alahmedalabdaloklah*, __F.4th__, No. 18-10435, 2023 WL 5082308, at *38 (9th Cir. Aug. 9, 2023) (notice requirement merely provides "fair opportunity" to prepare cross-examination).

Holmes had been aware of the substance of Das's testimony since at least mid-February 2021—more than half a year before trial was set to begin. *Compare* 8-ER-2222-29, *with* CR-727-2, 846-2. The government disclosed him as a

potential witness in June 2021 and as a potential expert in July 2021—more than a month before trial began. 8-ER-2231; *see* 13-ER-3494. The disclosure complied with the parties' agreed-upon deadline for supplemental expert disclosures related to patient-physicians who were expected to testify in a dual role capacity. *See* 1-ER-243-47 (requiring supplemental disclosures); CR-899 at 4 (noting parties agreed upon July 30, 2021, for supplemental expert disclosures). Holmes speculates without basis that the government called Das as an "end-run" around an anticipated *Daubert* hearing for the government's retained expert, Dr. Stephen Master. AOB-30-33, 38. But the government was ready to proceed with Master's *Daubert* hearing on June 30, 2021—it was Holmes who sought additional time. *See* 9-ER-2320, 2252-70.

Furthermore, Holmes cannot point to any prejudice from this timing. *See United States v. Gee*, 695 F.2d 1165, 1169 (9th Cir. 1983) ("The trial court should not impose a sanction harsher than necessary to accomplish the goals of Rule 16."). Within the month between the government's disclosure and trial, Holmes moved to exclude Das's testimony (*see* 9-ER-2236; CR-906), received a hearing on the issue (13-ER-3488-522), and received a pretrial order providing guidance. 1-ER-183-84. During argument, Holmes suggested that approximately 20% of Das's expected testimony could qualify as non-expert testimony—further indicating that she knew the substance of Das's expected testimony for months. *See* 13-ER-3512.

The court deferred ruling and permitted Holmes to object when she thought Das was straying into expert territory. 1-ER-183-84. The court further noted that any prejudice to Holmes from the disclosure's timing could be ameliorated by extending the already-contemplated mid-trial *Daubert* hearing for Master to cover Das. *Id.*; 13-ER-3488-89. Thus, Holmes cannot show any prejudice from the government's disclosure timing even if Das's testimony constituted expert opinion.[10]

C. The District Court Properly Admitted the CMS Report for a Limited Purpose

The district court did not abuse its discretion in admitting approximately 20 pages from the 125-page CMS Report during Das's testimony for the limited purpose of demonstrating Holmes's state of mind regarding Theranos's lab in 2015 and 2016. 1-ER-168-70; 33-ER-9431-49, 9469-84; 47-ER-13683-702; *see also* 11-ER-2931-47 (providing additional background); 1-SER-111-235 (full CMS Report). The evidence was admissible to counter Holmes's evidence and present a full picture to the jury of her state of mind. The admissibility of the CMS Report

[10] The related concerns outlined in *amicus curiae*'s brief, Dkt. 32, are simply not presented here because Das testified as a percipient rather than expert witness, the government did not "ambush" Holmes with the disclosure of Das as a potential expert, and the allegedly "no longer available" data supporting his opinions was destroyed by Holmes's company, not the government.

was extensively briefed below. *See*, *e.g.*, CR-574, 588, 659, 675, 717, 726, 798, 810, 846, 850, 887, 897, 906, 989, 1086, 1133, 1134, 1155, 1191, 1192, 1196.

Holmes's assertion that acts subsequent to charged conduct are irrelevant (AOB-42) runs contrary to well-established law that "acts both prior and subsequent to the indictment period may be probative of the defendant's state of mind." *United States v. Voorhies*, 658 F.2d 710, 715 (9th Cir. 1981). The CMS Report was relevant to the investor-related conspiracy of which Holmes was convicted because she continued to minimize the issues Theranos was facing to lull investors into believing the problems were surmountable. That evidence demonstrated consciousness of guilt: within weeks of Das telling Holmes that Theranos was required to void all Edison tests in response to the CMS Report, Holmes "downplayed what had been happening in the press" to investor-victim RDV and said that "CMS was questioning the process, not the accuracy of the tests." 29-ER-8313-20; *see also* 1-SER-85-90.

Holmes also fails to address that the CMS Report and test voiding were directly relevant to the charged conspiracy to defraud patients from 2013 to 2016 and patient-related counts. *See* 8-ER-2123-30; 37-ER-10485-87 (physician testifying about receiving in 2016 voided results for tests performed in 2015 for patient M.E. (Count 11)); *see also* 19-ER-5124-30 (cross-examining physician about Theranos patient results from October 2015 to October 2016). That Holmes

was ultimately acquitted on those counts does not retroactively make the evidence irrelevant. *See United States v. Holzer*, 840 F.2d 1343, 1349 (7th Cir. 1988) ("No rule of evidence is violated by the admission of evidence concerning a crime of which the defendant is acquitted [assuming counts were not misjoined]."); *see also United States v. Lazarenko*, 564 F.3d 1026, 1044 (9th Cir. 2009) (quoting *Holzer* in analyzing misjoinder).

Moreover, Holmes herself repeatedly introduced her state of mind in 2016 and 2017 as part of her so-called "good faith" defense regarding the capabilities of Theranos's technology. *See* 44-ER-12630-33; *cf.* 8-ER-2124-30. During opening statements, Holmes vividly described packing her car in 2018 and leaving the company she founded 15 years prior—implying that a guilty person would not have stayed with the company—and additionally described her conduct in 2016 after receiving the CMS Report. 16-ER-4246, 4295-99. Early in the trial, Holmes introduced—over objection—peer review articles from 2016 and 2017 and testimony about her convening a "scientific board" with distinguished members in 2016. 19-ER-5344-49; 20-ER-5352-57; 28-ER-7874-77; 33-ER-9531-34. Throughout trial, on cross-examination, Holmes questioned witnesses about her discussion of Theranos's device during the American Association of Clinical Chemistry conference in August 2016. 19-ER-5344-46; 29-ER-8206-08; 30-ER-8441-44; 34-ER-9537-38, 9640-44. Indeed, Holmes called a witness who joined

Theranos in May 2016 for the sole purpose of establishing Holmes's state of mind post-CMS Report. 38-ER-10812-67. Holmes herself testified to events in this time period (40-ER-11443-73) and reiterated these post-2015 events in closing argument. 44-ER-12633, 12647-51, 12789-91. The government's responsive evidence was plainly relevant.

For the same reasons, Holmes's argument that the evidence should have been excluded under Federal Rule of Evidence 403 fails. AOB-43-44. Holmes asserts as "unfair prejudice" that the jury might have improperly convicted her based on regulatory violations. AOB-43. But Holmes successfully advocated for a jury instruction to prevent this very risk. 6-ER-1506; *see United States v. Romero*, 282 F.3d 683, 688 (9th Cir. 2002) ("[A] cautionary instruction to the jury is ordinarily presumed to have cured prejudicial impact."). The risk of prejudice was thus quite low compared to its probative value. Given the extensive briefing and argument on this topic, the district court had ample opportunity to assess the Rule 403 balancing. *See* 1-ER-169, 208. It did not abuse its discretion. *See*, *e.g.*, *Lloyd*, 807 F.3d at 1152 ("A district court's Rule 403 determination is subject to great deference[.]" (quotation omitted)); *United States v. Hankey*, 203 F.3d 1160, 1172 (9th Cir. 2000) (Rule 403 "favors admissibility, while concomitantly providing the means of keeping distracting evidence out of the trial.").

Moreover, while Holmes laments that CMS inspectors did not testify (AOB-43), Holmes's own employee—Das—did testify and confirmed that his observations matched CMS's as described in the CMS Report. *See* 33-ER-9425-48, 9469-86. The district court did not abuse its discretion in admitting the CMS Report for a limited purpose.

