REDACTED

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.

On Appeal from the United States District Court
for the Northern District of California
No. 5:18-CR-258
Hon. Edward J. Davila

BRIEF OF APPELLANT ELIZABETH A. HOLMES

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INTRODUCTION

Beginning in October 2015, the *Wall Street Journal* published several articles claiming that blood tests run by a startup company called Theranos "failed … accuracy requirements" and "pose[d] immediate jeopardy to patient health."[1] Substantial negative publicity followed. In 2018, a grand jury indicted Theranos' founder and Chief Executive Officer, Elizabeth Holmes, for wire fraud and conspiracy to commit wire fraud. The government's case largely parroted the public narrative; the government put front and center the claim that Holmes knowingly and intentionally misrepresented to investors the capabilities of Theranos' technology.

But the reality differed significantly from that narrative. Highly credentialed Theranos scientists told Holmes in real time the technology worked. Outsiders who reviewed the technology said it worked. Theranos' groundbreaking developments received many patents. And in 2015 the U.S. Food & Drug Administration (FDA) approved an assay on Theranos' proprietary technology.

[1] J. Carreyrou, *'Deficient Practices' Are Found at Theranos*, Wall St. J. (Jan. 28, 2016); *see also* J. Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015); J. Carreyrou, *Theranos Machines Failed Accuracy Test*, Wall St. J. (Apr. 1, 2016).

The government, then, faced an uphill battle proving that Holmes knowingly misrepresented the capabilities of Theranos' technology. In a case about technology and science, one would expect the government to call an expert at trial. But the government lacked the data necessary to present a comprehensive, scientifically reliable expert analysis of Theranos' technology. The government never produced its retained expert at trial after the court ordered a *Daubert* hearing.

To compensate for this deficiency, the government—with the district court's indulgence—toppled the Rules of Evidence and cast aside the Confrontation Clause. It presented quintessential expert opinion in the guise of "lay" testimony. It presented after-the-fact regulatory findings as evidence of Holmes' "state of mind." It presented Theranos' voluntary remedial decision to void test results as evidence the technology did not work. And, after having its star witness, Theranos' former laboratory director, testify that Theranos' technology was uniquely problematic, it convinced the court to forbid cross-examination on similar problems that witness experienced in other laboratories he led, violating the Confrontation Clause.

These errors—together with the exclusion of prior testimony from Holmes' co-defendant taking sole responsibility for the company's financial

model—produced an unjust conviction. Making matters worse, the court—applying a preponderance-of-the-evidence standard—ratcheted up the offense level from 7 to 33, yielding a severe 135-month Guidelines sentence. The court could not have reached this calculation under the clear-and-convincing standard that the Due Process Clause required.

This Court should reverse the conviction or at a minimum remand for resentencing.

STATEMENT OF JURISDICTION

The district court announced its sentence on November 18, 2022. 1-ER-167. On December 2, 2022, Holmes filed a notice of appeal, 55-ER-15813, which became effective when the court entered judgment on January 11, 2023, 1-ER-2. Fed. R. App. P. 4(b)(2). Holmes filed an amended notice of appeal on January 17, 2023. 3-ER-592.

ISSUES PRESENTED

I. Whether the court abused its discretion in permitting the government to prove its core allegation—that Holmes knowingly misrepresented the capabilities of Theranos' technology—with (A) undisclosed and untested expert analysis based on lost data, (B) regulatory findings, and (C) evidence that

Theranos voided test results, all of which occurred after the at-issue representations.

II. Whether the court violated Holmes' confrontation right by restricting cross-examination on a key witness' credibility, competence, and bias.

III. Whether the court abused its discretion in excluding prior testimony of Holmes' co-defendant accepting sole responsibility for Theranos' financial model.

IV. Whether the court erred in finding facts supporting the loss and number-of-victim enhancements at sentencing by only a preponderance of the evidence, increasing the offense level from 7 to 33.

STATUTES AND RULES

Relevant constitutional provisions, statutes, regulations, rules, and Sentencing Guidelines provisions are set forth in the Addendum.

