FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Appellee*, v. ELIZABETH A. HOLMES, *Defendant-Appellant*.	No. 22-10312 D.C. No. 5:18-cr-00258-EJD-1 ORDER AND AMENDED OPINION
UNITED STATES OF AMERICA, *Plaintiff-Appellee*, v. RAMESH SUNNY BALWANI, *Defendant-Appellant*.	No. 22-10338 D.C. No. 5:18-cr-00258-EJD-2
UNITED STATES OF AMERICA, *Plaintiff-Appellee*, v.	Nos. 23-1040 23-1167 D.C. No. 5:18-cr-00258-

ELIZABETH A. HOLMES,

Defendant-Appellant.

EJD-1

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

RAMESH "SUNNY" BALWANI,

Defendant-Appellant.

No. 23-1166
D.C. No.
5:18-cr-00258-
EJD-2

Appeal from the United States District Court
for the Northern District of California
Edward J. Davila, District Judge, Presiding

Argued and Submitted June 11, 2024
San Francisco, California

Filed February 24, 2025
Amended December 22, 2025

Before: Mary M. Schroeder, Jacqueline H. Nguyen, and Ryan D. Nelson, Circuit Judges.

Order;
Opinion by Judge Nguyen

SUMMARY*

Criminal Law

The panel affirmed Elizabeth Holmes's and Ranesh "Sunny" Balwani's convictions on numerous fraud charges, their sentences, and the district court's $452 million restitution order, in a case in which Defendants defrauded investors about the achievements of their company Theranos's blood-testing technology.

Defendants argued that the district court erred by allowing former Theranos employees, who testified as lay witnesses, to offer improper expert testimony. The panel explained that if a witness offers an opinion that is based on specialized knowledge, experience, training, or education contemplated by Fed. Rule of Evidence 702, a party cannot evade the Rule by labeling a witness "percipient." And there is no "on-the-job" exception to Rule 702. But the fact that a witness's testimony pertains to scientific matters, or conveys opinions drawn from the witness's own experiences with such matters, does not automatically render it expert testimony within the ambit of Rule 702. Considering each of the challenged witnesses with these principles in mind, the panel held that some aspects of the testimonies veered into expert territory, but any error was harmless.

Holmes argued that a report prepared by the Center for Medicare and Medicaid Services was irrelevant under Federal Rule of Evidence 401 and should have been excluded pursuant to Federal Rule of Evidence 403 because

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

there was a significant risk that the report would mislead the jury. The panel held that the district court did not abuse its discretion in finding that the report was relevant to Holmes's knowledge, intent, or state of mind, and in finding that the probative value of the report was not substantially outweighed by its potential for unfair prejudice.

Holmes argued that the district court abused its discretion by allowing testimony that Theranos voided all patient sample tests run on a device used in Theranos's clinical lab. Federal Rule of Evidence 407 provides that when measures are taken that would have made an earlier injury less likely to occur, evidence of subsequent measures is not admissible to prove culpable conduct. The purpose of Rule 407—to avoid punishing the defendant for efforts to remedy safety problems—is not implicated in cases involving subsequent measures in which the defendant did not voluntarily participate. The panel held that the district court did not clearly err in finding that the decision to void was not voluntary, and did not abuse its discretion balancing the risk of prejudice against the probative value of the evidence.

Holmes argued that the district court violated her rights under the Confrontation Clause of the Sixth Amendment when it prohibited her from cross-examining a former Theranos laboratory director on aspects of his post-Theranos employment. The panel held that the district court did not abuse its discretion in limiting the scope of the cross-examination.

Holmes argued that the district court should have admitted, as statements against interest under Federal Rule of Evidence 804(b)(3), portions of deposition testimony given by Balwani to the Securities and Exchange

Commission. The panel held that the district court correctly recognized that the statements were not solidly inculpatory and did not abuse its discretion in declining to admit these statements.

Balwani argued that the indictment was constructively amended in violation of his Fifth Amendment rights when the government presented evidence concerning the accuracy and reliability of Theranos tests run on *conventional* technology even though the indictment only charged him with misrepresentations concerning the accuracy and reliability of tests run on *proprietary* technology. The panel rejected this argument because the indictment plainly gave Balwani notice that he was charged with misrepresenting the accuracy of a non-exhaustive list of patient tests, regardless of which type of device the tests were run on.

Balwani argued that his due process rights were violated under *Napue v. Illinois* by the government's failure to correct allegedly false testimony given by two investor-victims. The panel held that the *Napue* claim fails under plain error review.

The panel held that the district court did not err in applying the preponderance-of-the-evidence standard for proving loss at sentencing. Regarding Defendants' arguments concerning loss causation and the number of victims, raised for the first time in letters pursuant to Federal Rule of Appellate Procedure 28(j), the panel held that the district court's factual findings were not clearly erroneous.

Defendants argued that the district court erred by awarding restitution based on investors' total investments, rather than the diminution in value of the shares after the fraud came to light. The panel explained that, although the district court properly identified the money invested as the

lost property, it should have also considered possible credits against Defendants' restitution obligation by accounting for the residual value of the shares after the fraud came to light. The panel concluded that any error was harmless because the district court's factual findings compel the conclusion that the victims' actual losses were equal to the total amount of their investments.

COUNSEL

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ORDER

The opinion filed on February 24, 2025 (Dkt. No. 88), and reported at 129 F.4th 636, is amended. The amended opinion will be filed concurrently with this Order.

The panel has unanimously voted to deny Balwani's petition for panel rehearing. Judge Nguyen and Judge Nelson voted to deny the petition for rehearing en banc, and Judge Schroeder so recommended. The full court was advised of the petition for rehearing en banc, and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 40.

The petitions for panel rehearing and rehearing en banc, Dkt. No. 92, are **DENIED**. Balwani's motion for leave to file a reply in support of the petition for rehearing en banc or panel rehearing, Dkt. No. 100, is **GRANTED**.

OPINION

NGUYEN, Circuit Judge:

"[O]ne tiny drop changes everything." That was the vision shared by Elizabeth Holmes and Ramesh "Sunny" Balwani, who set out in the mid-2000s to revolutionize medical laboratory testing through a biotechnology company called Theranos. In the early 2010s, Theranos claimed that it could run fast, accurate, and affordable tests with just a drop of blood drawn from the prick of a finger, in contrast to traditional testing methods that require large needles to draw blood from a vein.

Investors, health care professionals and companies, and Silicon Valley spectators were captivated by the potential of Theranos's revolutionary technology. As a result, Holmes and Balwani were able to establish relationships with major companies, investors, and prominent figures, including high-ranking members of the United States military.

But the vision sold by Holmes and Balwani was nothing more than a mirage. In late 2015, news reporting revealed internal struggles within the Theranos laboratory and the limitations of its technology. The grandiose achievements touted by Holmes and Balwani were half-truths and outright lies. Theranos's blood-testing device failed to deliver faster and more accurate testing results than conventional technology. Pharmaceutical companies never validated the technology, as Holmes and Balwani had told investors. Contrary to the rosy revenue projections shared with investors and business partners, Theranos was running out of money.

After a two-and-a-half-year investigation, a grand jury returned an indictment against Holmes and Balwani. They were tried separately in lengthy jury trials, and each was convicted on numerous fraud charges. Holmes and Balwani now bring several challenges to the district court's decisions at trial and sentencing. We affirm.

Factual Background

The Third Superseding Indictment (the "Indictment") charged Holmes and Balwani (collectively, "Defendants") with conspiracy to commit wire fraud against investors from 2010 to 2015 (Count 1), six wire fraud counts involving investors who invested in Theranos in 2013 and 2014 (Counts 3 to 8), conspiracy to commit wire fraud against patients from 2013 to 2016 (Count 2), and four wire fraud counts involving patients (Counts 9 to 12).

A. Holmes Starts Theranos

Holmes founded Theranos in 2003 and served as its Chief Executive Officer until 2018. Theranos aimed to revolutionize medical laboratory testing through innovative methods for drawing blood, testing blood, and interpreting patient data. Holmes's claimed goal was to create technology to run blood tests on small samples of blood drawn from a fingerstick.

Balwani, who was in a romantic relationship with Holmes from 2004 to 2016, joined the company in 2009 and was later appointed its President and Chief Operating Officer. The precise division of responsibilities between Holmes and Balwani was disputed at their respective trials. But evidence offered at both showed that Balwani oversaw operations in Theranos's patient-testing lab and served as the primary contact for Theranos's relationships with retailers,

including Safeway and Walgreens. Both Holmes and Balwani communicated with investors and business partners on behalf of Theranos. And they were both informed of Theranos's financial position on a regular basis. Holmes admitted that although not everyone directly reported directly to her, "ultimately all roads" led to her as the CEO.

B. Theranos's Technology

Theranos's technology was structured around "three core areas: the first was the chemistry or the assays; the second was hardware; and the third was software." One of Theranos's early developments was a miniaturized device called the "Edison."[1] The Edison was used in Theranos's clinical lab to test patient samples. While other devices, including the "minilab" and the "4.0" (or "4s"), were in development while Holmes ran Theranos, the Edison was the only device developed by Theranos that was ever used to test patient samples.