D. Theranos's Voiding of Edison Tests Was Properly Admitted

The district court did not abuse its discretion in permitting testimony that Theranos voided all patient blood tests run on its Edison device. Holmes moved *in limine* to exclude this evidence (*see* 12-ER-3367), and the court deferred ruling until the government proffered "evidence that clearly ties the events in 2016 to the charged conduct," and presented "a factual basis for its assertion that Theranos' decision was involuntary for purposes of Rule 407." 1-ER-219-28. Before Das's testimony, the government met this burden. 8-ER-2131-33. After further argument, the court ultimately admitted the evidence. 33-ER-9332-33, 9348, 9450-60. On appeal, Holmes argues that voiding the tests was a remedial measure under Rule 407 and unduly prejudicial under Rule 403. AOB-44-47.

Starting with Rule 403, the probative value of this evidence was not outweighed, let alone substantially outweighed, by the dangers listed in Rule 403. Theranos's voiding had significant probative value as it amounted to Theranos conceding the unreliability of its blood tests despite years of Holmes's misleading

statements to the contrary. The voiding, and Holmes's attempt to minimize its significance and reasons to CMS and RDV, undercut her "good faith" defense, and thus was directly responsive to state-of-mind evidence that Holmes introduced. By contrast, there was minimal danger of unfair prejudice: the voiding was compelled by regulation and Holmes was free to, and did, characterize these efforts as evidence of her attempt in leadership to fix problems. Accordingly, the evidence fit within the district court's expressed Rule 403 calculus that the 2016 events tie to the charged conduct. *See United States v. Wells*, 879 F.3d 900, 924 (9th Cir. 2018) (Rule 403 demands are met if it appears "from the record as a whole" that judge conducted balancing). There was no abuse of discretion. *See Hinkson*, 585 F.3d at 1267.

Next, Holmes urges error under Rule 407. That rule prohibits admission, for certain purposes, of subsequent remedial "measures" voluntarily taken—to encourage voluntary improvement of safety conditions. *See In re Aircrash in Bali, Indonesia*, 871 F.2d 812, 816-17 (9th Cir. 1989). By contrast, "[t]he purpose of Rule 407 is not implicated" if the company "was legally obligated to cooperate with" a governmental or regulatory authority. *Id.*

Here, voiding the Edison tests was not a voluntary remedial measure because it was *required* by regulation, as Das repeatedly testified. 33-ER-9450-51; 34-ER-9559, 9575-82, 9655-57. CMS is authorized by federal statute and

regulations to inspect laboratories testing patients. *See* 42 U.S.C. § 263a(g); 42 C.F.R. §§ 493.1773 *et seq.* (available in trial exhibit 7603 (49-ER-14129-251) admitted at trial (21-ER-5691)). Once CMS finds deficiencies posing immediate jeopardy, federal law requires a company to take corrective action. 42 C.F.R. § 493.1812(a). In addition, when errors in "reported patient test results are detected, the laboratory must" "notify the authorized person ordering the test [and] the individual using the test results of reporting error" and "[i]ssue corrected reports[.]" 42 C.F.R. § 493.1291(k).

CMS inspected Theranos's clinical laboratory and found deficiencies that rose to the level of "immediate jeopardy" to patient health, triggering § 493.1812. 1-SER-111-235. CMS's notice to Theranos "require[d] the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance." *Id.* In pretrial interviews available to the court, Das consistently stated that the regulations required Theranos to cure these deficiencies. 8-ER-2222-24, 2228; 33-ER-9450-51; 1-SER-95. Das testified that the Edison devices were "apparently not performing from the very beginning" and generating "erroneous results" as exemplified by its prostate test. 33-ER-9448-60. He testified that he detected errors in the patient-reported results and was required by § 493.1291(k) to act. 33-ER-9450-51. Theranos determined that "[t]he fraction of patient results truly impacted, and the nature and magnitude of any effect are

unknown," rendering compliance with § 493.1291(k) impossible absent "void[ing] all patient test results reported from [the Edison] instruments." 33-ER-9458; 47-ER-13708. In a subsequent response to CMS, Theranos expressly linked its test voiding to the quality control deficiencies CMS found. *See* 11-ER-3068-69 ("The laboratory values CMS's feedback[.] As corrective action, the laboratory has" "voided results reported for assays run on the [Edison.]").

Holmes claims these regulations did not require Theranos to void "*all* Edison test results." AOB-45-46. Even assuming Holmes's interpretation of regulatory requirements is correct (and Das's was incorrect), the policy behind Rule 407 is not meant to exclude evidence of steps that, while not directly compelled by government regulators, were undertaken to comply with a regulatory regime. *See* 23 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 5283 (2d ed. Apr. 2023) ("The clear majority of the cases conclude that Rule 407 does not apply to conduct required by a government agency.") (collecting cases); *see also United States v. Pac. Gas & Elec.*, 178 F. Supp. 3d 927, 952–53 (N.D. Cal. 2016) (upholding admissibility of corrective action where regulatory agency "was heavily involved" in directing aftermath of accident). Indeed, Holmes elicited on cross-examination that "[t]here was no disagreement about voiding" among all involved, including Theranos lawyers, Das and other clinical consultants, and Holmes herself—the only disagreement surrounded the

root cause. 34-ER-9543-45, 9575-82, 9658-61. CMS scrutiny and the regulations compelled Theranos to act, but, in any event, it is manifest everyone in the moment believed they were compelled to do so—and thus the policy behind Rule 407 is not implicated.

Das's testimony and the regulations support the conclusion that Theranos's decision to void all Edison tests was in direct response to the CMS Report, required by regulation, and not a voluntary remedial measure for purposes of Rule 407.[11] The district court did not abuse its discretion.

E. Any Error Was Harmless

Evidentiary errors are harmless if "it is more probable than not that the erroneous admission of the evidence did not affect the jury's verdict." *United States v. Charley*, 1 F.4th 637, 651 (9th Cir. 2021) (quotation omitted); *see also Perez*, 962 F.3d at 435 (similar standard for admitting lay rather than expert testimony). Even if this Court identifies error in any of the above, such errors were harmless because of the overwhelming evidence of Holmes's guilt from numerous sources compared to the limited scope of Das's testimony.

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[11] Regardless, Theranos's internal analysis leading to the voiding—such as the Patient Impact Assessment—would not be protected under Rule 407. *See*, *e.g.*, *Aguilar v. City of Los Angeles*, 853 F. App'x 92, 95 (9th Cir. 2021); *accord 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.").

The government called Das as its twenty-third witness, and he testified for less than three hours on direct examination out of 46 total trial days. 33-ER-9406-86. Holmes herself, AOB-49-50, can only point to eight passing references to the allegedly erroneous 2016 evidence beyond Das's testimony. During closing argument, other than describing him as a government witness (43-ER-12510-11), the government only referenced Das and Theranos's decision to void all Edison test results when arguing in support of the patient-related counts, on which Holmes was acquitted. *See* 44-ER-12574-79. The government did not reference the substance of the CMS Report in its closing arguments at all. *See* 43-ER-12486-530; 44-ER-12533-609, 12817-30; 45-ER-12833-904.

Contrary to Holmes's claim, AOB-53, this was not a close case. Thirty-two witnesses testified, including Holmes herself, and not a single witness claimed that Theranos's device ever tested more than 12 assays. Not a single witness ever testified that the minilab or 4.0 worked such that it could be used to test patients. Das was one among several witnesses who testified to the inability of Theranos's device to provide accurate and reliable results. *See*, *e.g.*, 17-ER-4479-540, 4648-72 (Cheung); 18-ER-4879-916 (Gangakhedkar); 20-ER-5404-530 (Rosendorff); 38-ER-10855-66 (Bonnani). Even insiders without scientific backgrounds eventually realized that the device could not deliver as promised. *See*, *e.g.*, 20-ER-5362 (Mattis); 28-ER-7915-16 (Edlin). Notably, Das did not testify in Balwani's

trial, and yet Balwani was convicted on all counts. *See* CR-1507, 1562.