STATEMENT OF THE CASE

A. Factual Background

1. Theranos and its technology

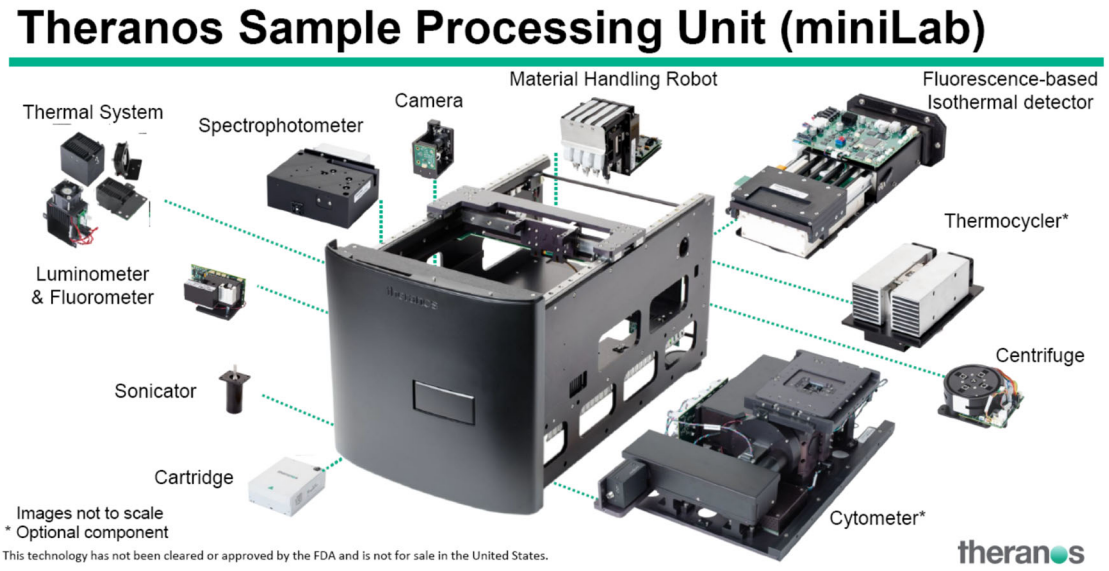
Elizabeth Holmes started Theranos in 2004 when she was nineteen years old. 38-ER-10869; 31-ER-8929. Holmes was Theranos' Chief Executive Officer; at all relevant times her co-defendant Ramesh (Sunny) Balwani was

President and Chief Operating Officer. 27-ER-7619; 40-ER-11609. Holmes' goal was to create technology to run blood tests on small samples of blood drawn from a "fingerstick," allowing for frequent testing at the point of care, such as doctors' offices or homes. 38-ER-10869; 39-ER-11094. Accomplished scientists and advisors joined the company. 17-ER-4538, 4683-4685; 18-ER-4958; 35-ER-10069. As relevant here, the company developed three forms of technology: small-sample chemical assays for testing blood; physical hardware ("devices" or "analyzers") for running the chemical assays; and associated software. 38-ER-10887-88.

Theranos' small-sample assays used four methodologies: general chemistry, immunoassays, nucleic acid amplification, and cytometry. 38-ER-11019, 11026; 53-ER-15519. Its devices' capacity to use these methodologies evolved over time. The 3-series device, known as the "Edison," was developed in the company's early years and received positive feedback. 54-ER-15536 (June 2008: "Performance design goals have been demonstrated" and "[r]esults have been excellent"). The Edison device principally ran small-sample immunoassays. 20-ER-5414-15; 38-ER-10987. Theranos deployed the Edison in clinical studies with pharmaceutical companies and research institutes and

used it to test patient samples in its clinical laboratory. 27-ER-7691-93, 7737-38; 38-ER-10941-46, 10948-52; 49-ER-14253, 14261; 53-ER-15514.

In 2010, Theranos shifted focus to a 4-series system, the "miniLab." 27-ER-7466-67; 38-ER-10989-92. The miniLab could perform small-sample testing across all four methodologies. 38-ER-10870, 10988-93; 54-ER-15537, 15761. The following depicts a 2016 version of the miniLab:



49-ER-14252.

Theranos' Research & Development (R&D) team informed Holmes in 2010 that the miniLab would perform any test outside a traditional laboratory setting. 38-ER-10991-94; 48-ER-13763-64. A senior Theranos scientist told her that year that the data showed the 4-series system's capabilities were

"fully equivalent" to testing in a traditional lab. 53-ER-15519. Two years later, Dr. Daniel Young, head of R&D, told Holmes that Theranos' proprietary tests covered over 1000 blood-test billing codes. 48-ER-13880. Theranos validated hundreds of small-sample assays in its R&D laboratory. 18-ER-4958-59; 28-ER-7877; 38-ER-10870; *see, e.g.*, 50-ER-14471-14528.

Through 2016, Theranos' innovations had generated nearly 150 issued U.S. patents, and more patent assets worldwide. 53-ER-15333; 4-ER-977. Holmes and the Theranos team proactively worked with FDA to obtain approval of the 4-series miniLab, small-sample assays, and software. 45-ER-13116; 54-ER-15761, 15753; 49-ER-14270; 54-ER-15537, 48-ER-13944. Theranos submitted 4-series data for each assay methodology in 2013 and sought FDA approval for the 4-series system in 2014, with the support of company scientists and regulatory counsel. 48-ER-13958; 54-ER-15549, 15775; 53-ER-15356, 15389, 15407; 40-ER-11452-53. FDA approved Theranos' 4-series system for the HSV-1 assay in 2015. 53-ER-15490.