Theranos also developed proprietary "nanotainers" that were used to collect blood samples from a fingerstick. These nanotainers contrasted with traditional "vacutainers," which are used to collect higher volumes of blood from traditional venous blood draws. Blood samples that were collected by Theranos from a fingerstick using the nanotainer would be tested on either the Edison device or a modified third-party device.

Although Theranos developed 300 small-sample assays during Holmes's time at the company, only twelve assays were ever run on the Edison. Other "general chemistry tests" conducted by Theranos were run on third-party-

[1] The "Edison" is also referred to as the "3.5" device, the "Edison 3.5" device, or the "Theranos Proprietary System" ("TPS").

manufactured machines. Theranos made various modifications to third-party machines to run certain tests. Theranos's goal was to get as many tests to run on the Edison as possible, and Holmes and Balwani pushed employees in the clinical laboratory to do so despite their expressed concerns about the Edison's accuracy.

C. Scheme to Defraud Investors

In 2010, Theranos partnered with Walgreens to use Theranos's propriety device to conduct patient tests in Walgreens's retail pharmacies. After publicly launching its testing services at Walgreens in the fall of 2013, Theranos raised funds by offering shares to investors. Three investors purchased C-1 shares in late 2013: Chris Lucas (Count 4), John Bryan Tolbert (Count 5), and Alan Eisenman (Count 3). In 2014, Theranos offered C-2 shares to new investors: Brian Grossman (Count 6), Lisa Peterson (Count 7), and Daniel Mosley (Count 8). Theranos shares were not publicly traded.

The Indictment alleged that, in procuring these investments, Holmes and Balwani made materially false and misleading statements to the investors, which generally fell in the following categories: (A) the technological 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 United States military; (F) the use of third-party devices to test patients; and (G) pharmaceutical companies' purported validation of Theranos's technology.

Theranos employees testified at both trials that the Edison device consistently failed quality control checks and was unable to provide accurate results. They conveyed their concerns about the reliability of Theranos's testing to

Holmes and Balwani in real time, but Holmes and Balwani dismissed these concerns or shifted blame away from any problems with the Theranos device.

One extensively litigated item of evidence was a report prepared by the Center for Medicare and Medicaid Services ("CMS") ("the Report" or "the CMS Report"). CMS, the federal agency responsible for overseeing blood testing laboratories, conducted an unannounced inspection of Theranos in late 2015. The CMS Report summarized the findings from that inspection, including the conclusion that deficiencies in Theranos's clinical laboratory practices and procedures presented "immediate jeopardy" to patient health. The Report identified quality control failures within the lab relating to tests that were run on the Edison device as well as patient tests from modified, commercial third-party devices.

One form of deception charged in the Indictment is Theranos's use of third-party devices to conduct patient samples and tests. Theranos employees explained how patient tests were run on machines that were commercially available and manufactured by third parties. Some patient tests were run on "modified" versions of the third-party machines, while some tests were run on unmodified versions. Multiple investors testified that Holmes and Balwani misled them to believe that Theranos ran its tests solely on devices manufactured by Theranos. The truth, according to these investors, would have impacted their investment decisions.

Holmes and Balwani took steps to conceal their use of third-party devices. Employees testified that Theranos would invite "VIP" guests, including investors, to observe technological demonstrations of the Theranos device. These

VIP guests would be placed in a room with an Edison or "minilab" and would be led to believe that the device was running a sample of their blood. In reality, the device was running a "null protocol" while some of the VIP samples were surreptitiously run on third-party devices.

Holmes and Balwani also shared false financial projections with investors. In the early 2010s, Theranos's business partnerships with pharmaceutical and retail companies were failing to generate revenue. Theranos's Corporate Controller, Han Spivey, testified that Theranos did not have any revenue in 2012 and 2013 and, in fact, suffered $57 million and $92 million in net losses, respectively. In November 2013, Balwani told Holmes that Theranos was down to $15 million in cash, but the company was spending up to $2 million weekly. In 2015, Theranos reported only $1,944,948 in total income to the IRS. But Holmes and Balwani painted a very different picture to investors. For example, investor-victim Peterson testified at Holmes's trial that financial documents she received from Holmes and Balwani showed that Theranos was projecting a profit of $230 million by the end of 2015. And investor-victim Grossman testified that, prior to his investment, Holmes and Balwani told him that Theranos had generated $200 million in revenue from the Department of Defense.

Theranos's work with the military, and various false representations Holmes and Balwani made to investors about that work, was explored in significant detail at both trials. General James Mattis testified at Holmes's trial regarding Theranos's relationship with the military. Although Theranos had developed a relationship with the Department of Defense to explore the potential use of the Edison device in combat settings, that application never materialized. General Mattis testified that the Edison device

was never put into the field by the military, it was never installed on a military medevac, and it was never used to treat servicemembers on the battlefield. But multiple C-1 and C-2 investors testified that Holmes and Balwani led them to believe otherwise. At Holmes's trial, the government introduced a recording of Holmes speaking to investors on a call in December 2013 in which she made various statements about Theranos's partnership with the military.[2] For instance, Holmes told investors that "we have also been doing a lot of work for special operations command in the context of missions in remote areas" and that Theranos had "created a distributed system that can be used in remote areas."

Finally, the Indictment alleged that Holmes and Balwani also misrepresented to investors the status of Theranos's partnerships with other companies, including retailers and pharmaceutical companies. A Walgreens representative testified that, while Holmes and Balwani were touting to investors that Theranos's partnership with Walgreens was expanding, the partnership was actually contracting, and the pilot program was not going as hoped. Walgreens's decision to reduce the number of stores launching Theranos's testing services was motivated in part by the high percentage of blood draws that were being performed venously (a traditional blood draw), rather than through a finger prick.

Theranos's partnerships with pharmaceutical companies—which began in 2008 and 2009 with the purpose of conducting studies of the Theranos technology—quickly soured. A representative of Pfizer testified that he believed that Theranos's answers to technical due diligence questions

[2] As relevant to Balwani's *Napue* claim, the government did not introduce this recording at his trial.

were oblique, deflective, or evasive, and that after 2008, Pfizer and Theranos had no meaningful business dealings. But once again, Holmes and Balwani projected a very different image to investors. Holmes admitted that she personally affixed the logo of various pharmaceutical companies, including Pfizer, GlaxoSmithKline, and Schering-Plough, onto reports containing favorable conclusions about Theranos's device. In emails to Walgreens, Holmes described these reports as representing the pharmaceutical companies' independent and technical validation of the Theranos device. At trial, representatives from these companies testified that they neither independently validated the Theranos technology nor authorized the use of their company logo on these reports. These reports were shared with investors, who found it significant that large, independent, third-party companies were vouching for the technology.

D. Scheme to Defraud Patients

The Indictment further alleged that Holmes and Balwani devised a scheme to defraud patients through advertisements and marketing materials boasting about the accuracy, cost, and reliability of Theranos's blood testing services. Multiple patients testified at the trials. One patient testified that an HIV test she took through Theranos came back positive, but two subsequent tests showed that she was in fact negative. Another patient testified that she received incorrect results from a Theranos blood test about her pregnancy. The evidence linked Balwani to the transmission of these inaccurate results, as well as the purchase of advertisements for Theranos Wellness Centers in Arizona.

Procedural History

The district court severed Defendants' trials based on Holmes's disclosure of Balwani's abuse in their personal relationship. Holmes was tried first in late 2021. Balwani was then tried in early 2022. Each trial lasted nearly four months.

A. Holmes's Conviction and Sentence

During Holmes's trial, the government dismissed Count 9. The jury acquitted Holmes on the patient-related counts: conspiracy (Count 2) and wire fraud (Counts 10–12). The jury convicted Holmes of four investor-related counts: the investor-related conspiracy (Count 1), and wire fraud relating to three investor-victims (Counts 6–8). The jury hung on the wire-fraud counts related to C-1 investors (Counts 3–5).

At Holmes's sentencing, the district court found that the offense involved ten or more victims, resulting in a two-level sentencing enhancement under United States Sentencing Guidelines ("USSG") § 2B1.1(b)(2). *United States v. Holmes (Holmes I)*, 2023 WL 149108, at *7–9 (N.D. Cal. Jan. 10, 2023). It further found that the offense caused a loss of $120 million, resulting in a 24-level enhancement under § 2B1.1(b)(1). *Id.* at *6–7. These calculations yielded a sentencing range of 135 to 168 months. The district court sentenced Holmes to 135 months of imprisonment.

B. Balwani's Conviction and Sentence

The jury convicted Balwani of all counts: conspiracy to commit wire fraud against Theranos investors (Count 1), conspiracy to commit wire fraud against Theranos patients (Count 2), investor wire fraud (Counts 3–8), and patient wire fraud (Counts 9–12).