Furthermore, the above-challenged evidence relates to only one of several categories of misrepresentations Holmes made to investors. For example, the following lies would be wholly unaffected by any error Holmes alleges:

- Investors repeatedly testified that they would have been shocked to learn Theranos was using third-party machines—not Theranos's device—to run patient tests. *See supra* pp.13-17.

- Holmes repeatedly sent reports to investors purporting to validate Theranos's device on which she emblazoned logos of large pharmaceutical companies—without those companies' authorization. *See supra* pp.5-8. Holmes admitted to adding the logos and enhancing the conclusions shortly before she sent the reports to Walgreens in 2010. 41-ER-11703-37.

- In 2013 and 2014, Holmes repeatedly told investors that the military was using Theranos's device on medevac helicopters, in the battlefield, and to treat soldiers in Afghanistan and Iraq. *See supra* pp.8-9. These statements were flatly untrue. *Id.*

- Holmes told PFM in December 2013 that Theranos had historically earned over $200 million from its work with the military and pharmaceutical companies, when Theranos had never earned more than $10 million from both combined. *See supra* pp.9-10.

- In August 2013, Holmes misled Walgreens executives by indicating their blood was tested on Theranos's device, when in reality it was tested on a third-party machine. *See supra* p.13.

- In August 2014, Holmes knew Walgreens would not expand further beyond the few stores within which Theranos already operated unless venous draws were significantly reduced. 4-SER-773. Yet, two months later, Holmes told RDV that Theranos expected to provide testing services within 900 Walgreens locations by 2015. 29-ER-8262-65, 8291.

PFM, RDV, and Mosley found the above misrepresentations material to their decisions to invest. *See*, *e.g.*, 29-ER-8258-308 (RDV); 31-ER-8709-51 (Mosley); 35-ER-10014-74 (PFM).

At most, this case is like *United States v. Cardenas-Mendoza*, 579 F.3d 1024, 1032-33 (9th Cir. 2009), where the Court found a witness's testimony and evidentiary errors harmless where it "played only a small part in the government's case," and other evidence proved the same elements of conviction. This, in turn, distinguishes the two unpublished cases Holmes cites, which held improper lay rather than expert testimony was not harmless. AOB-37-38.

In contending otherwise, Holmes attempts to lump together all false statements she made to investors. AOB-51-53. While Holmes partially quotes the government's closing argument (AOB-52), the full quote ties the capabilities of

Theranos's device as the underlying theme between the two fraud schemes—while stating that it was not the only misrepresentation made to investors. 44-ER-12538. Similarly, for Walgreens, the government argued that the technology's failure was an *alternative* reason Holmes knew that what she said to investors was false. 43-ER-12497-98; 44-ER-12544. Finally, Holmes claims that the government confuses the harmless error standard with sufficiency of the evidence (AOB-51-53, 75-76)—but the opposite is true. The government has consistently argued that any one category of misrepresentations could be sufficient to uphold the jury's verdict on the investor-related counts, but no one category by itself was necessary to do so. 3-ER-578-81.

In any multi-month trial "involving dozens of witnesses and hundreds of exhibits, there is likely to be some evidentiary error"—but that does not end the Court's inquiry. *United States v. Mikhel*, 889 F.3d 1003, 1049 (9th Cir. 2018) (finding evidentiary error harmless). Here, even if the court erred in one of hundreds of evidentiary rulings it made over the months-long trial, overwhelming evidence supported Holmes's convictions, and thus any error in admitting Das's testimony, the Patient Impact Assessment, the CMS Report, or voiding-related evidence was harmless.

II. THE DISTRICT COURT DID NOT ERR IN LIMITING ROSENDORFF'S CROSS-EXAMINATION

A. Standard of Review

District courts "retain wide latitude" in limiting cross-examination, and this Court reviews such limitations for abuse of discretion where, as here, the defendant challenges a "limitation on the scope of cross-examination within an area of inquiry[.]" *United States v. Larson*, 495 F.3d 1094, 1100-02 (9th Cir. 2007) (*en banc*). Holmes asserts that *de novo* review applies. AOB-26, 65. Regardless, this Court should affirm under either standard.

B. Rosendorff's Testimony

Rosendorff testified for approximately two trial days on direct examination, and Holmes's cross-examination spanned four trial days—longer than any other cross-examination. *See* 20-ER-5388-649; 21-ER-5668-948; 22-ER-5951-6000, 6126-247; 23-ER-6250-518; 24-ER-6554-686. During direct, Rosendorff described how, as Theranos's laboratory director in the first year after the Walgreens launch, he witnessed the severe limitations of Theranos's device. *See* 20-ER-5404-649. Rosendorff warned Holmes that he "didn't feel [proprietary tests] were ready for launch." 20-ER-5411-35. Nevertheless, throughout the following year, Holmes and Balwani constantly pushed for Theranos's device to be used to test patients—even without adequate internal controls—while Rosendorff observed the third-party, FDA-approved machines consistently performed in a

superior manner to Theranos's device. 20-ER-5457-78, 5515-30, 5612-20. Rosendorff expressed increasing dismay at the "number and severity of issues" and "high frequency of doctor complaints." 20-ER-5642; *see*, *e.g.*, 47-ER-13662-81, 13703-06; 48-ER-13757-60; 2-SER-385-95, 426-35. He ultimately resigned in November 2014 as a result. 20-ER-5405, 5642-49; 21-ER-5652-63; 23-ER-6480.

Over four days of cross-examination, Holmes challenged Rosendorff on a host of topics, including attacking his purported bias in favor of the government and alleged incompetence as a lab director. 21-ER-5668-77, 5738-44, 5771-78, 5828-36, 5866-72; 22-ER-5965-69, 6173, 6185-224; 23-ER-6337-71, 6441-51. Using two binders of Rosendorff's prior testimony from various civil lawsuits and before the grand jury, and reports from his prior meetings with the government, Holmes repeatedly attempted to impeach Rosendorff. 21-ER-5667, 5679-96, 5723-39; 22-ER-5965-81, 6186, 6272-74; 23-ER-6389-440.

One consistent topic was that Rosendorff would not have permitted testing real patient samples on Theranos's device if he "thought the assay was inherently unreliable" or likely to produce inaccurate patient results. 21-ER-5924; *see*, *e.g.*, 21-ER-5741-44, 5773-802, 5894-96 (admitting dozens of validation reports via stipulation at 8-ER-2189), 5896-933; 22-ER-6167-73; 23-ER-6368-71. Holmes admitted more than 100 pages of federal regulations governing clinical laboratories and questioned Rosendorff about his familiarity with them. *See*, *e.g.*, 21-ER-5689-

710, 5740-55, 5828, 5859-61; 23-ER-6279-80. Holmes repeatedly insisted that Rosendorff was ultimately responsible for test results provided to patients according to those regulations, and thus Holmes could not have acted with the intent to defraud. *Id.*

Holmes also sought to contradict Rosendorff's testimony regarding the Walgreens launch (21-ER-5677, 5710-40, 5782-83; 23-ER-6367), response to physician inquiries (22-ER-6185-224; 23-ER-6276-85), interactions with regulators at Theranos (21-ER-5819-56), proficiency testing (22-ER-5964-99, 6131-52, 6174-85), and specific assays (22-ER-6152-73, 6224-47; 23-ER-6250-69, 6338-407). Holmes also focused on the fall of 2014 and, while Rosendorff testified that he was "becoming frustrated at [his] inability to explain discrepant results" to physicians, Holmes painted Rosendorff as checked out, unwilling to answer physician phone calls, and interviewing and applying for his next position with "a foot out the door the whole time." 22-ER-6185-224; 23-ER-6412-51.