2. Theranos' business relationships

Theranos formed relationships with third parties to test and deploy its technology.

First, Theranos partnered with pharmaceutical companies—including AstraZeneca, Bristol-Meyers Squibb, Celgene, GlaxoSmithKline, Merck, Novartis, Pfizer, and Schering-Plough. 49-ER-14261. Theranos employees reported to Holmes in 2009 that Theranos had "completed successes" with many of these companies, explaining that the work yielded "[g]reat" and "very promising" results. 49-ER-14266. As one example, GlaxoSmithKline wrote in 2008 that "[t]he Theranos system eliminates the need for a lab and provided quality data[.]" 45-ER-13003. Theranos' contracts with these companies generated millions of dollars in revenue. 50-ER-14470.

Second, Theranos invested millions of dollars to develop customized 4-series devices for the military. 28-ER-7762; 40-ER-11339. The company had engagements with U.S. Central Command (CENTCOM), U.S. Special Operations Command (SOCOM), and U.S. Africa Command (AFRICOM). 52-ER-14952; 53-ER-15336, 15486; *see* 28-ER-7743-45, 7757, 7771. Theranos provided customized devices to CENTCOM and SOCOM. 28-ER-7760, 7773-74. AFRICOM deployed Theranos' device in 2012 in Africa to assess potential use, telling Holmes the device "traveled well and functioned well." 52-ER-14950; *see also* 53-ER-15489, 15491; 52-ER-14948.

Third, Theranos built retail partnerships. In 2010, Walgreens and Theranos entered a contract whereby Theranos would provide blood-testing services in Walgreens stores. 45-ER-13006. In its due diligence, Walgreens hired Johns Hopkins to evaluate Theranos' technology; Johns Hopkins reported that "[t]he technology [was] novel and sound … [and could] accurately run a wide range of routine and special assays." 45-ER-13005; 25-ER-7052-58.

Due to regulatory requirements, Walgreens and Theranos shifted their relationship in 2012 to a two-phase model. 25-ER-7074; 39-ER-11054, 11058; 45-ER-13079. In Phase 1, Theranos operated centralized blood-testing laboratories. 49-ER-14271-72; 45-ER-13049; 45-ER-13126-27; 25-ER-7068-75; 39-ER-11129-32. In the anticipated Phase 2, after regulatory approval, Theranos would place its devices in Walgreens stores. 49-ER-14271-72; 45-ER-13126-27; 25-ER-7068-75; 39-ER-11129-32.

Theranos began offering blood-testing services in Walgreens stores in fall 2013. 45-ER-13120; 46-ER-13155. Theranos produced at least 8 million patient test results. 40-ER-11384. The clinical laboratories, where patient testing occurred, were distinct from the company's R&D laboratory, where it

was developing new assays. 17-ER-4488-89, 4506; 21-ER-5741-45; 39-ER-11103-04.

As Theranos told FDA, the company deployed various devices in its clinical laboratory. 49-ER-14271; 54-ER-15753. Some small-sample tests were run on the company's Edison device, after the clinical laboratory director and other scientists validated the tests for patient use. 21-ER-5714, 5896, 5899, 5743-45, 5750-51; *e.g.*, 51-ER-14857. Other tests, involving standard vein (as opposed to fingerstick) draws, were run on analyzers manufactured by third parties. 17-ER-4503-04. A third set of tests used Theranos' proprietary small-sample assays on analyzers manufactured by third parties that Theranos modified. 18-ER-4810-12; 21-ER-5840-41; 39-ER-11097.

The company viewed its ability to run small samples on modified third-party analyzers as a trade secret but disclosed such use to regulators. 53-ER-15484; 55-ER-15884; 39-ER-11099-101. That Theranos was not exclusively using its small-sample technology in its clinical laboratory was no secret, however. The company told the public it would use vein draws; Holmes told a journalist in 2014 it would take time to "bring up new and more finger-stick-based tests in our lab"; an investor acknowledged the possibility that some tests would "remain venous blood draw tests"; and Walgreens customers

sometimes had vein draws. 45-ER-13120; 46-ER-13383; 47-ER-13660; 48-ER-13937; 53-ER-15509, 15512; 48-ER-13761; 29-ER-8166-67; 36-ER-10164; 32-ER-9156; *see also* 25-ER-7123.