Based on the same findings of the number of victims and the amount of the loss as in Holmes's case, Balwani faced the same sentencing range of 135 to 168 months. *United States v. Balwani*, 2023 WL 2065045, at *15 (N.D. Cal. Feb. 16, 2023). The district court sentenced him to 155 months of imprisonment. *Id.*

C. Restitution Order

The district court issued its restitution order in May 2023. *United States v. Holmes, et al. (Holmes II)*, 673 F. Supp. 3d 1049 (N.D. Cal. 2023). It first determined that the twelve investors who had been induced by Defendants' fraud to invest in Theranos were "victims" under the Mandatory Victims Restitution Act of 1996 ("MVRA"), 18 U.S.C. § 3663A. *Id.* at 1056. The district court found that the "property" each victim "lost" was the money that each invested in exchange for ownership shares in Theranos. *Id.* at 1058. The district court credited the amount that Theranos had already paid to three investors in civil settlements, but it rejected the proposition that the residual value of the Theranos shares qualified as "returned" property within the meaning of § 3663A(b)(1)(B)(ii). *Id.* at 1057–58. The court held Holmes and Balwani jointly and severally liable for $452 million in restitution, including $397 million for the twelve victims identified at sentencing and $54.5 million for two other victims, Safeway and Walgreens. *Id.* at 1066.

Holmes and Balwani timely appealed, challenging their convictions, sentences, and the restitution order.

Conviction Challenges

I. Expert Testimony

Holmes and Balwani argue that the district court erred by allowing former Theranos employees, who testified as lay

witnesses, to offer improper expert opinions. We review the district court's determination of whether testimony is offered as an expert or a lay witness for abuse of discretion. *United States v. Perez*, 962 F.3d 420, 434 (9th Cir. 2020).

A. Legal Standard

Under Federal Rule of Evidence 701, a lay witness may provide opinions "rationally based on the witness's perception" that are "not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. Opinion testimony requiring special "knowledge, skill, experience, training, or education" is subject to the requirements of Federal Rule of Evidence 702, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the disclosure requirements of Federal Rule of Criminal Procedure 16.

"[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 (quoting *United States v. Barragan*, 871 F.3d 689, 704 (9th Cir. 2017)). If the basis of a witness's opinion is "technical or specialized knowledge," then that opinion falls within Rule 702. *Id.* at 437. But if the basis of the opinion is "just familiarity with the subjects," then it is proper lay opinion under Rule 701. *Id.*

Drawing that line is a particularly difficult task in a case like this one. By the very nature of the underlying facts and the alleged fraud, the testimony of percipient witnesses will inevitably involve observations made in a scientific setting and relate to scientific or technical concepts. But the fact that a witness's testimony pertains to scientific matters, or conveys opinions drawn from the witness's own experiences with such matters, does not automatically render it expert

testimony within the ambit of Rule 702. Indeed, "[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." *United States v. Gadson*, 763 F.3d 1189, 1208 (9th Cir. 2014). A lay witness's opinion is permissible so long as it is not "based on scientific, technical, or other *specialized* knowledge." Fed. R. Evid. 701 (emphasis added).

By the same token, the "mere percipience of a witness to the facts on which he wishes to tender an opinion does not trump Rule 702." *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246 (9th Cir. 1997). In other words, there is no "on-the-job" exception to Rule 702. *See id.* at 1247. The fact that a witness personally observes a matter does not take the witness's opinion about that matter outside the scope of Rule 702 if that opinion is the product of "*specialized* knowledge." *Id.* at 1246. Thus, as we explained in *Figueroa-Lopez*, if a witness offers an opinion that is based on specialized knowledge, experience, training, or education contemplated by Rule 702, a party cannot evade the Rule by labeling a witness "percipient." *See id.* at 1243. But the converse is also true—an opinion is not automatically deemed "expert" within the meaning of Rule 702 merely because it is offered by a lay witness drawing on their own unique experiences or personal knowledge.

With these principles in mind, we consider each of the challenged witnesses in turn.

B. Dr. Kingshuk Das

Holmes argues that the district court erroneously allowed Dr. Kingshuk Das, who worked as a laboratory director at Theranos, to offer expert opinion testimony. Das began

working at Theranos in March of 2016. Holmes hired him to review and respond to the CMS Report, a task that became Das's near "sole responsibility." In carrying out this role, Das had many conversations with Holmes about the CMS Report, the company's response to its findings, and Theranos's quality control data from Edison tests run in 2014 and 2015.

Das testified that, in responding to the CMS Report, he was involved in Theranos's performance of Patient Impact Assessments (PIAs)—one of two retrospective analyses of the Edison. According to Das, the PIAs were "descriptions of [Theranos's] assessment on [its] evaluation of whether these tests led to potential for patient harm." To perform these assessments, Das reviewed three categories of Theranos documents: validation reports for tests performed, quality control results and reports, and patient test result distributions and calculations. The PIAs were sent to CMS as part of Theranos's response to CMS's deficiency findings.

Over Holmes's objection, the government introduced the PIA concerning Theranos's proprietary Edison device. That document states, and Das confirmed, that the Theranos "laboratory conducted an expanded retrospective analysis for 2014 and 2015 [quality control] data," with the goal of "see[ing] how far the poor performance extended." Based on that comprehensive analysis, the laboratory concluded that "there [was] a possible patient impact for every test reported from the laboratory's TPS 3.5 [Edison] instruments." Das confirmed that, based on the data analyzed in the PIA, he found the Edison "unsuitable for clinical use."

Das further testified that he conveyed these results and conclusions to Holmes. While Theranos was preparing its

response to CMS, Das shared with Holmes his concerns that, based on "the validation data," he believed that "these instruments apparently were not performing from the very beginning." Das then explained that, when he raised these issues, Holmes attributed the poor results to laboratory control failures rather than an issue with the device itself—an explanation that Das found unsatisfying.

Holmes claims that "[t]he government's examination of Das was an 'end-run around Rule 702 and *Daubert*.'" *See In re: Taxtore (Docetaxel) Prods. Liab. Litig.*, 26 F.4th 256, 264 (5th Cir. 2022). The PIA and Das's opinions about Theranos's quality control data, according to Holmes, "rested on sophisticated data analysis based on extensive scientific training." In response, the government argues that Das properly testified as a percipient witness because he merely described the job he was hired to do, and the PIA is not expert testimony but rather an admission by Theranos—and, by extension, Holmes—that there were serious reliability issues with the Edison device.

The government's argument is misplaced. As we explained, there is no "on-the-job" exception to Rule 702. That Das described personal observations made while performing his job would not take his testimony outside the scope of Rule 702 if Das offered opinions that relied on specialized knowledge, training, or skill. *See Figueroa-Lopez*, 125 F.3d at 1246. And there is little doubt that the PIA and Das's opinions concerning the suitability of the Theranos device for clinical use were based on specialized knowledge. Das testified that he reviewed data collected by Theranos (*i.e.*, validation reports, quality control data, and patient test result distributions and calculations), conducted a comprehensive retrospective analysis of this data, and reached conclusions about the Edison device based on this

statistical analysis. In his conversations with Holmes, Das used "terms of the validation data in describing that these instruments apparently were not performing from the very beginning." Das's conclusion, reached after a comprehensive statistical analysis and interpretation of the results, was clearly based on highly specialized knowledge.

Moreover, the district court recognized before trial that the "Six Sigma" data analysis—the second retrospective analysis of the Edison that Das conducted—would have approached expert witness territory. Holmes argues, and the government does not refute, that the analysis contained in the PIA was not meaningfully different from the Six Sigma data analysis in terms of the specialized training or knowledge required to reach the resulting opinions. We therefore conclude that certain aspects of Das's testimony, including the PIA, and Das's accompanying opinions about the Edison device, amounted to expert opinions. To the extent that the government used Das's testimony to prove that there were significant problems with the accuracy and reliability of the Edison device, Rule 702 required that Das's opinions be subject to *Daubert* scrutiny.

Nevertheless, any error in admitting these opinions was harmless. To the extent that Holmes is now challenging Das's qualifications as an expert, we conclude he was qualified. *See id.* at 1247. Based on his extensive experience working in clinical laboratories, Das would have easily qualified as an expert to deliver the disputed opinion testimony. *See United States v. Holguin*, 51 F.4th 841, 855–56 (9th Cir. 2022) (finding error in admitting expert testimony harmless and recognizing that "[e]xperience alone" could be reliable basis for certain expert testimony). "[T]he failure formally to go through the usual process—

although an error—was clearly harmless." *Figueroa-Lopez*, 125 F.3d at 1247.

Holmes also stresses that *Daubert* required the district court to scrutinize the reliability of Das's opinions under Rule 702.[3] It is not likely however that the admission of Das's opinion testimony affected the jury's verdict, given the weight of other evidence against Holmes. The standard of harmlessness for evidentiary errors in this circuit is clear. *See United States v. Charley*, 1 F.4th 637, 651 (9th Cir. 2021). "Evidentiary errors 'are not harmless unless it is more probable than not that the erroneous admission of the evidence did not affect the jury's verdict.'" *Id.* (quoting *United States v. Hill*, 953 F.2d 452, 458 (9th Cir. 1991)). Holmes objects to Das's opinions concerning the accuracy and reliability of the Edison device, but his was not isolated testimony on that subject. Multiple former Theranos employees reported similar problems with the technology, and Das's testimony was essentially cumulative of theirs.