At the end of four days of cross-examination, Holmes sought to further explore whether Rosendorff was purportedly an incompetent laboratory director by questioning him about three of his post-Theranos jobs. 23-ER-6295-325, 6451-63; *see also* 21-ER-5803-11. The court permitted limited inquiry, and Holmes continued cross-examination. *See* 23-ER-6464-68. Holmes also continued to challenge Rosendorff's testimony post-trial. *See* 5-ER-1179-254.

C. Rosendorff's Post-Theranos Employment

After leaving Theranos, Rosendorff worked at several biotechnology companies, some of which had faced scrutiny from government entities. *See* 8-ER-2175 (Rosendorff's resume). Holmes and Balwani each sought to impugn Rosendorff's credibility with this subsequent work history. *See* CR-1405.

First, from January 2015 until September 2017, Rosendorff worked as a lab director at Invitae, which announced in September 2017 that it would retest 50,000 samples for a rare genetic mutation, estimating that a testing error might have generated false negative results for 2 to 15 patients. 23-ER-6311-12. There was no evidence of regulatory intervention—merely an article describing Invitae's decision. *Id.*; *see* 8-ER-2161-67 (article).

Second, Rosendorff was employed as uBiome's laboratory director for a few months in 2016, but was absent for a substantial portion of that time due to a medical issue. 23-ER-6312-14, 6319-20. He estimated that he was only onsite approximately six times total. *Id.*; 56-ER-16051. Subsequently, in March 2021, a federal grand jury returned an indictment against the two co-CEOs of uBiome with charges related to fraudulent healthcare billing and reimbursement practices. 1-SER-20-25. There is no indication that Rosendorff knew about the fraudulent billing practices in his laboratory role—indeed, the co-CEOs had reason to conceal this practice from Rosendorff given it had caused the prior lab director to quit. 23-

ER-6312-14. Furthermore, as the government represented below, Rosendorff was never a target of the uBiome investigation, and the two former co-CEOs of uBiome were the only individuals charged. *Id.*

Third, from January 2021 through mid-2022, Rosendorff worked as a laboratory director at a PerkinElmer branch lab, which was operated in partnership with the California Department of Public Health ("CDPH Branch Lab"), providing COVID-19 testing services. 23-ER-6277, 6314. During a routine CMS inspection, CMS alerted the CDPH Branch Lab to certain deficiencies. 8-ER-2135-59. One possible outcome was a sanction that could have involved Rosendorff's professional license. 23-ER-6464-67. Within months, CMS declined to impose any sanctions after finding that the CDPH Branch Lab had corrected the identified deficiencies. 1-SER-4-19.

Holmes sought to question Rosendorff on these three post-Theranos employments—claiming they were relevant to show his bias under *United States v. Abel*, 469 U.S. 45 (1984). 23-ER-6295-326. The court partially granted the request: it prohibited Holmes from questioning Rosendorff about his employment at uBiome and Invitae but permitted limited inquiry about his then-current role at PerkinElmer, in part because the same CMS employees were involved. 21-ER-5803-11; 23-ER-6295-326, 6451-63. In doing so, the court reasoned that Holmes sought to introduce "inappropriate character evidence"—attempting to discredit

Rosendorff as an incompetent lab director—that was cumulative and more prejudicial than probative under Rule 403. *Id.* The court also referenced Rule 608 and its purpose of "avoid[ing] mini trials," and found that the proposed cross-examination would be cumulative. *Id.*

As the court reiterated in denying Holmes bail pending appeal, Holmes "fully availed herself of the right to confront Rosendorff, who was cross examined over four days of trial." 55-ER-15893-94.

D. The District Court Did Not Abuse Its Discretion by Limiting Cross-Examination of Rosendorff After Four Days

The court did not err, let alone abuse its discretion, in limiting Holmes's cross-examination of Rosendorff after four days and with respect to irrelevant topics. A district court "has considerable discretion in restricting cross-examination." *United States v. Shih*, 73 F.4th 1077, 1095 (9th Cir. 2023). The court may impose reasonable limits "to avoid extensive and time-wasting exploration of collateral matters." *Id.*; *see also Larson*, 495 F.3d at 1101-02. "[T]he Confrontation Clause guarantees an *opportunity* for effective cross-examination, not cross-examination that is effective in whatever way, and to whatever extent, the defense might wish." *Delaware v. Van Arsdall*, 475 U.S. 673, 679 (1986) (quotation omitted). This Court has "identified three factors" to determine "whether a defendant's Confrontation Clause right to cross-examination was violated[,]" namely, whether: (1) "the excluded evidence was relevant,"

(2) "there were other legitimate interests outweighing the defendant's interest in presenting the evidence," and (3) "the exclusion of evidence left the jury with sufficient information to assess the credibility of the witness." *Larson*, 495 F.3d at 1103 (quotation omitted).

Here, Holmes fails all three factors. First, Rosendorff's post-Theranos employment was irrelevant to his observations at Theranos and to the charges. Indeed, Holmes successfully asserted at trial that witness Erika Cheung's post-Theranos employment was "totally irrelevant," and prevented her from testifying on that topic. 17-ER-4677-81; 20-ER-5392-95. Perhaps recognizing this inconsistency, Holmes's main argument below for admitting Rosendorff's post-Theranos employment was his purported bias, citing *Abel*. *See* 23-ER-6295-326. Yet on appeal, Holmes does not cite *Abel* and references bias only in passing—and only with respect to uBiome and PerkinElmer, not Invitae—arguing instead solely that the topics were relevant to undermine Rosendorff's testimony. AOB-59-62.

Holmes argues that she needed to cross-examine Rosendorff on his post-Theranos employment to rebut testimony about his pre-Theranos work at the University of Pittsburgh. *See* AOB-55, 58. But Holmes had the opportunity to cross-examine Rosendorff with respect to the comparison she emphasizes—his previous employer—and even impeached Rosendorff on this topic. 23-ER-6389-94. Moreover, comparing errors at non-Theranos labs—as Holmes asserts made

the Invitae topic relevant (AOB-56, 60, 63)—was accomplished through questioning about the University of Pittsburgh (23-ER-6389-94) and would have been cumulative.

Holmes also claims that the additional cross-examination was necessary because the government "opened the door" on redirect (AOB-62), but the district court struck the government's question and the response and instructed the jury not to consider it. 24-ER-6616, 6639-40. Jurors are presumed to follow such instructions. *See United States v. Saelee*, 51 F.4th 327, 345 (9th Cir. 2022).

Second, the court properly found that other legitimate interests outweighed Holmes's. *See Larson*, 495 F.3d at 1103. The court specifically cited Rules 403 and 608(b), noting that this was inappropriate character evidence and that opening the door would lead to mini-trials (in an already lengthy trial) with diminishing returns. 21-ER-5803-11; 23-ER-6295-326, 6451-63; *see*, *e.g.*, *United States v. Bowen*, No. 22-10115, 2023 WL 3300518, at *1 (9th Cir. May 8, 2023) (affirming exclusion of impeachment evidence under Rules 403 and 608(b) that was irrelevant and cumulative). District courts enjoy broad discretion when excluding evidence after balancing interests under Rule 403. *See Sprint/United Mgmt. Co. v. Mendelsohn*, 552 U.S. 379, 384 (2008) ("In deference to a district court's familiarity with the details of the case and its greater experience in evidentiary matters, courts of appeals afford broad discretion to a district court's evidentiary

rulings"—particularly "with respect to Rule 403"). Holmes's desire to redo that balancing, AOB-64-65, fails in the face of this requisite deference.