Balwani became the primary contact for Walgreens. 26-ER-7184, 7246. In December 2013, Walgreens and Theranos executed an agreement to facilitate opening Theranos centers in thousands of Walgreens stores over two years. 55-ER-15897, 15806; 26-ER-7248-54. In March 2014, Walgreens set a goal of rolling out services to 2500 stores over two years. 46-ER-13359. Walgreens told Holmes in September 2014 they were "making great progress in our partnership." 49-ER-14123.[2]

3. Investments in Theranos

The company raised funds by offering shares to investors. Theranos' shares were not publicly traded. 42-ER-12185-86. To purchase shares, investors had to warrant they had "substantial [private placement investment] experience." *E.g.*, 46-ER-13323. Investors acknowledged awareness that investments in Theranos were "highly speculative and involve[d] substantial risks." 46-ER-13323-24. They also "expected" that "some or all of the assumptions

[2] Theranos and Safeway also contracted to develop testing centers at Safeway stores, but Safeway never launched Theranos services to the public. 24-ER-6692-93.

underlying [Theranos'] projections will not materialize or will vary significantly from actual results." *Id.*

In late 2013, the company offered "C-1" shares to existing Theranos investors. 53-ER-15252. There were twenty-three C-1 investments. 53-ER-15335. Three witnesses testified about C-1 investments: Chris Lucas (nephew of former Theranos Board Chairman Don Lucas), Brian Tolbert (employee of Hall Group, the investment vehicle for billionaire Craig Hall), and Alan Eisenman. 29-ER-8047-8183; 32-ER-9009-9177; 34-ER-9665-35-ER-9923.

In 2014, the company offered "C-2" shares to new investors. 39-ER-11177. There were twenty-three C-2 investments. 53-ER-15335. The jury heard from representatives of three: Lisa Peterson (employee of RDV Corporation, the DeVos family's investment vehicle), Brian Grossman (managing partner at PFM Health Sciences hedge fund), and Daniel Mosley (a former partner at Cravath, Swaine & Moore). 35-ER-10004-36-ER-10372 (Grossman); 31-ER-8687-32-ER-9001 (Mosley); 29-ER-8249-30-ER-8632 (Peterson).

4. Theranos' closure

By June 2015, Theranos' laboratory leadership had transitioned away from the Edison device for patient testing. *See* 47-ER-13682; 40-ER-11402-05. Two events occurred soon thereafter that triggered substantial scrutiny

of the company. First, in October 2015, the *Wall Street Journal* began its investigative coverage. *See, e.g.*, 27-ER-7455-56; 29-ER-8310; 37-ER-10597. Second, in late 2015, the Centers for Medicare & Medicaid Services (CMS) inspected Theranos' clinical laboratory. *Infra* pp. 28-29. In January 2016, CMS issued a report finding Theranos to have violated certification conditions. 47-ER-13683. CMS later imposed sanctions. 11-ER-3022.

In response, Holmes hired a new clinical laboratory director, Dr. Kingshuk Das, and other experts to improve laboratory operations. 33-ER-9409-10, 9487-93; 34-ER-9539-40; 38-ER-10844-45. Das testified that Holmes fully supported his efforts and encouraged him to "turn over … rocks." 34-ER-9560-61, 9572, 9624-25. Holmes asked Balwani to leave the company in May 2016. 40-ER-11440-41, 11446-48; 41-ER-11653.

Notwithstanding Holmes' reform efforts, the company closed after the 2018 indictment. Holmes remained CEO until the indictment. 38-ER-10869. She never sold a single Theranos share. 16-ER-4470; 40-ER-11479. As multiple witnesses affirmed, Holmes worked tirelessly pursuing the company's mission. *See, e.g.*, 27-ER-7461; 32-ER-9017, 9069; 34-ER-9644; 38-ER-10852-53.

B. Procedural Background

1. Pre-trial proceedings

After a two-and-a-half-year investigation, a grand jury returned an indictment against Holmes and Balwani in June 2018. 13-ER-3664. The operative Third Superseding Indictment charged the following twelve counts:

- Count 1: conspiracy to commit wire fraud against Theranos investors between 2010 and 2015, 18 U.S.C. § 1349;
- Count 2: conspiracy to commit wire fraud against Theranos patients between 2013 and 2016;
- Counts 3-5: wire fraud in connection with three payments by C-1 investors in 2013, 18 U.S.C. § 1343;
- Counts 6-8: wire fraud in connection with three payments by C-2 investors in 2014;
- Counts 9-12: wire fraud in connection with patients in 2015.

13-ER-3526. The indictment alleged that Holmes and Balwani made false representations to investors about the capabilities of Theranos' analyzer; Theranos' current and future revenue; its relationships with Walgreens, the Department of Defense, and pharmaceutical companies; and its use of its proprietary analyzers to test patient samples. 13-ER-3530-32 (¶ 12).