Das's testimony was relevant to misrepresentations concerning the technological capabilities of the device, but such misrepresentations constituted only one of numerous types of misrepresentations to investors that the government

[3] Holmes also argues a discovery violation based on the government's failure to disclose Das as an expert. *See* Fed. R. Crim. P. 16. "[A] violation of Rule 16 does not itself require reversal, or even exclusion of the affected testimony." *Figueroa-Lopez*, 125 F.3d at 1247. The discovery violation must have resulted in prejudice to the defendant's substantial rights. *United States v. Basinger*, 60 F.3d 1400, 1407 (9th Cir. 1995). Holmes was aware of the substance of Das's testimony as early as February 2021. And as Holmes recognizes, the substance of Das's scientific opinions largely overlapped with that of Dr. Stephen Master, who was timely disclosed. On these facts, any untimely disclosure did not result in prejudice.

alleged and presented evidence to prove. The government offered evidence that Holmes misrepresented Theranos's financial status, its reliance on third-party testing devices, its partnerships with Walgreens and the military, and pharmaceutical companies' purported validation of Theranos's technology. Das's testimony about the technology's unreliability was not essential to proving any of these misrepresentations.

Moreover, after the district court permitted the government to call Das as a percipient witness, Holmes never requested a *Daubert* hearing to test the reliability of his testimony. Nor did she object when Das offered the opinions she now challenges. Only when the court admitted the PIA itself did Holmes raise a Rule 702 objection. There was no reversible error by the district court.

C. Dr. Adam Rosendorff and Dr. Mark Pandori

Balwani challenges certain testimony given by two other former Theranos laboratory directors—Dr. Adam Rosendorff and Dr. Mark Pandori. Both testified that there were problems with Theranos's laboratory tests. During Rosendorff's tenure, he developed concerns about the systemic inaccuracy of the Theranos device, specific tests offered to patients, management's unwillingness to perform proper proficiency testing as required by federal regulations, and the pressure he felt to explain problematic results when patients and physicians complained.

Like Rosendorff, Pandori testified that the "failure rate of the controls on the Edisons was notably higher than what [he] would see on the assay equipment with which [he] had familiarity." Pandori detailed his experience with the proficiency testing at Theranos, which he described as a regulatory requirement that was meant to be "a neutral way

to ascertain the quality of [a] test." His concern stemmed from the fact that the proficiency tests were performed on third-party devices, whereas actual patient samples were run on Theranos-manufactured devices. And when the same tests were run on Theranos devices and third-party devices, the significant differences in the results led him to question the accuracy of Theranos's device.

We conclude that, as with Das, some aspects of these witnesses' testimonies veered into expert territory. A prime example is Rosendorff's explanation of hemolysis. Rosendorff testified that hemolysis is the "bursting of red blood cells," which can happen "when you collect the blood." Rosendorff explained that damage to the red blood cells can cause "whatever is inside of the red blood cells [to] get[] into the sample, and it can really interfere with the detection of a lot of different things." This, according to Rosendorff, interfered with the ability of the Theranos devices to read the sample, thereby affecting the accuracy and reliability of the tests. Rosendorff further explained that hemolysis was more common in Theranos fingerstick samples rather than standard vein samples. This is plainly expert opinion within the meaning of Rule 702 because a lay person without specialized scientific training or education would not know what hemolysis means, why it more commonly occurs when blood is collected from via a fingerstick rather than a venous blood draw, or how it can interfere with the accuracy of test result. *See United States v. Finley*, 301 F.3d 1000, 1008, 1013 (9th Cir. 2002) (describing expert testimony as that which goes "beyond the common knowledge of the average layman"). The fact that Rosendorff personally observed a relationship between hemolysis and the accuracy of certain Theranos tests would

not remove this testimony from the ambit of Rule 702. *See Figueroa-Lopez*, 125 F.3d at 1246.

Similarly, Pandori's testimony about the results of Theranos's proficiency testing constituted expert opinion. Pandori explained that Theranos conducted proficiency testing by running certain tests on third-party machines, and then ran the same tests on Theranos devices, and compared the results. Pandori explained that the third-party machines were "extraordinarily vetted methodolog[ies]," meaning "one might feel very confident that a [third-party] method will give an accurate result." Pandori then testified that there were "large differences" between the third party and Theranos testing. He specifically stated that "*you would need to be an expert to appreciate the differences* because the differences don't look large." By Pandori's own explanation, a lay person would not know whether the differences in the results were significant.

These opinions required the witnesses to draw on their respective specialized experience and background in clinical labs. The government's questions illustrate the expert nature of these opinions because they called on the witnesses to compare the quality control issues experienced at Theranos with quality control issues at other labs and to explain why problems were worse at Theranos. Only one with specialized experience in clinical laboratory science could understand whether the problems suffered at Theranos were unique or particularly problematic—an average lay person without that background would not be able to opine on Theranos's problems *relative* to other laboratories.

Still, any error in permitting Rosendorff's or Pandori's testimonies was harmless for the same reason the erroneously admitted testimony in *Figueroa-Lopez* was

harmless. *See* 125 F.3d at 1247. Rosendorff testified as to his medical background and qualifications to serve as laboratory director. Rosendorff completed medical school, a fellowship in basic science research in a laboratory, worked as a post-doctoral fellow at Harvard University in a laboratory, completed specialized training in laboratory medicine, and oversaw laboratory testing at a children's hospital for five years. Pandori received a doctoral degree and was trained as a public health microbiologist at the California Department of Public Health. He worked as a postdoctoral research fellow at Harvard University School of Medicine and became an instructor of medicine there. Pandori then served as the chief microbiologist at the San Francisco Department of Public Health Laboratory, which was a Clinical Laboratory Improvement Amendments ("CLIA")-certified diagnostic laboratory that ran blood tests. Both Rosendorff and Pandori would have easily qualified as experts, and their extensive experiences allowed them to draw reliable conclusions about problems with Theranos's device and testing services. *See Holguin*, 51 F.4th at 855 ("The Rules Advisory Committee has explicitly recognized that 'the application of extensive experience' is a 'method' that can reliably support expert testimony." (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment)).[4] Thus, because the facts of this case demonstrate that Rosendorff and Pandori would have met all the requirements under Rule 702 and *Daubert*, any error in admitting their testimonies was harmless.

[4] Additionally, Balwani failed to object to the vast majority Rosendorff's testimony, including instances where he expressed concerns about the accuracy of certain tests and problems in the laboratory. Even if certain portions of his testimony were erroneously admitted, it is unlikely they materially affected the impact of Rosendorff's testimony in its entirety.

D. Erika Cheung

Balwani argues that Erika Cheung, a former Theranos laboratory associate, also offered expert testimony in violation of Rule 702.

Cheung was hired immediately after graduating college. During her time at Theranos, Cheung ran test samples on the Edison device and became familiar with which types of tests each device ran. Cheung was responsible for running quality controls, which she described as "essentially a check that you have to do before you run the patient samples." According to Cheung, in "[quality control], you have a known concentration of a particular test." The known sample is put into the machine, which "gives . . . an answer" that should reflect the known value of the sample or a value "in some acceptable range." Cheung explained that quality control testing "gives you some level of confidence that all of the parts and pieces of the system are working properly."

Cheung testified, and documentary evidence presented by the government corroborated, that the Edison device frequently failed these quality control checks. Cheung eventually concluded that the Theranos blood testing devices were "highly unreliable" because quality controls were failing with such high frequency across multiple tests. Although devices that failed quality control were not used for patient testing, Cheung nevertheless harbored concerns about the accuracy of patient tests. Over Balwani's Rule 702 objection, Cheung explained that "if you just extrapolate out essentially the percentage of failures that are happening across the system, even if we change the device, there's something still going on that is causing one out of four failures of every single test that we do on this . . . system."

Balwani argues that Cheung's testimony concerning the capabilities and accuracy of the Theranos technology constituted impermissible expert opinions. Even though Cheung did not have any relevant expertise or special statistical training, Balwani nevertheless contends that because Cheung's opinions about quality control were derived from her on-the-job training at Theranos, her testimony falls within Rule 702 pursuant to *Figueroa-Lopez*. Not so. *Figueroa-Lopez* does not stand for the proposition that testimony given by a percipient witness is "expert" merely because the testimony concerns a matter that a witness learned about at her job. *See* 125 F.3d at 1244, 1247. *Figeroa-Lopez* involved officers who offered an interpretation of a specific set of facts based on an application their prior law enforcement training and experience that were completely unrelated to those facts. *See* 125 F.3d at 1246. In contrast, Cheung testified about her training at Theranos for the purpose of explaining what she understood that training to mean, not for the purpose of applying that training to reach conclusions about an unrelated set of facts.

Importantly, Balwani does not argue that any scientific expertise is required to know whether a given sample passed or failed quality control. Had Cheung testified as to the mechanics or operation of the Edison device, or how the device generated quality control results, that may have hewed closer to expert testimony. But Cheung only testified that she ran samples in the Theranos device and that the device indicated that those samples failed quality control. Balwani himself described this as nothing more than "scan[ning] barcodes, load[ing] samples into cartridges and machines, and then 'hit[ting] start.'" Such testimony resembles that offered in *United States v. Jimenez-Chaidez*,

96 F.4th 1257, 1267–68 (9th Cir. 2024), where we found that an FBI agent appropriately testified as a lay witness when the agent used software to extract information from a cell phone. The agent did not testify as to the mechanics of the software, but rather testified as to the report that the software produced. *Id.* The agent's testimony about the report was "based on his perception and not specialized knowledge." *Id.* at 1267. Similarly, Cheung's testimony did not require specialized knowledge.