Third, Holmes cross-examined Rosendorff for four trial days and exhaustively explored his purported bias and alleged incompetence. *See supra* Section II.B. The jury had more than sufficient information to assess his credibility. *See Larson*, 495 F.3d at 1103. The court acted well within its discretion under Rules 403 and 608 to prevent mini-trials, exclude inappropriate character evidence, and avoid cumulative evidence with marginal relevance.

Nor was this post-Theranos evidence important to demonstrate Rosendorff's bias. *Contra* AOB-62-64. "The point of a bias inquiry is to expose to the jury the witness' special motive to lie by revealing facts such as interest in the outcome of the trial or personal animosity or favoritism toward the defendant" or prosecution. *Hankey*, 203 F.3d at 1171 (citations omitted); *see also United States v. Adamson*, 291 F.3d 606, 609-14 (9th Cir. 2002). Holmes has not shown—and cannot show—that subsequent investigations of companies where Rosendorff worked provided a motive for Rosendorff to lie. Her proffered reasons do not logically connect to bias. For the uBiome investigation, the government never considered Rosendorff a target, meaning at most any questioning would be to improperly imply guilt by association. *See*, *e.g.*, *United States v. Dickens*, 775 F.2d 1056, 1058 (9th Cir. 1985) ("Evidence of association with others" engaged in criminal activity "did not

bear on [witness's] truthfulness."). And, while PerkinElmer is the one company where Rosendorff may have faced personal, governmental reprimand, that is the very topic on which the district court permitted inquiry. 23-ER-6464-67; *see also Shih*, 73 F.4th at 1095 (holding that additional testimony on a topic explored in cross-examination "was unlikely to affect the verdict" and thus was harmless).

Tellingly, both of the investigations that Holmes references began in 2021—*after* Rosendorff had already given prior consistent statements to the government and under oath regarding his observations while at Theranos. *Compare* 1-SER-20-25 (uBiome indictment March 2021), 15 (CMS sent findings to CDPH Branch Lab in February 2021), *with*, *e.g.*, 21-ER-5681 (describing civil deposition in February 2019). This timeline cuts strongly against any purported motive to slant Rosendorff's testimony favorably for the prosecution. The court did not abuse its discretion in limiting cumulative further inquiry.

E. Any Error Was Harmless

Any error in a modest limitation on one line of inquiry on Rosendorff's purported bias based on his post-Theranos employment was harmless. Holmes's desired topics would do nothing to undercut Rosendorff's testimony relating to his time working at Theranos—nor the corroborating contemporaneous documentary evidence admitted as exhibits. *See supra* Section II.B. At most, Holmes is claiming that subsequent investigations—unrelated to Theranos, unrelated to

Rosendorff, and unrelated to the prior consistent statements he had already made—should be permitted to attack his character as incompetent. Despite her emphasis on appeal regarding the centrality of this cross-examination, Holmes was permitted to question Rosendorff about his subsequent employment at PerkinElmer—and yet it accounted for one sentence out of her multi-hour closing argument. *Cf.* 44-ER-12768-86 (describing points jury should glean from Rosendorff's cross-examination).

Furthermore, Rosendorff was but one of several witnesses that testified to the problems with Theranos's device. *See* 17-ER-4479-81, 4531-536, 4648-62 (Cheung describing Edison's constant quality control failures); 18-ER-4879-83, 4910-16 (Gangakhedkar observing consistent problems with multiple iterations of Theranos's device leading up to Walgreens launch). Cheung also testified that Theranos did the vast majority of its patient testing on unmodified third-party machines. 17-ER-4490-504. None of this testimony would have been undermined even if Holmes had been permitted to cross-examine Rosendorff to the extent she requested.

Finally, as described above, Holmes's misrepresentations about Theranos's device was only one of several misrepresentations she made to investors—the remainder of which remain unaffected even if the Court identified error here. This led the district court to find that "[t]estimony and evidence pertaining to

Theranos's lab conditions" "are substantially attenuated from [] Holmes's varied misrepresentations to Theranos investors, *e.g.*, regarding the companies' [sic] external relationships with pharmaceutical companies or Walgreens." 55-ER-15893. Any error in the court's modest limitation of one line of inquiry was thus harmless.

III. THE DISTRICT COURT PROPERLY EXCLUDED CO-DEFENDANT'S PRIOR TESTIMONY AS HEARSAY

A. Standard of Review

"Orders to exclude evidence are reviewed for abuse of discretion" and subject to harmless error review. *United States v. Pineda-Doval*, 614 F.3d 1019, 1031-32 (9th Cir. 2010). "A conviction may be reversed on the basis of an incorrect evidentiary ruling only if the error more likely than not affected the verdict." *Id.* (quotation omitted).

B. The District Court Did Not Abuse Its Discretion by Excluding Balwani's Uncorroborated and Self-Serving Prior Testimony

The court did not abuse its discretion by excluding as hearsay Balwani's prior testimony before the Securities and Exchange Commission ("SEC") as outside the exception in Federal Rule of Evidence 804(b)(3). 1-ER-171-80.[12] Under Rule 804(b)(3), the proponent must show that (1) the declarant is

[12] Holmes abandons on appeal her alternative argument that the testimony was admissible under Rule 804(b)(1). AOB-69 n.10.

unavailable, (2) the statement tended to subject the declarant to criminal liability such that a reasonable person would not have made the statement unless he believed it to be true, and (3) corroborating evidence supports the statement's trustworthiness. *United States v. Paguio*, 114 F.3d 928, 932 (9th Cir. 1997). Balwani was unavailable after invoking his Fifth Amendment right not to testify. 1-ER-171-80. The court properly held that Holmes could not demonstrate the remaining two requirements. *Id.*

1. Balwani's Prior Statements Were Not Self-Inculpatory

It is well-established—and uncontested here—that this hearsay exception requires "truly self-inculpatory" statements that are "sufficiently against the declarant's penal interest that a reasonable person in the declarant's position would not have made the statement unless believing it to be true[.]" *Williamson v. United States*, 512 U.S. 594, 599, 603-04 (1994); *see* 1-ER-177; AOB-70-71. "Statements that curry favor or deflect (or share) blame do not fall within the scope of Rule 804(b)(3)(A)." *Gadson*, 763 F.3d at 1200 (citation omitted); *accord Williamson*, 512 U.S. at 603.

Balwani's statements were not truly self-inculpatory because they did not tend to expose him to liability. In August 2017, Balwani, represented by counsel, testified in an SEC investigation regarding Theranos. 1-ER-172. Holmes sought to admit four categories of Balwani's prior SEC testimony below (*id.*), but only

challenges one on appeal—the court's exclusion of seven pages of transcript from that testimony related to Theranos's financial model. AOB-67-76; *see* 6-ER-1616-19, 1625-27. Balwani testified that:

- Danise Yam "was in charge of all the financials," and while he "knew about the finances" because he had loaned money to Theranos, Yam provided Balwani with updates on the company's cash position (6-ER-1625);
- Balwani built a financial model—not projections—starting in 2010 with Safeway and Walgreens that Balwani "owned" until he left Theranos; Balwani subsequently clarified that he built the model "over time" with "input from a lot of people" (6-ER-1616-18, 1625-26); and
- the financial model—rather than balance sheets—was shown to the company's board of directors (6-ER-1626-27).

When the SEC asked Balwani who had labeled the model as "projections" at the top, Balwani deflected by pointing to Yam and a potential October 2014 investor (BDT). 6-ER-1616-18; *see* 46-ER-13157 ("Projected Statement of Income"). When the SEC asked about Holmes's involvement, Balwani also deflected blame away from her. 6-ER-1619.