The court severed the two cases in 2020 based on Holmes' disclosure of Balwani's abuse in their personal relationship and its relevance to her defense. 56-ER-16159 (sealed). Holmes was tried first. *Id.*

Holmes contested the government's allegation that she knowingly and intentionally misrepresented the capabilities (including the accuracy and reliability) of Theranos' technology. Before trial, Holmes moved to exclude evidence of CMS' 2016 findings as hearsay and as irrelevant and unfairly prejudicial. 12-ER-3351. The government moved to admit part of the CMS report. 11-ER-2962. The court denied Holmes' motion and granted the government's. 1-ER-209; *infra* Part I.A. Holmes also moved to exclude evidence that Theranos voided Edison test results in 2016; the court deferred ruling. 1-ER-225, 227; *infra* Part I.A.

On the expert-disclosure deadline, the government disclosed a report from a retained blood-testing expert, Dr. Stephen Master. 12-ER-3154. The court ordered the government to produce Master for a *Daubert* hearing. 9-ER-2344. But the government never produced Master, either at a *Daubert* hearing or trial.

Instead, five weeks before trial (and after the court had ordered the *Daubert* hearing), the government disclosed in a four-sentence email that it

may call Das, the clinical laboratory director from 2016 to 2018, as an expert. 8-ER-2231. Holmes moved to strike the late, inadequate disclosure. 9-ER-2236. The court deferred ruling. *See infra* Part I.A.

Holmes also moved to suppress evidence derived from Theranos' Laboratory Information Systems (LIS) database, the most comprehensive repository of patient-testing and quality-control data. 9-ER-2321, 2272; *see* 11-ER-2921; 18-ER-4773-74; 21-ER-5794-95. By trial, the LIS data had been lost, through no fault of Holmes. 1-ER-246. Although the government learned of the database in December 2016, 11-ER-2902, it took no steps to secure it until June 2018, the eve of the indictment, 11-ER-2863; 11-ER-2902; 11-ER-2882, 2884, 2890. Theranos' outside counsel produced a copy of the database shortly before the company closed. 11-ER-2919, 2860. The government was unable to access the copy, in part because it was encrypted. 11-ER-2856-57, 2893; 5-ER-1323. Government staff proposed steps for attempting to access the database, 5-ER-1335, 1331; but government lawyers took almost none of those steps, 11-ER-2898 (¶¶46-47). The court denied Holmes' motion to suppress, reasoning that [redacted] and that the government did not cause the database's loss. 56-ER-16141 (sealed).

2. Trial

The four-month trial commenced in September 2021. To prove purported misrepresentations to investors, the government called the following witnesses:

First, the six investor witnesses testified about conversations with Holmes and/or Balwani, materials they received from Holmes and/or Balwani, and the importance of various representations they claimed Holmes or Balwani made. *Supra* p. 12; *see* 46-ER-13131-34 (recording of call with certain C-1 investors).

Second, representatives of some of Theranos' business partners—Walgreens, Safeway, and three pharmaceutical companies—testified about their relationships with Theranos, Holmes, and/or Balwani. *See* 24-ER-6688-6749; 24-ER-6772-6914; 25-ER-6915-6954, 6973-7124; 26-ER-7176-7312; 22-ER-6002-6079; 28-ER-7970-29-ER-8046; 30-ER-8633-31-ER-8686.

Third, four former Theranos employees testified concerning the capabilities of Theranos' technology, principally the Edison. The government did not call the company's R&D leaders to testify to the capabilities of the miniLab at the time of representations to C-1 and C-2 investors.

Das testified (over Holmes' objection, as applicable, under Rules 401, 403, 407, and 701-702) about (1) his retrospective, comprehensive data analysis (which used the lost LIS data), (2) CMS' findings, and (3) Theranos' decision to void Edison test results. *See infra* Part I. Das provided the only comprehensive analysis of Theranos' technology.

Dr. Adam Rosendorff was Theranos' clinical laboratory director from mid-2013 to November 2014. 20-ER-5404-05, 5411. Rosendorff reported to Balwani, not Holmes. 20-ER-5413; 40-ER-11396. Rosendorff testified about certain incidents when the company investigated potentially erroneous results or other testing issues. *E.g.*, 20-ER-5482-5530; 21-ER-5735-40. The government used this testimony to argue that Holmes knew Theranos' technology did not work. *Infra* pp. 65-67. In the end, however, Rosendorff testified that he never validated tests he believed were inappropriate for patient use, never offered tests he thought were inaccurate or unreliable, and was never told by Holmes to report inaccurate results. 21-ER-5695-96, 5714; 23-ER-6368. And, on cross-examination, the defense introduced documents showing Holmes and/or others proactively addressing issues in good faith. *See, e.g.*, 47-ER-13662-72; 53-ER-15344-51, 15473-76, 15574; 46-ER-13135-47; 48-ER-13757; 49-ER-14127.