Moreover, it takes no special knowledge, training, or education to infer that when a device consistently fails measures designed to test the accuracy of the device, the device may in fact suffer from accuracy issues. To borrow the district court's analogy, if a certain model of a toaster consistently burned bread or short-circuited when run on regular settings, and those problems consistently manifested across multiple toasters of the same model, a lay person using the toaster could reasonably reach the conclusion that there is a problem with the design or manufacturing of the toaster. Similarly, Cheung could offer lay opinion testimony that repeated quality control problems with the Edison device signaled a problem with the device.

We therefore conclude that the district court did not abuse its discretion in admitting Cheung's testimony about quality control problems that led her to question the accuracy and reliability of the Theranos device as lay opinion.

II. CMS Report

The CMS Report was the subject of intense litigation below. The district court denied Holmes's pre-trial motion in limine to exclude the Report, rejecting her arguments that its probative value was substantially outweighed by its risk of unfair prejudice. Over Holmes's renewed objection at

trial, the government introduced the CMS Report into evidence during its direct examination of Das. After Das's testimony, Holmes moved to strike the report and Das's related testimony, which the district court denied.

On appeal, Holmes argues that the CMS Report was irrelevant under Federal Rule of Evidence 401 first, because the Report was issued in January 2016—after the alleged misrepresentations to investors took place—and second, because the Report made no findings as to whether Theranos's technology was in fact accurate or reliable. Holmes further argues that the Report should have been excluded pursuant to Federal Rule of Evidence 403 because there was a significant risk that the Report would mislead the jury. We review the district court's decision as to the admissibility of the Report for an abuse of discretion. *See Figueroa-Lopez*, 125 F.3d at 1244. Under this standard, we will only reverse a district court's decision if the decision "(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).

First, the district court did not abuse its discretion in finding that the CMS Report was relevant to questions about Holmes's state of mind, intent, and knowledge regarding the alleged misrepresentations about the accuracy and reliability of Theranos's blood tests. As the district court recognized, the Report and the related testimony were probative of Holmes's knowledge of the state of Theranos's clinical laboratory in late 2015, when the CMS inspection occurred, and early 2016, when the Report was received by Theranos. The Report therefore makes it more likely that Holmes also knew about the condition of the lab during the charging period even if Holmes did not receive the Report itself until

after the alleged misrepresentations were made. *See United States v. Bibo-Rodriguez*, 922 F.2d 1398, 1400 (9th Cir. 1991) (recognizing that subsequent acts may raise an inference of prior knowledge); *United States v. Nelson*, 137 F.3d 1094, 1106–07 (9th Cir. 1998) (same); *United States v. Boulware*, 384 F.3d 794, 805 (9th Cir. 2004) ("Evidence is relevant if it has '*any* tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.'" (quoting Fed. R. Evid. 401) (emphasis added)).

Second, the district court did not abuse its discretion in finding that the probative value of the CMS Report was not substantially outweighed by its potential for unfair prejudice. "A district court's decision to exclude or admit evidence under [Rule] 403 is reviewed 'with considerable deference.'" *United States v. Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000) (quoting *United States v. Cordoba*, 194 F.3d 1053, 1063 (9th Cir. 1999)).

With the benefit of extensive briefing and oral argument, the district court fully and carefully considered Holmes's arguments and declined to exclude the CMS Report on three separate occasions: first, in denying Holmes's motion in limine to exclude the Report, again in deferring ruling on Holmes's proposed redactions to the Report and its cover letter, and finally, in denying her motion to strike the Report. The district court's decision to admit the Report certainly does not "lie[] beyond the pale of reasonable justification under the circumstances." *United States v. Hollis*, 490 F.3d 1149, 1153 (9th Cir. 2007) (quoting *Harman v. Apfel*, 211 F.3d 1172, 1175 (9th Cir. 2000)).

Importantly, the district court implemented appropriate safeguards to minimize the risk of unfair prejudice to

Holmes by instructing the jury that its limited purpose was to show Holmes's state of mind and that she could not be found guilty merely because she may have violated regulations or industry standards. Holmes cites *United States v. Wolf*, 820 F.2d 1499 (9th Cir. 1987), to argue that jury instructions are not always curative of prejudice associated with evidence of regulatory violations. But unlike the instruction in *Wolf*, which vaguely described the regulations at issue as "background evidence," 820 F.2d at 1505, the instructions given by the district court here explicitly informed the jury that any CLIA violations reported by CMS were not independently relevant of Holmes's guilt. Nothing in the record rebuts the "strong[] presum[ption] that the jury followed the court's instruction." *United States v. Ubaldo*, 859 F.3d 690, 704 (9th Cir. 2017).

In sum, the district court did not err in admitting the CMS Report as evidence of Holmes's knowledge, intent, or state of mind.

III. Voiding Results

Holmes also argues that the district court abused its discretion by allowing Das to testify that Theranos voided all patient tests run on the Edison. That testimony, Holmes claims, is evidence of a "subsequent remedial measure" that Theranos took out of "an abundance of caution." As such, it should have been excluded under Federal Rule of Evidence 407, which provides that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove . . . culpable conduct." Fed. R. Evid. 407. We assume, without deciding, that Theranos's decision to void results of patient tests run on the Edison constitutes a

"measure" within the meaning of the Rule.[5] We nevertheless find that the district court did not abuse its discretion in admitting this evidence.

"The purpose of Rule 407 is not implicated in cases involving subsequent measures in which the defendant did not voluntarily participate." *In re Aircrash in Bali, Indonesia*, 871 F.2d 812, 817 (9th Cir. 1989). Rule 407 is meant to avoid "'punish[ing]' the defendant for his efforts to remedy his safety problems," so the rule does not contemplate exclusion of evidence that the defendant took actions that it was legally obligated to take. *Id.* The central issue here is whether Theranos's decision to void tests was truly "voluntary." Because this issue goes to the admissibility of the voiding evidence under Rule 407, it is a preliminary question for the district court to decide. Fed. R. Evid. 104(a). Where a preliminary question turns on a question of fact, it must be established by a preponderance of the evidence, and the district court's fact-finding on that question is subject to clear error review. *See Bourjaily v. United States*, 483 U.S. 171, 175–76 (1987).

When the district court overruled Holmes's Rule 407 objection and allowed Das to testify regarding the voiding, it implicitly found that the decision to void was not voluntary. As Holmes's counsel recognized prior to Das's testimony, there was evidence in the record that could support a finding either way on the voluntariness issue. And "[w]here there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly

[5] The government urges us to conclude that "Theranos's internal analysis leading to the voiding" is not a "measure" protected by Rule 407. But we reach the same conclusion regardless of whether voiding results is a "remedial measure" rather than an "internal analysis."

erroneous." *United States v. Working*, 224 F.3d 1093, 1102 (9th Cir. 2000) (en banc) (quotation omitted).

Additionally, the district court carefully balanced the risk of prejudice against the probative value of the evidence pursuant to Rule 403.[6] The district court reasonably concluded that this evidence is highly probative of Holmes's knowledge and state of mind because the decision to void every single patient test result generated by the Edison is an admission by Theranos, and by extension Holmes, that the test results were, and always had been, unreliable, despite Holmes's representations to investors saying exactly the opposite. Moreover, the district court reasonably concluded that the government proffered adequate evidence linking Holmes's 2016 conduct and the charged conduct, where investor-victims testified that in 2016, Holmes "downplayed" the CMS inspection and kept investors in the dark regarding the seriousness of the problems with Theranos's tests. We cannot say that the district court's decision to admit the evidence of voiding is so illogical, implausible, or without support in the record as to constitute an abuse of discretion. *See Hinkson*, 585 F.3d at 1251.

[6] We reject Holmes's assertion that we must apply *de novo* review because the district court failed to explicitly perform any Rule 403 balancing. In overruling Holmes's objection, "it is clear from the record that the district court implicitly made the necessary finding." *United States v. Ramirez-Jiminez*, 967 F.2d 1321, 1326 (9th Cir. 1992). The parties' motions in limine concerning the voiding evidence addressed Rule 403 considerations, the district court entertained oral argument on those motions, and it acknowledged the Rule 403 considerations in its order deferring ruling on the motions. The record is sufficient for us to conclude that "the court considered [Rule 403's] requirements before admitting the evidence." *United States v. Lillard*, 354 F.3d 850, 855 (9th Cir. 2003). We therefore review the district court's decision for an abuse of discretion.

IV. Rosendorff Cross-Examination

Holmes argues that the district court violated her rights under the Confrontation Clause of the Sixth Amendment when it prohibited her from cross-examining Rosendorff on certain aspects of his post-Theranos employment. As the laboratory director at Theranos, Rosendorff was "responsible for ensuring that the tests that come out of a lab are appropriate for patient care," which included monitoring the accuracy of tests.