The court did not abuse its discretion in holding that "it is unclear how the identified statements expose [] Balwani to civil or criminal liability." 1-ER-172. In urging this was error, Holmes details the scrutiny that Theranos faced from

government entities and concludes that "any reasonable person in Balwani's shoes would appreciate that Theranos'[s] financial *projections* were in the grand jury's and SEC's crosshairs." AOB-72 (emphasis added). But, as the district court identified: Balwani never admitted to creating or sharing the *projections* with investors, only to creating a financial model for Theranos with input from many sources. 6-ER-1616-19, 1625-27. Indeed, when the SEC asked questions about the *projections* shared with investors, Balwani corrected the SEC and spoke only of the "model." *Id.* As the court observed, it "is not a crime" "to take ownership over the creation of a financial model" as Balwani admitted—it can be a crime to make material misrepresentations with the intent to deceive and cheat, but Balwani denied he did that. 1-ER-179-80.

Similar statements are routinely excluded as insufficiently inculpatory. *See*, *e.g.*, *United States v. Lynch*, 903 F.3d 1061, 1071-73 (9th Cir. 2018); *Gadson*, 763 F.3d at 1200; *United States v. Shryock*, 342 F.3d 948, 981-82 (9th Cir. 2003). In *Shryock*, a defendant charged with murder and attempted murder sought to admit his co-defendant's statement that the co-defendant had shot one of the victims in self-defense. 342 F.3d at 981-82. The district court excluded it, and this Court affirmed, noting that the co-defendant's statement could "absolve him of criminal liability" and thus was "not against his penal interest." *Id.* Similarly, in *Lynch*, the district court excluded a statement that another witness made that the defendant did

not know anything about the deal at issue. 903 F.3d at 1071-73. This Court upheld that exclusion because "that another person does not know about a crime[] hardly inculpates the declarer" and thus was not against penal interest. *Id.*; *cf.* *Paguio*, 114 F.3d at 929-34 (father was "accept[ing] undiluted responsibility" rather than his son and was not "fingering someone else").

Here, Balwani never took ownership of the financial projections or even sole responsibility for providing them to investors. Indeed, one would expect that if these portions of Balwani's statements were self-inculpatory, the government would have admitted them at Balwani's trial. It did not. *See* CR-1562 (final admitted exhibit list). That is because whenever it came to the allegedly "critical" topic in the "crosshairs" of the SEC's investigation—the financial projections—Balwani deflected blame onto others, such as Yam or BDT. *See* 6-ER-1616-18. "[A] statement [] collateral to a self-inculpatory statement says nothing at all about the collateral statement's reliability" and "[is] generally excluded." *Williamson*, 512 U.S. at 600. Owning a financial model is at best a collateral statement to who labeled the model as financial projections—the question on which Balwani deflected blame.

Holmes also takes umbrage with the exclusion of the statements that deflected blame from her. AOB-69-73; *see* 6-ER-1619. But, here, the Court's precedent in *Gadson* is instructive: the Court held that a declarant's prior

statements that tended to help the defendant were not self-inculpatory with respect to the declarant. 763 F.3d at 1200; *see also Lynch*, 903 F.3d at 1071-73. So too here. Balwani claimed that he shared the financial model with Holmes, but that she did not edit it. 6-ER-1619. Even if credited, these statements do not inculpate anyone regarding the provision of misleading financial projections to investors.

2. Balwani's Prior Statements Lack Trustworthiness

The court also did not abuse its discretion in holding that these statements lacked corroborating circumstances that supported their trustworthiness. 1-ER-180. The statements that Holmes asserts are "critical"—those stating she herself never made edits to this financial model (AOB-73-74)—are the most lacking in trustworthiness.

Initially, Balwani's prior statement is itself contradictory; he described sharing the model with Holmes and asking her questions. 1-ER-180. He even "put a model with her name on it so she could edit"—but then claimed that he "never even looked at that model." 6-ER-1619. Holmes dismisses this ambiguity (AOB-74), but this Court has held that it "is vital" that "a reasonable person in the declarant's position would not have made [the statement] unless it were true," and there is no such assurance here. *United States v. Magana-Olvera*, 917 F.2d 401, 407 (9th Cir. 1990) (quotation omitted). In addition, "a codefendant's statements about what the defendant said or did are less credible than ordinary hearsay

evidence." *Williamson*, 512 U.S. at 601. This is particularly true here, where Balwani was deflecting blame from his long-time romantic partner and co-conspirator.

Moreover, the record simply does not support Balwani's statement. 1-ER-180. Holmes focuses on one text message where Holmes texted Balwani in May 2012 that they needed to "work together on the rev piece," and Holmes testified that she might have meant revenue. AOB-73-74 (citing 1-ER-180); 4-SER-640. But that one message was not in isolation. For example, in May 2012, Holmes and Balwani also discussed "later in [the] year once we get revenue flowing in[.]" 4-SER-643-53. In April 2013, they discussed "the model" showing Theranos "can make $20M in 3-6 months from just 15 sites," and, by November 2013, Holmes promised that she would "get [] comfortable" with "financial models" while Balwani was abroad. *Id.* Balwani also stated that he would only be "ok with [sharing] projections but not financials" with a potential investor. *Id.* The court's decision to exclude Balwani's prior uncorroborated statements was not illogical, implausible, or without support in the record.

Finally, the district court did not rule on the government's alternative argument that "[a] motive of love" might be a reason to lie that "cuts against the trustworthiness" typically inherent in Rule 804(b)(3) statements. *Paguio*, 114 F.3d at 933; *see Gadson*, 763 F.3d at 1200. Here, Balwani made the statements before

the SEC approximately one year after his 12-year romantic relationship with Holmes had ended. CR-1166 at 3-4. Balwani continued to express feelings of love and support toward Holmes up through June 2016 even after she had asked him to leave the company (and had moved out of their shared residence). 1-SER-101-09; *see* 40-ER-11440-43.

C. Any Error Was Harmless

Any error in excluding Balwani's self-serving, non-inculpatory, and uncorroborated SEC testimony was harmless given it was not contested at trial that Balwani largely handled the finances at Theranos. *See* AOB-74. Holmes testified that Balwani prepared the financial model and financial projections that were provided to investors and Theranos's board of directors. 39-ER-11217-26. Both parties made nearly identical points during their closing arguments. *Compare* 43-ER-12520-22 (government stating "Balwani handled the finances . . . more than [] Holmes at Theranos" as part of his "active role in the conspiracy"), *with* 44-ER-12763-64 (Holmes stating projections were based on "a model that [] Balwani prepared and controlled" and "in terms of preparing these financial projections, this was not [] Holmes's province. This was work that was done by [] Balwani."). There was no dispute that Balwani played the larger role in that aspect of the conspiracy. These seven pages of transcript would not have altered the trial outcome.

Moreover, Holmes repeatedly provided false or substantially inflated projections (and even historical revenue) to investors for years, despite receiving weekly updates on Theranos's nominal finances from the company's controller. *See supra* pp.5-6, 9-10; *see also* 4-SER-636-68, 701 (messages between Holmes and Balwani about needing to "get revenue flowing in" and Theranos's cash position). Regardless of who created, edited, and owned the financial model, Holmes knowingly "represented to investors that Theranos was presently a financially strong and stable company" when, "in truth, [she] knew that Theranos had and would generate only modest revenues, roughly a few hundred thousand dollars or so, in 2014 and 2015[.]" 13-ER-3530.

Holmes's continued response to this unassailable evidence is that Theranos's deferred revenue could account for her purported belief that the projections were attainable. AOB-68; 39-ER-11217-26; 44-ER-12760-64. But the sources of deferred revenue still did not match the detailed breakdown of sources of projected revenue that Holmes and Balwani provided to investors in 2014 and 2015. *Compare* 4-SER-792 (only $3 million of deferred revenue from pharma), *and* 16-ER-4396-404 (no pharma revenue after 2010), *with* 35-ER-10081 (projecting $30 million 2014 revenue from pharma in January 2014), *and* 46-ER-13157

(projecting $40 million 2014 revenue from pharma in October 2014).[13] The jury clearly rejected Holmes's argument.