Although Rosendorff compared Theranos to other laboratories on direct examination, and relied on his experience to offer opinions, the court refused to let Holmes cross-examine Rosendorff (with one limited exception) about the poor performance and investigations of laboratories he directed after Theranos. *Infra* Part II.

Entry-level lab associate Erika Cheung testified about her brief experience at Theranos from October 2013 to April 2014. 17-ER-4480, 4702. Cheung testified about five occasions when Edison devices did not pass quality-control testing. 17-ER-4534, 4605-07, 4614-16, 4647, 4652-53. According to Cheung, she discussed these issues with scientists, including Young (an MIT Ph.D.), but was dissatisfied with their analysis. *See* 17-ER-4612-14, 4708. Cheung never reported her concerns to Holmes. 17-ER-4664; 40-ER-11385-86, 11538.

Finally, R&D scientist Surekha Gangakhedkar testified that she believed Theranos was pressuring the R&D laboratory to validate Edison tests before launching services at Walgreens. 18-ER-4883. Gangakhedkar, however, left the company before Walgreens services commenced and before the at-issue representations to investors. 18-ER-4844. Gangakhedkar's testimony otherwise supported Holmes' contemporaneous belief that "the

machines worked well." 18-ER-4930; *see* 18-ER-4850, 4853, 4926-27, 4964-66, 4969, 4971, 4974-75.

Other government witnesses included two doctors and three patients, 19-ER-5075-5133, 5133-45; 36-ER-10373-90; 37-ER-10448-60, 10460-10513, 10514-22, two other company employees, 16-ER-4302-27; 16-ER-4372-17-ER-4477; 35-ER-9986-10004; 27-ER-7453-7739; 28-ER-7742-7924, a Fortune journalist, 37-ER-10522-10638, 10682-10712, and Theranos Board member James Mattis, 19-ER-5222-20-ER-5363. The government also offered snippets of Balwani and Holmes' text-message exchanges, mostly through witnesses not party to the exchanges. *See, e.g.*, 19-ER-5196-5213; 20-ER-5366-77 (citing 47-ER-13709); 26-ER-7230-42 (citing 48-ER-13741). Despite representing before trial that Holmes would be able to cross-examine the CMS report's authors, *see, e.g.*, 11-ER-2936, 2938, 2942, 2962; 10-ER-2562, 2567, the government never called them.

The government dismissed Count 9 at trial after confessing it had not disclosed the at-issue blood test in its bill of particulars because of "confusion on the government's side" about the difference between two blood tests. 31-ER-8817; 37-ER-10712.

Holmes testified in her own defense over seven trial days. 38-10869-42-ER-12197. The defense case also featured Dr. Fabrizio Bonanni, a former Amgen executive and Theranos Board member from May 2016 to September 2018. 38-ER-10813-68. Holmes moved to admit Balwani's sworn deposition testimony concerning his sole responsibility for Theranos' financial model, but the court denied the motion. *Infra* Part III.

After deliberating for seven days, the jury returned a mixed verdict. 6-ER-1471-73. The jury acquitted Holmes on the patient-related counts: conspiracy (Count 2) and wire fraud (Counts 10-12). *Id.* The jury convicted Holmes of conspiracy to commit wire fraud as to investors (Count 1) and on the three wire-fraud counts related to C-2 investors (Counts 6-8). *Id.* The jury hung on the three wire-fraud counts related to C-1 investors (Counts 3-5), *id.*, and the court dismissed those counts, 1-ER-1.

3. Post-trial proceedings

After trial, the court denied Holmes' pending motion for acquittal, concluding a rational jury could find that Holmes and Balwani knowingly and

intentionally made misrepresentations to investors "about Theranos's technology, growth, and potential." 5-ER-1345.[3]

On November 18, 2022, the court sentenced Holmes to 135 months' imprisonment, the low end of the Guidelines range of 135-168 months calculated by the court. 1-ER-118, 163. The court reached this range by adding a 26-level enhancement to the base offense level of 7, based on factual findings made by the preponderance of the evidence related to investor loss and number of victims. 1-ER-19, 25, 29-30; *see infra* Part IV. At sentencing, Holmes submitted more than 130 letters of support; more than 30 were from Theranos employees, directors, consultants, or investors. 5-ER-1101.

The court entered judgment on January 11, 2023. 1-ER-2. Holmes is released on bail but is scheduled to report on April 27, 2023. The court denied Holmes' motion for release pending appeal on April 10, 2023. 55-ER-15886.