Holmes sought to cross-examine Rosendorff about his employment at three different companies after he left Theranos, which she claimed "bore directly on Rosendorff's credibility and competence." The district court allowed cross-examination as to Rosendorff's employer at the time of trial, PerkinElmer, but prohibited further questioning as to the other employers. At the time of trial, PerkinElmer was under investigation by the same CMS investigators who had conducted the inspection of the Theranos laboratory. The district court permitted Holmes's counsel "to probe any issues of bias that may exist" regarding Rosendorff's personal stake in the PerkinElmer investigation.

The district court's ruling was well within its discretion. *See United States v. Larson*, 495 F.3d 1094, 1101 (9th Cir. 2007) (en banc) (setting forth the standard of review for a Confrontation Clause challenge to the district court's "limitation on the scope of questioning within a given area"). Holmes was allowed to question Rosendorff about the personal consequences attached to the pending CMS investigation at PerkinElmer, which was adequate to expose Rosendorff's stake in cooperating with CMS. *Id.* (identifying the relevant issue as whether "the exclusion of

evidence left the jury with sufficient information to assess the credibility of the witness" (quotation omitted)).

Holmes argues that evidence of problems elsewhere would have bolstered her defense that Rosendorff's incompetence obscured any problems in the lab from her. Even assuming this is true, "[di]strict courts have 'considerable latitude even with admittedly relevant evidence in rejecting that which is cumulative.'" *United States v. Shih*, 73 F.4th 1077, 1097 (9th Cir. 2023) (quoting *Hamling v. United States*, 418 U.S. 87, 127 (1974)). Holmes's cross-examination of Rosendorff lasted nearly four-and-half trial days, during which Holmes thoroughly attacked Rosendorff's competence. The Confrontation Clause does not require more. *See United States v. Weiner*, 578 F.2d 757, 766 (9th Cir. 1978) (per curium) ("The court in its discretion may limit cross-examination in order to preclude repetitive questioning, upon determining that a particular subject has been exhausted, or to avoid extensive and time-wasting exploration of collateral matters.").[7]

Therefore, the district court did not abuse its discretion in limiting the scope of Holmes's cross-examination into Rosendorff's post-Theranos employment.[8]

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[7] Holmes argues that Rosendorff's employment at another company, uBiome, was relevant to show Rosendorff's motive to testify favorably for the government. But the uBiome criminal investigation centered on billing practices, not the reliability of its tests. And Rosendorff was not a target of that investigation. Any relevance of this evidence would have been marginal.

[8] Holmes also argues that the government "opened the door" when it elicited testimony that the problems Rosendorff experienced at Theranos were worse than expected based on experience at other labs. But the

V. Balwani's Statement Against Interest

During trial, Holmes moved to admit excerpts of deposition testimony given by Balwani to the Securities and Exchange Commission ("SEC"), under Federal Rule of Evidence 804(b)(3), as statements against interest. On appeal, Holmes argues that the following statements should have been admitted:

> A: Around 2010, when we started engaging with the retail pharmacies, Safeway and Walgreens, I started building a financial model with the help initially from Safeway and Walgreens that I owned . . . until I left the company.
> Q: By saying you owned, you mean you were the person responsible for the company's financial projections as you just described?
> A: Financial model.
>
> ***
>
> Q: Was there anyone else from Theranos who was working on the model while you were working on it?
> A: I don't think so . . . . Nobody with direct access to the model. I don't think anybody else modified it.

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district court struck that question and answer from the record and instructed the jury to disregard it. Holmes does not persuasively explain why that instruction was inadequate. *See United States v. Saelee*, 51 F.4th 327, 345 (9th Cir. 2022) (citing *United States v. Parks*, 285 F.3d 1133, 1139 (9th Cir. 2002)).

> Q: [Holmes] was generally familiar with the kinds of inputs that went into the financial model?
> A: She may have been at some point, but I was revving the model and adding so many assumptions that she may not be familiar with all of them or even most of them.
>
> ***
>
> Q: Did she ever edit the model?
> A: To the best of my knowledge, no.

We conclude that the district court did not abuse its discretion in declining to admit these statements.

Under the exception to the rule against hearsay for statements against penal interest, the proponent of the statement must show "(1) the declarant is unavailable as a witness; (2) the statement so far tended to subject the declarant to criminal liability that a reasonable person in the declarant's position would not have made the statement unless he believed it to be true; and (3) corroborating circumstances clearly indicate the trustworthiness of the statement." *United States v. Paguio*, 114 F.3d 928, 932 (9th Cir. 1997). Neither party disputes that Balwani was unavailable after invoking his Fifth Amendment privilege against self-incrimination. To satisfy the second element, the prior statements must "solidly inculpate" the declarant—mere speculation that the statement may have subjected the declarant to criminal liability will not suffice. *United States v. Monaco*, 735 F.2d 1173, 1176 (9th Cir. 1984).

The district court correctly recognized that Balwani's statements were not solidly inculpatory because "[it] is . . . not a crime to take ownership over the creation of a financial

model." Even if a reasonable person in Balwani's position knew that Theranos's "financial projections" were in the SEC's crosshairs, he did not clearly or unequivocally take responsibility for those projections. To the contrary, when the government asked if he was the person responsible for the company's "financial projections," Balwani clarified that he was responsible for the "financial model." Balwani admitted to owning the financial *model* while expressly disclaiming responsibility for the financial *projections*, with the latter being the primary interest of the SEC and U.S. Attorney's Office. *See United States v. Oropeza*, 564 F.2d 316, 325 (9th Cir. 1977) (disagreeing that a hearsay statement was exculpatory of the defendant where the co-conspirator "averred that [the defendant] was not involved in the heroin distribution scheme, that the .357 magnum pistol belonged to [the co-conspirator], and that [the defendant] never 'possessed' the pistol" because the "statement was merely a general assertion of [the defendant's] innocence rather than an assertion of [the co-conspirator's] own culpability"); *United States v. Lynch*, 903 F.3d 1061, 1072–74 (9th Cir. 2018) (finding the statement that "[Defendant] didn't know anything about this deal" not admissible under Rule 804(b)(3) because "[s]tating the negative, that another person does not know about a crime, hardly inculpates the declarer, and certainly neither 'so far' nor so clearly that a reasonable person would not say so if the statement were false" (quotation omitted)).

We therefore conclude that the district court did not abuse its discretion in declining to admit these statements.

VI. Constructive Amendment

Balwani argues that the district court violated his Fifth Amendment rights by constructively amending the

Indictment. Specifically, Balwani claims that evidence concerning the accuracy and reliability of Theranos tests run on *conventional* technology constructively amended the Indictment, which, according to Balwani, only charged him with misrepresentations concerning the accuracy and reliability of Theranos tests run on *proprietary* technology. Upon *de novo* review, we reject this argument.[9]

Under the Fifth Amendment, "a court cannot permit a defendant to be tried on charges that are not made in the indictment against him." *United States v. Miller*, 471 U.S. 130, 143 (1985) (quotation omitted).

> Discrepancies between an indictment and evidence presented at trial amount to a constructive amendment in two general situations: first, when "there is a complex set of facts distinctly different from those set forth in the charging instrument" such that the defendant lacked notice; and second, when "the crime charged was substantially altered at trial, so that it was impossible to

[9] We generally review allegations of constructive amendment *de novo*. *United States v. Bhagat*, 436 F.3d 1140, 1145 (9th Cir. 2006). The government argues for plain error review because Balwani did not object at trial. We decline to do so because, as the district court recognized in its order denying Balwani's motion for release pending appeal, it considered the substance of this argument, including Balwani's interpretation of the scope of the indictment, in its prior order denying his motion in limine. *See United States v. Valera-Rivera*, 279 F.3d 1174, 1177 (9th Cir. 2002) (recognizing that issue is preserved for appeal where substance was "thoroughly explored" in district court (quoting *United States v. Palmer*, 3 F.3d 300, 304 (9th Cir. 1993))).

> know whether the grand jury would have indicted for the crime actually proved."

United States v. Lopez, 4 F.4th 706, 727–28 (9th Cir. 2021) (quoting *United States v. Von Stoll*, 726 F.2d 584, 586 (9th Cir. 1984)). Balwani describes this case as the first kind: By presenting evidence concerning the inaccuracy of Theranos tests run on conventional technology, the government presented a complex set of facts distinctly different from those set forth in the indictment.

We begin our analysis of Balwani's constructive amendment claim by determining what the Indictment may be fairly read to charge. In so doing, we are guided by the principle that the purpose of an indictment is "to provide the defendant with fair notice of the charges against him and to ensure that the defendant is not placed in double jeopardy." *United States v. Luong*, 965 F.3d 973, 985 (9th Cir. 2020). "[A]n indictment is not to be read in a technical manner, but is to be construed according to common sense with an appreciation of existing realities." *United States v. Anderson*, 532 F.2d 1218, 1222 (9th Cir. 1976).