In sum, Balwani's SEC testimony would not be any more persuasive than the evidence Holmes already presented on this misrepresentation—which was itself only one category among several—and thus any error was harmless.

* * *

Contrary to Holmes's assertion (AOB-76), there was no cumulative error where "many of [her] alleged errors are not errors at all[,]" and she has "not established that any errors made h[er] defense far less persuasive than it might otherwise have been." *Shih*, 73 F.4th at 1102. At bottom, Holmes claims 22 pages of exhibits were erroneously admitted; testimony that spanned approximately 80 trial transcript pages were erroneously categorized as non-expert testimony; 7 pages of transcript were erroneously excluded; and one category within a category of her already four-day long cross-examination that she herself claims would have only required a "small amount of additional time" (AOB-65) was erroneously limited. These are not prejudicial claims of error—individually or cumulatively. The trial spanned 46 trial days, covered 9,439 pages of trial transcript, and included over 900 exhibits that easily spanned thousands of pages.

[13] Indeed, Holmes made minor adjustments to the detailed breakdown in her meeting with RDV. 29-ER-8294-99.

See Dkt. 27. These numbers are not dispositive, but they do have something to say. Like in *Cardenas-Mendoza*, the challenged testimony "played only a small part in the government's case[,]" other evidence established the same points, and "all other evidence offered by the government supports the jury's verdict." 579 F.3d at 1032-33. Therefore, any error was harmless—individually and cumulatively.

IV. THE DISTRICT COURT PROPERLY CALCULATED THE LOSS AMOUNT

A. Standard of Review

This Court "review[s] the district court's identification of the correct legal standard *de novo* and the district court's factual findings for clear error." *United States v. Gasca-Ruiz*, 852 F.3d 1167, 1170 (9th Cir. 2017) (*en banc*).

B. The District Court Correctly Employed a Preponderance-of-the-Evidence Standard

Holmes challenges the district court's calculation of the loss that ten or more investor-victims suffered. AOB-77-90. Holmes maintains that no loss enhancement should apply under U.S.S.G. § 2B1.1, and thus her Guidelines range should have been "0-7 months." *Id.*; CR-1655 at 35-47. The government and Probation Office both calculated the loss amount as more than $730 million from at least 29 investor-victims—the actual investment loss to all investors from 2010 to 2015—which resulted in a Guidelines range of life imprisonment. 3-ER-775-

80; PSR ¶¶ 102-113, 169. The court did not err in choosing an approach grounded in the facts demonstrated at trial, as well as other reliable testimony, and finding the loss was more than $120 million, yielding a Guidelines range of 135 to 168 months of imprisonment. 1-ER-2-166.

The court correctly held that the preponderance of the evidence rather than clear and convincing standard should apply given that Holmes was convicted of a conspiracy to defraud investors from 2010 to 2015 and the "extent of the conspiracy" provided a basis for the loss calculation. 1-ER-9-13. "Because [Holmes] was convicted of conspiracy, and because the losses were incurred because of that conspiracy, the 'preponderance of the evidence' standard applies." *United States v. Laurienti*, 611 F.3d 530, 556-57 (9th Cir. 2010); *see also United States v. Lonich*, 23 F.4th 881, 910 (9th Cir. 2022) ("We have declined to apply the clear and convincing standard of proof [when] the enhancement at issue was based entirely on the extent of the conspiracy." (quotations omitted)); *Perez*, 962 F.3d at 447-49. This is because, "if a defendant has already been convicted of certain conduct (whether through a jury verdict or a guilty plea), enhancements that are based on the conduct of conviction do not require proof by clear and convincing

evidence." *Lonich*, 23 F.4th at 913; *see id.* at 910 (noting that the "preponderance of evidence" standard applies "[a]s a general rule" for sentencing enhancements).[14]

Holmes's reliance on *Lonich* to assert that the clear and convincing standard should have applied because the government did not adequately prove causation is misplaced. AOB-80-86. In *Lonich*, the defendants were convicted of bank fraud and conspiracy, and the sentence was largely driven by an enhancement for the defendants having caused the bank's failure—even though the bank failed shortly after the 2008 financial crisis. *Lonich*, 23 F.4th at 907-16. As this Court held, one did not necessarily include the other—the bank fraud convictions did not include evidence on causation of the bank's collapse. *Id.* at 915-19. Indeed, "the jury was not even permitted to hear evidence on why the bank failed." *Id.* at 915. Accordingly, this Court held that the heightened clear-and-convincing standard of proof at sentencing was appropriate, as the enhancement was not driven by "conduct for which the jury found the defendant guilty[.]" *Id.* at 913; *see id.* at 907-16 (discussing at length six non-exhaustive factors from *United States v. Valensia*, 222 F.3d 1173, 1182 (9th Cir. 2000)).[15]

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[14] The government maintains that the preponderance standard should govern all factfinding under the advisory Guidelines. This Court currently stands alone among the circuits in holding otherwise, though the Court will revisit the matter *en banc* in January 2024. *See United States v. Lucas*, No. 22-50064, Dkts. 48-49 (9th Cir. Aug. 16, 2023).

[15] Notably, the first four factors assess whether the conduct underlying the enhancement was captured by the jury's verdict (*id.*), which is true here.

But that causation question is not present here. Instead, this is the "straightforward case" that the Court in *Lonich* referenced. *Id.* at 913 (citing *United States v. Garro*, 517 F.3d 1163 (9th Cir. 2008)). Here, the enhancement was entirely based on the extent of the conspiracy and loss stemming directly from the counts of conviction. The government argued below that the "actual loss" for purposes of U.S.S.G. § 2B1.1 should be determined by the full loss to investors, particularly given that Theranos was a private rather than public company for which there was no market to sell shares once the fraud was exposed. 3-ER-775-80. Under this approach, the court could have calculated the loss as:
(1) $144,336,613, the amount alleged in the indictment for counts on which Holmes was convicted (6-ER-1471-73; 13-ER-3535); (2) $381,197,283, the total loss to the specific ten investor-victims the court identified (1-ER-14);
(3) $730 million, the amount invested by C-2 investors in 2014 and 2015, the same time period as the counts of conviction, given trial testimony that Holmes approved written materials that were similar across investors (16-ER-4392; 27-ER-7601-09; *see also* 31-ER-8835-55 (hundreds of millions invested contemporaneously with Counts 7 and 8)); or (4) more than $800 million, which was the amount lost by all investors in Theranos from 2010 to 2015, including Walgreens and Safeway. 3-ER-775-80; *see Garro*, 517 F.3d at 1168-69 (affirming 135-month sentence for fraud convictions after trial with loss based on amount alleged in indictment); *see*

also Perez, 962 F.3d at 449 (upholding enhancement because conduct occurred within conspiracy timeframe).

Holmes asserts that the government failed to meet its causal burden because reliance on the defendant's misrepresentations is not an element of wire fraud. AOB-85. But that standard is not sourced in any of this Court's cases, which have not required a count of conviction to include, as an element, reliance for the preponderance burden to apply. *See*, *e.g.*, *United States v. Armstead*, 552 F.3d 769, 776-77 (9th Cir. 2008) (rejecting clear-and-convincing standard for loss amount, number of victims, and role-in-offense enhancements, despite none of those being requisite elements of bank fraud). The case upon which Holmes chiefly relies—*Lonich*—stated that the preponderance standard may have been appropriate if the loss was based on the value of defaulted loans in the bank fraud, rather than the ultimate collapse of the bank. *Lonich*, 23 F.4th at 915. But the dollar amount of a defaulted loan and the fact that the default occurred as a result of the fraud are not elements of bank fraud. In any event, investors at Holmes's trial repeatedly testified that Holmes's false statements were material to their (lost) investments. *See* 29-ER-8258-308 (RDV); 31-ER-8709-51 (Mosley); 35-ER-10014-74 (PFM). This was not a case without evidence of causation.