SUMMARY OF ARGUMENT

I. To bolster its unscientific case that Holmes knowingly misrepresented the capabilities of Theranos' technology, the government introduced evidence of three events in 2016, after any representations to investors or

[3] The court found it unnecessary to resolve Holmes' arguments that the government failed to prove the indictment allegations regarding pharmaceutical companies and the Department of Defense and that the government's contrary argument constructively amended the indictment. 5-ER-1344.

patients: (1) Das' retrospective data analysis and related testimony, (2) CMS' inspection findings, and (3) Theranos' remedial decision to void Edison test results. The admission of this evidence flouted the Federal Rules of Evidence.

A. Das' retrospective expert analysis violated Rules 701 and 702. As a lay witness, Das could offer opinions only if they were "not based on scientific, technical, or other specialized knowledge." Fed. R. Evid. 701(c). But Das' opinions and related testimony, including his retrospective Patient Impact Analysis, were based on highly specialized knowledge. Moreover, the government's untimely, bare-bones "disclosure" violated Federal Rule of Criminal Procedure 16, and the underlying data were missing, making assessing its reliability under Rule 702 impossible.

B. The CMS report and related testimony were inadmissible under Rules 401 and 403. The court admitted excerpts of the report for Holmes' state of mind. But it had no relevance to her state of mind because she received it in 2016—after any alleged misrepresentations. The report also was irrelevant because it did not assess the performance of Theranos' proprietary technology. And it was unfairly prejudicial because it encouraged the jury to convict based on regulatory violations, and because the court and government

improperly encouraged the jury to use the report to assess Holmes' earlier state of mind.

C. Finally, Rules 407 and 403 barred evidence of voiding. Because no law or regulation obligated Theranos to void *every* Edison test, the voiding was a voluntary remedial measure. The risk of prejudice substantially outweighed any probative value because voiding was irrelevant to Holmes' pre-2016 knowledge, and the jury likely was confused into thinking it was an admission that Theranos' technology did not work.

D. Because misrepresentations regarding the capabilities of Theranos' technology were central to the government's case—and its evidence on that score was otherwise unscientific and anecdotal—the erroneous admission of the 2016 evidence prejudiced Holmes' defense.

II. The court violated Holmes' confrontation right by excluding areas of cross-examination of Rosendorff, a key government witness. Rosendorff criticized Theranos' technology and compared Theranos unfavorably to other laboratories on direct examination. But the court restricted Holmes' ability to elicit on cross-examination that Rosendorff's post-Theranos laboratories suffered serious problems and that two were under federal scrutiny. This evidence called into question Rosendorff's competence and the credibility of his

opinions regarding Theranos' technology. It also exposed Rosendorff's motive to fault Holmes and cater to the government's narrative. The court's restriction of Holmes' cross-examination prejudiced her ability to defend against the government's reliance on Rosendorff to establish her knowledge that Theranos' technology (allegedly) did not work.

III. The court abused its discretion by excluding prior testimony from Holmes' co-defendant, Balwani, that he, not Holmes, was responsible for the model that generated the allegedly false financial projections given to C-2 investors. The court erred in holding that Balwani's statements were insufficiently inculpatory or trustworthy under Rule 804(b)(3). Balwani made the statements when the SEC and the grand jury were investigating the financial projections. And his statements were corroborated by the trial record. The error prejudiced Holmes' defense to this important allegation.

IV. Finally, the court erred at sentencing by finding the facts supporting its drastic, combined 26-level enhancement by a preponderance of the evidence. The Due Process Clause required the court to apply the clear-and-convincing standard. The court reasoned that the heightened standard did not apply because the enhancements were based on the extent of the conspiracy count of conviction. But neither the evidence nor the conspiracy conviction

proved reliance by the investors the court selected as "victims" or the amount of their "loss." Given the weak foundation for the court's enhancements, the clear-and-convincing standard would have made a difference.

STANDARD OF REVIEW

This Court reviews evidentiary rulings for abuse of discretion. *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1244 (9th Cir. 1997). But a district court's "interpretation" of the Federal Rules of Evidence, "including whether particular evidence falls within the scope of a given rule, is subject to *de novo* review." *United States v. Durham*, 464 F.3d 976, 981 (9th Cir. 2006). And "[w]here the district court fails to engage in necessary Rule 403 balancing, [this Court] review[s] *de novo*." *United States v. Wells*, 879 F.3d 900, 914 (9th Cir. 2018).

Non-constitutional challenges to restrictions on cross-examination are reviewed for abuse of discretion. *United States v. Larson*, 495 F.3d 1094, 1101 (9th Cir. 2007) (en banc). But whether a court violated the Confrontation Clause by excluding "an area of inquiry" is reviewed *de novo*. *Id.*

"Whether the district court violated due process by using an improper standard of proof" at sentencing is reviewed *de novo*. *United States v. Berger*, 587 F.3d 1038, 1042 (9th Cir. 2009).