In support of the constructive amendment claim, Balwani distinguishes the Indictment's background references to Theranos's "blood testing services" from the charging allegations that only identify "Theranos technology." But parsing out the charging allegations from the background allegations in the way that Balwani proposes is not the most logical way to read the Indictment. The Indictment includes multiple statements that refer not specifically to Theranos's proprietary analyzer, but rather to Theranos and its "testing services" or "technology" more generally. Importantly, the Indictment also alleges that, as part of their scheme to defraud investors, Holmes and

Balwani "represented to investors that Theranos conducted its patients' tests using Theranos-manufactured analyzers; when, in truth, Holmes and Balwani knew that Theranos purchased and used for patient testing third party, commercially-available analyzers." In other words, Balwani was charged with misrepresenting the capabilities of Theranos's testing services, and as part of the fraud against investors, those services included tests run on conventional technology. Applying basic transitive rules, the Indictment can be fairly read to charge Balwani with misrepresenting the accuracy of tests run on conventional technology.

Both the government and Balwani ascribe significance to the Indictment's inclusion of a list of specific tests for which Theranos was unable to consistently produce accurate and reliable results. The government argues that the list includes assays that were not run (and were never run) on Theranos technology, including the HIV test, meaning that the reliability of tests run on conventional technology was squarely at issue in the Indictment. On the other hand, Balwani argues that the reference to HIV testing cuts in his favor because, at the time of the Indictment, the government (incorrectly) *believed* that HIV tests were conducted using proprietary rather than conventional technology. We decline Balwani's invitation to inject a subjective component into the constructive amendment analysis because the primary consideration is not what the government believes, but rather the notice that an indictment fairly and objectively gives to the defendant. *Luong*, 965 F.3d at 985 (finding an indictment sufficient where it named the charges against the defendant even though it did not identify facts for every single element of the charge); *see also Simpson v. United States*, 289 F. 188, 189 (9th Cir. 1923) (recognizing that indictment is sufficient if "[i]ts meaning is plain" and "a

person of ordinary intelligence could not be misled as to the nature of the charge"). The Indictment plainly gave Balwani notice that he was charged with misrepresenting the accuracy of a non-exhaustive list of patient tests, regardless of which type of device the tests were run on, especially when viewed alongside the Indictment's allegation that he and Holmes fraudulently used conventional machines to run patient tests.

Therefore, Balwani's constructive amendment claim fails.

VII. *Napue* Challenge

Balwani brings a claim under *Napue v. Illinois*, 360 U.S. 264 (1959), that his due process rights were violated by the government's failure to correct allegedly false testimony given by two investor-victims, John Bryan Tolbert and Chris Lucas. According to Balwani, Tolbert's and Lucas's testimonies inaccurately describe Holmes's representations regarding Theranos's military relationships made on a December 2013 investor phone call. Applying plain error review, we reject this claim.

A. Plain error review applies to Balwani's *Napue* challenge.

Balwani failed to contemporaneously object to the aspects of Lucas's and Tolbert's testimonies that he now argues are false. Nor did he attempt to argue that, once those witnesses testified, playing the tape of the recording was necessary to impeach their credibility, refresh their recollections, or correct false testimony. *See United States v. Castillo*, 181 F.3d 1129, 1132 (9th Cir. 1999) (recognizing that "impeachment by contradiction permits courts to admit extrinsic evidence that specific testimony is false, because

contradicted by other evidence"). Indeed, Balwani raised this *Napue* claim for the first time *after* trial, at his bail motion before the district court.

Balwani nevertheless argues that the issue is preserved because his attempts to introduce the recording prior to the witnesses' testimonies put the district court "on notice" of the same *Napue* arguments he raises now. We disagree. Before Tolbert testified, the government signaled that it would not introduce the recording. Invoking the best evidence rule and the rule of completeness, Balwani urged the district court to allow him to play portions of the recording during cross-examination. But these arguments did not sufficiently bring to the district court's attention the substance of his *Napue* claim.[10] We therefore review the *Napue* claim for plain error. *See United States v. Bingham*, 653 F.3d 983, 995 (9th Cir. 2011) (holding that a *Napue* claim is reviewed for plain error when it was not raised at trial). Plain error is found where there is "(1) error, (2) that was clear or obvious, (3) that affected substantial rights, and (4) that seriously affected the fairness, integrity, or public reputation of the judicial proceedings." *United States v. Romero-Avila*, 210 F.3d 1017, 1022 (9th Cir. 2000).

[10] We are also not persuaded that the district court's rejection of Balwani's best evidence and rule of completeness arguments precluded Balwani from using the recording to impeach Tolbert or Lucas or otherwise raising *Napue* claims. To the contrary, the district court left open the possibility of introducing the tape at a later point, stating in its ruling that it "[did]n't see grounds to allow the defense *at this time* to put" the tape in.

B. Balwani's *Napue* claim fails under plain error review.

In *Napue*, the Supreme Court held that a prosecutor violates a defendant's due process rights by eliciting or failing to correct false testimony.

> To establish a *Napue* violation, a defendant must show: (1) that the testimony was actually false, (2) that the government knew or should have known that it was false, and (3) that the testimony was material, meaning there is a "reasonable likelihood that the false testimony could have affected the judgment of the jury."

United States v. Renzi, 769 F.3d 731, 751 (9th Cir. 2014) (quoting *United States v. Houston*, 648 F.3d 806, 814 (9th Cir. 2011)). Balwani argues that three statements by Tolbert and Lucas are false, each of which is discussed below. We conclude that the challenged statements are not so clearly or obviously false such that Balwani has demonstrated plain error.

First, Balwani fails to establish the falseness of Lucas's testimony that Holmes told him that the "technology was being used in the Middle East and . . . on the battlefield." Even if this testimony is inconsistent with Holmes's statements in the recording, that is insufficient to demonstrate actual falsity. Lucas testified that he had regular contact with Holmes between 2006 and 2013 leading up to his investment and that Holmes provided updates on Theranos's business activities during these conversations. Balwani has not negated the possibility that Holmes discussed Theranos's relationship with the military with

Lucas in one of these other conversations. Thus, Balwani cannot show that Lucas's statement is actually false.

Second, Balwani argues that Tolbert gave false testimony when he testified that "Holmes had claimed that Theranos' military work would advance, in a 'broadening of the[] [company's] business opportunities.'" Once again, Balwani has failed to show that this testimony is false. Although Holmes said on the call that Theranos had paused some of its military programs, she also stated that she anticipated continuing Theranos's work with the military: "[W]e will proceed with the pharmaceutical and military business in leveraging some of this infrastructure and the resources from it that we're building out now." Moreover, Tolbert did not testify that Holmes herself said the military work would "broaden" Theranos's business opportunities. Rather, Tolbert testified that he perceived Theranos's work with the military as broadening Theranos's business opportunities as compared to Theranos's work in 2006. Thus, this testimony is not "false" and cannot form the basis of a *Napue* violation.

Third, Balwani argues that Tolbert's testimony that Holmes said Theranos devices were "employed on the medevac helicopters" and "being used to kind of improve survival rates" on the December 2013 phone call was false and misleading. Balwani is technically correct: On the December 2013 call, Holmes never explicitly said that Theranos devices were *actively* employed by the military or used on the battlefield, so Tolbert's testimony that Holmes did say that is in fact "actually false." According to Balwani, this created a "false impression" that Holmes definitively stated that the military was currently using Theranos devices on the battlefield. *See Dickey v. Davis*, 69 F.4th 624, 636 (9th Cir. 2023).

Tolbert's testimony as to Holmes's statements on the December 2013 call may have been inaccurate. Although the record is unclear whether the testimony was anything more than a mistaken recollection, we assume without deciding that the government had a duty to correct the inaccurate statement. Regardless, however, Balwani's *Napue* claim fails under plain error review because the testimony did not seriously affect Balwani's substantial rights. *See United States v. Alli,* 344 F.3d 1002, 1007–08 (9th Cir. 2003). Significantly, the jury heard similar testimony from at least two other witnesses that Holmes misrepresented the use of the device on medivac helicopters. Further, any effect of the misstatement on Tolbert's testimony is mitigated by the fact that Tolbert admitted during cross examination that he did not remember Holmes's exact words during the call. And despite Balwani continually criticizing the government for not playing the recording of the call, Balwani did not attempt to use the recording to impeach Tolbert. Thus, because there was ample evidence in the record to convict Balwani, the government's failure to correct Tolbert's testimony did not affect Balwani's substantial rights. Balwani's *Napue* claim therefore fails under plain error review.

Sentencing Challenges

Defendants argue that the district court erroneously applied the lower standard of preponderance of the evidence for proving loss at sentencing, rather than the higher standard of clear and convincing evidence. This argument is foreclosed by our recent decision in *United States v. Lucas*, 101 F.4th 1158, 1163 (9th Cir. 2024) (en banc), where we held that "clear and convincing evidence is not required for factual findings under the Guidelines, even when potentially large enhancements are at stake." The district court

therefore did not err in applying the preponderance-of-the-evidence standard.

After *Lucas*, both Holmes and Balwani filed letters pursuant to Federal Rule of Appellate Procedure 28(j), arguing for the first time that the district court's findings on loss causation and number of victims do not satisfy the preponderance-of-the-evidence standard because there was no evidence introduced at trial as to five of the ten investors. Ordinarily, we do not consider arguments raised for the first time in a 28(j) letter. *See Kilpatrick v. Kijakazi*, 35 F.4th 1187, 1195 n.1 (9th Cir. 2022). But even on the merits, the argument fails.