In sum, losses to specific investors were alleged, proven at trial, and resulted in convictions. There was no contrary evidence at trial regarding the investment

amounts—just a defense on the merits of the fraud. Neither of the two special carveouts identified in *Lonich*—loss amounts relying on a "substantial amount of uncharged or acquitted conduct" or suffering from a causal connection that went unproven at trial—are present. *Lonich*, 23 F.4th at 915. Holmes "had ample opportunity at trial to challenge the government's evidence of the extent of losses caused by the conspiracy," and chose instead to present a defense to intent, not the investment amounts lost when Theranos failed. *Id.* (quoting *United States v. Treadwell*, 593 F.3d 990, 1001 (9th Cir. 2010)).

C. The District Court Did Not Clearly Err in Calculating Loss

The court did not clearly err in finding that the preponderance standard was met and conservatively calculating the loss amount as $120,146,247. 1-ER-9-30. The preponderance standard requires only that a fact be more likely than not. *See United States v. Mercado-Moreno*, 869 F.3d 942, 957 (9th Cir. 2017). Courts "need only make a reasonable estimate of the [actual or intended financial] loss" suffered by victims of a fraudulent scheme. U.S.S.G. § 2B1.1(b)(1) cmt. 3(A), 3(C); *United States v. Zolp*, 479 F.3d 715, 718 (9th Cir. 2007).[16] The evidence presented here easily met that threshold—indeed, the government could have met its burden to prove loss in the hundreds of millions of dollars under even the

[16] The government argued that *Zolp* should not apply to a private company without liquidation options. 3-ER-778-79.

heightened clear and convincing standard. *See* CR-1743 at 16 (district court indicating clear and convincing threshold could be met in denying Balwani bail pending appeal).

As an alternative to the true loss amount suffered by all investors during the conspiracy period, the government provided a report from retained valuation expert Carl Saba, a partner with the Forensic Consulting Group at Hemming Morse LLP and a Certified Valuation Analyst and Accredited Senior Appraiser with decades of experience in the valuation of businesses. *See* 3-ER-595-750 (Saba's report). Saba provided a detailed analysis and multiple options for ascribing value to Theranos's stock at the time of investment, which could then be subtracted—to Holmes's benefit—from the victims' investment to determine a loss amount. *Id.*

The district court opted to find some value in the stock at the time the investor-victims purchased it—akin to companies that have publicly-traded stock with some value assigned at the time of purchase to offset the loss. 1-ER-9-25 (citing *Zolp*, 479 F.3d at 719). The court found that at least ten investor-victims during the conspiracy period lost more than $380 million. 1-ER-9-25.[17] Relying on Saba's report, the district court chose the Income Method (which was more

[17] The court also noted the likely "reality" that Holmes's "fraud affected many more qualifying investor-victims" given the widespread nature of her numerous misrepresentations. 1-ER-24; *see also* 53-ER-15335 (Holmes admitted summary exhibit showing 275 total investors in Theranos).

favorable to Holmes) and found that the fraud inflated the value of Theranos's stock by approximately 31.5%. *Id.* The court rejected Holmes's argument (renewed here (AOB-89-90)) that Theranos's intellectual property portfolio would have increased its value further, as that was accounted for in an alternative method, the Asset Method, which resulted in a lower company value (*i.e.*, was less favorable to Holmes). *Id.* Using the Income Method, the court concluded that a reasonable loss estimate was $120,146,247. *Id.* This approach aligns with this Court's instruction that "district courts should 'take a realistic, economic approach to determine what losses the defendant truly caused or intended to cause, rather than the use of some approach which does not reflect the monetary loss.'" *United States v. Martin*, 796 F.3d 1101, 1110 (9th Cir. 2015) (quotation omitted).

While Holmes asserts that no evidence supports five of the ten investor-victims, she applies too narrow of a scope. AOB-84, 88-90. "[A] federal judge in deciding to impose a sentence may appropriately conduct an inquiry broad in scope, largely unlimited either as to the kind of information he may consider, or the source from which it may come." *Concepcion v. United States*, 142 S. Ct. 2389, 2399-400 (2022); *United States v. Egge*, 223 F.3d 1128, 1132 (9th Cir. 2000) (reiterating that court is "not restricted to evidence that would be admissible at trial" so long as "sufficient indicia of reliability" exist (quotation omitted)); *see also Beaty v. Stewart*, 303 F.3d 975, 985 (9th Cir. 2002) (holding same for victim

impact statements). The court reasonably relied upon the trial testimony of three C-1 investors who lost more than $10 million within the conspiracy period. *See* 13-ER-3535.[18] The court also did not err in relying on the testimony of investor-victim Patrick Mendenhall from Balwani's trial and prior sworn testimony relating to multiple other investors, including Kovacevich and Murdoch (for whom trial exhibits also demonstrated that they were told similar lies as other C-2 investors). 1-ER-21-24; *see also* 19-ER-5282-90; 27-ER-7555-64, 7604-09. There was no clear error.

In sum, the district court did not err in determining that the loss to investors was within the range of $65 million to $150 million under U.S.S.G. § 2B1.1(b)(1), supporting a 24-level increase to the Guidelines range (and an additional 2-level increase for more than ten victims). 1-ER-20-25.

Finally, contrary to Holmes's statement that the combined 26-level enhancement was "excessive" (AOB-86-87), the increase "was based on the magnitude of the conspiracy" and "was not disproportionate relative to the offense of conviction." *United States v. Riley*, 335 F.3d 919, 925-27 (9th Cir. 2003). The district court remarked that "[t]here was significant evidence about manipulation

[18] While the jury did not reach a verdict with respect to those specific counts, the jury did convict Holmes of conspiracy to defraud investors in that time frame. Under the lower burden of proof applicable at sentencing, the district court was well within its discretion to find their testimony sufficient to support a loss amount connected with their investments. 1-ER-20-25.

and untruths that were being used" perhaps due to "intoxication with the fame that comes with being a young entrepreneur" or perhaps "hubris[.]" 1-ER-153-62. "This is a fraud case where an exciting venture went forward with great expectations and hope only to be dashed by untruth, misrepresentations, hubris, and plain lies." *Id.* Holmes committed an extensive fraud that lasted many years and duped investors out of more than $800 million. Her conduct triggered a recommended Guidelines range of "life" but for the district court's willingness to significantly discount the loss amount. *See* PSR ¶¶ 102-113, 169. The low-end Guidelines sentence of 135-months was not excessive, but based on the facts underlying Holmes's convictions and a reasonable—and defendant-favorable—calculation of the loss amount. *See Garro*, 517 F.3d at 1171-72 (affirming 135-month sentence connected to approximately $78 million loss amount). This Court routinely considers within Guideline-sentences to be reasonable. *See Perez*, 962 F.3d at 447. This one certainly was.

CONCLUSION

For the reasons set forth above, this Court should affirm.

Dated: August 17, 2023

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
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[ ] is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).

[ ] is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.

[ ] complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one)*:
- [ ] it is a joint brief submitted by separately represented parties;
- [ ] a party or parties are filing a single brief in response to multiple briefs; or
- [ ] a party or parties are filing a single brief in response to a longer joint brief.

[ ] complies with the length limit designated by court order dated _____.

[X] is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature *s/ Kelly I. Volkar* **Date** August 17, 2023
*(use "*s/[typed name]*" to sign electronically-filed documents)*