We review factual findings made at the sentencing phase for clear error. *United States v. Buenrostro-Torres*, 24 F.3d 1173, 1174 (9th Cir. 1994). The thrust of Holmes's argument—which Balwani adopts—is that the government did not introduce evidence *at trial* that five out of the ten investor-victims relied on any alleged misrepresentation when they made their investment. But this argument rests on the faulty premise that the district court was limited to admissible trial evidence. "In making factual determinations, a sentencing judge is generally not restricted to evidence that would be admissible at trial." *United States v. Egge*, 223 F.3d 1128, 1132 (9th Cir. 2000). The test is whether the evidence bears "sufficient indicia of reliability to support its probable accuracy." *Id.* (quoting *United States v. Hopper*, 27 F.3d 378, 382 (9th Cir. 1994)).

Here, in finding that ten investors qualified as victims—and whose investments were relevant for loss purposes—the district court relied on trial testimony, prior sworn testimony given by witnesses to the SEC, and FBI memoranda summarizing statements made by investors in interviews.

See Holmes I, 2023 WL 149108, at *9; *Balwani*, 2023 WL 2065045, at *9–10. There is no basis to conclude that this evidence lacked sufficient indicia of reliability. Because the district court's factual findings are not clearly erroneous, we affirm Defendants' sentences.

Joint Challenge to Restitution Order

Finally, we address the district court's restitution order requiring Defendants to pay $452 million to fourteen victims under the MVRA. *See Holmes II*, 673 F. Supp. 3d at 1065–66. Defendants argue that the district court erred by awarding restitution based on investors' total investments, rather than the diminution in value of the shares after the fraud came to light. We review *de novo* "the legality of a restitution order" as well as "the district court's 'valuation methodology.'" *United States v. Gagarin*, 950 F.3d 596, 607 (9th Cir. 2020) (quoting *United States v. Berger*, 473 F.3d 1080, 1104 (9th Cir. 2007)). "If 'the order is within statutory bounds,' then the restitution calculation is reviewed for abuse of discretion, with any underlying factual findings reviewed for clear error." *Id.* (quoting *United States v. Galan*, 804 F.3d 1287, 1289 (9th Cir. 2015)).

The MVRA provides instructions for calculating restitution "in the case of an offense resulting in damage to or loss or destruction of property of a victim of the offense." 18 U.S.C. § 3663A(b)(1). In such cases, the offender must "return the property to the owner," *id.* § 3663A(b)(1)(A), or if return of the property lost by the victim is "impossible, impracticable, or inadequate," the offender must pay the victim "an amount equal to . . . the value of the property" less "the value (as of the date the property is returned) of any part of the property that is returned," *id.* § 3663A(b)(1)(B).

The district court determined that the twelve investors who were induced by Defendants' fraud to invest in Theranos were "victims" under the MVRA.[11] *Holmes II*, 673 F. Supp. 3d at 1055–56. It next concluded that the "property" that these victims "lost" within the meaning of the statute was the money that they invested in the company. *Id.* at 1058. Relying on *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005), Defendants argue that the relevant lost "property" was not the money that each victim invested, but rather the victim's ownership interest in Theranos.

In *Dura Pharmaceuticals*, the Supreme Court considered a claim of securities fraud under the Securities Exchange Act § 10(b), which requires a plaintiff to show both economic loss and loss causation. *Id.* at 338. The Court rejected the proposition that a plaintiff alleging a claim of fraud on the market could establish these elements merely by showing that she paid an inflated price for a security in reliance on the integrity of the market. *Id.* The Court reasoned that merely purchasing securities at a fraudulently inflated price does not establish economic loss because "at the moment the transaction takes place, the plaintiff has suffered no loss; the inflated purchase payment is offset by ownership of a share that at that instant possesses equivalent value." *Id.* at 342 (emphasis removed). Furthermore, even if the plaintiff sells the securities at a loss, this does not necessarily establish loss causation, because the lower price may reflect factors unrelated to the misrepresentations. *Id.* at 343.

[11] These represent the same twelve investors whose losses had been included in the district court's loss calculation under USSG § 2B1.1(b)(2) at sentencing.

We do not read *Dura Pharmaceuticals* to support the proposition that the victims here suffered no loss under the MVRA. Defendants' reliance on *Dura Pharmaceuticals* conflates the concept of *economic* loss with *property* loss, and the MVRA speaks in terms of the latter. *See* 18 U.S.C. § 3663A(b)(1) (directed toward cases involving "loss or destruction of *property* of a victim" (emphasis added)). Under the plain text of the MVRA, the victims need not necessarily have suffered an economic loss in order to have suffered a loss of property. This reading is consistent with the Supreme Court's decision in *Robers v. United States*, 572 U.S. 639 (2014), a case involving fraudulent loan applications to banks. The Court determined that "the property the banks lost" under the MVRA was "the money they lent to" the defendant, not the economic loss the banks suffered when they ultimately sold the houses at foreclosure sales for less than the banks were owed. *Id.* at 642; *see also id.* at 640–41 ("In our view, the statutory phrase 'any part of the property' refers only to the specific property lost by a victim . . . . Therefore, no 'part of the property' is 'returned' to the victim until the collateral is sold and the victim receives money from the sale.").

We find more merit in Defendants' argument that they are entitled to credit for the residual value of a victim's investment under the MVRA. The district court rejected this contention, reasoning that the MVRA only authorizes offsets for "property that is returned." 18 U.S.C. § 3663A(b)(1)(B)(ii). The district court reasoned that because the lost "property" was the money invested, no money was returned, and the residual value of the investment would not justify a reduction in the restitution award. But *Robers* clearly stated that the MVRA "provides room for credits against an offender's restitution obligation to prevent

double recovery to the victim." 572 U.S. at 645 (cleaned up); *see also id.* ("These provisions [of the MVRA] would seem to give a court adequate authority to count, as part of the restitution paid, the value of collateral previously received but not sold.").

The district court's failure to discount the restitution value by the residual value of the shares is at odds with the well-settled principle that "[a] district court may not order restitution such that victims will receive an amount greater than their actual losses; to do so is plain error." *United States v. Rizk*, 660 F.3d 1125, 1137 (9th Cir. 2011). This limitation stems from the basic premise that "[t]he purpose of restitution is to put the victim back in the position he or she would have been but for the defendant's criminal conduct," *United States v. Gossi*, 608 F.3d 574, 581 (9th Cir. 2010), not to provide a windfall.

Thus, although the district court properly identified the money invested as the lost property, it should have also considered possible credits against Defendants' restitution obligation—given that the victims still owned their Theranos shares—by accounting for the residual value of the shares after the fraud came to light. *See United States v. Zolp*, 479 F.3d 715, 719 (9th Cir. 2007) ("[W]hen the court confronts a 'pump-and-dump' scheme involving an otherwise legitimate company" and "the stock continues to have residual value after the fraudulent scheme is revealed, the court may not assume that the loss inflicted equals the full pre-disclosure value of the stock; rather, the court must disentangle the underlying value of the stock, inflation of that value due to the fraud, and either inflation or deflation of that value due to unrelated causes.").

But we find that any error by the district court was harmless because the district court's factual findings compel the conclusion that the victims' actual losses were equal to the total amount of their investments. Most importantly, the court found that the victims were "[un]able to liquidate their shares" after the fraud came to light. *Holmes II*, 673 F. Supp. 3d at 1059. In other words, for restitution purposes, the victims were never able to recover any amount of residual value that the stock may have retained. One investor who testified at both trials explained that he had no opportunity to sell his stock "once the cascade of negative publicity was unleashed" and that "there was never a legitimate opportunity from the company or from a third party to buy my stock." The evidence Holmes and Balwani cite—which suggests, at best, that there was some opportunity to sell shares to some parties at some unidentified time—is not enough to render the district court's finding clearly erroneous.

The significant difference in sentencing loss versus restitution was driven in part by the district court's determination that although investors were unable to sell their shares and that their shares ultimately became worthless, our case law, including *Zolp*, required the court to give Defendants credit for the residual value of the shares for the purpose of loss calculation under USSG § 2B1.1. *Cf. Holmes I*, 2023 WL 149108, at *4; *Balwani*, 2023 WL 2065045, at *4. As we just explained, the investors' inability to sell their shares effectively meant that they lost out on any residual or inherent value in those shares, which justifies restitution in the full amount of each investment to make the victim "whole." It does not necessarily follow that the same reasoning must be applied for loss calculation at sentencing, which focuses on actions of the criminal defendant. *See*

United States v. Leonard, 529 F.3d 83, 93 (2d Cir. 2008) (finding that the "district court erred in not deducting from the purchase price the actual value of" illiquid securities). The investors' inability to resell their shares would justify awarding them the full value of their investment for purposes of restitution, as that amount made them "whole," while the inability to sell shares would not necessarily require an offset of residual value for purpose of the court's punitive assessment of the defendant's conduct. *See United States v. Crandall*, 525 F.3d 907, 916 (9th Cir. 2008).

We therefore affirm the district court's restitution order in its entirety.

AFFIRMED.