ARGUMENT

I. THE COURT'S ADMISSION OF DAS' EXPERT OPINIONS, THE CMS REPORT, AND THE VOIDING EVIDENCE REQUIRES REVERSAL.

The government alleged that Theranos' technology did not work as promised. But the government's case that Theranos' technology did not work—and that Holmes knew that fact—largely rested on anecdotal evidence about clinical laboratory incidents that Theranos addressed in real time—as occurs in all laboratories. In other words, the government charged and set out to prove a scientific case, but it lacked reliable scientific evidence to prove that case.

This flaw devastated the government's case. To compensate, the government successfully encouraged a breakdown in the Rules of Evidence. The government convinced the court to admit evidence of events in 2016, *after* Holmes made the at-issue representations and *after* Theranos had stopped using its proprietary technology in its clinical laboratory: (1) Das' retrospective data analysis, (2) CMS' inspection findings, and (3) evidence of the company's remedial decision to void Edison test results. The government urged the jury to use this evidence to validate the government's otherwise patchwork, unscientific case.

None of this evidence was admissible. And all of it undermined Holmes' defense to what the government called the "underlying" allegation, 44-ER-12538: that Holmes knowingly misrepresented the technology's capabilities.

A. Background

1. Holmes' pre-trial motion to exclude the CMS inspection findings

Laboratories performing clinical diagnostic testing must be certified under and comply with regulations and conditions of certification. *See* 42 C.F.R. §§ 493.2, 493.5(c), 493.20. CMS determines compliance with those requirements.

In late 2015, CMS inspected Theranos' certified clinical laboratory. 40-ER-11405-07. CMS did not assess whether test results were unreliable or inaccurate. 11-ER-2985-86, 3013. Instead, CMS assessed Theranos' documentation of its compliance with internal policies and CMS requirements. 11-ER-2985-86.

In January 2016, CMS issued a letter and statement of deficiencies (CMS report) stating that Theranos had violated certain certification requirements. 47-ER-13683. CMS concluded that the laboratory's noncompliance

posed "immediate jeopardy to patient health and safety,"[4] *id.*, and imposed sanctions in July 2016, 11-ER-3022.

Before trial, the government noticed its intent to introduce CMS' findings and sanctions as evidence that "[Theranos'] proprietary analyzer had accuracy and reliability problems." 12-ER-3293-94. Holmes moved to exclude this evidence as irrelevant, unfairly prejudicial hearsay. 12-ER-3351. The government moved to admit the report's statement-of-deficiencies component as evidence of falsity and knowledge. 11-ER-2962.

The court denied Holmes' motion and granted the government's. 1-ER-209. It found the evidence admissible for its truth under the hearsay exception for public records, Rule 803(8)(A)(ii). 1-ER-209. It further held that the evidence was "more probative than prejudicial," and was relevant to "Holmes's state of mind … [regarding] the accuracy and reliability of Theranos' blood tests." 1-ER-207-08.

2. Holmes' pre-trial motion to exclude evidence that test results were voided

Following the CMS finding, Theranos undertook what the company called "aggressive corrective actions," including voiding test results from the

[4] "Immediate jeopardy" connotes that the lab's "noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause … serious injury or harm, or death." 42 C.F.R. § 493.2.

Edison device, which totaled 50,000 to 60,000 tests. 11-ER-3057; 33-ER-9458. In correspondence with CMS, Theranos explained it had voided those results "out of an extreme abundance of caution and based on its dissatisfaction with prior [quality assurance] oversight." 11-ER-3057.

Holmes moved under Rules 403 and 407 to exclude evidence that Theranos had voided Edison test results. 12-ER-3367. The court deferred ruling, concluding that (1) the Rule 407 objection involved "a factual dispute over the voluntariness of Theranos' decision," and (2) the Rule 403 objection required a "proffer of evidence that clearly ties the events in 2016 to the charged conduct." 1-ER-225, 227.

3. Pre-trial motion practice regarding expert testimony

a. The government produced its expert disclosures on the court-ordered deadline of March 6, 2020. 13-ER-3660, 3662; 12-ER-3219. It supplemented its disclosures in September 2020. 12-ER-3204.

The government's initial disclosure included several hybrid fact/expert witnesses, none of whom was Das. 12-ER-3219. The disclosure also included a report from Master, whom the government retained less than two-and-a-half weeks before the disclosure deadline. 12-ER-3152, 3154. Master opined that Theranos was unable "to produce accurate and reliable fingerstick

results" for six Theranos tests and that he had "questions" regarding another four tests. 12-ER-3165. Master's opinion about one assay (Vitamin D) relied on the 2016 CMS findings. 12-ER-3165-66. Other opinions rested on anecdotal evidence such as customer email "complaints." 12-ER-3168-69.

b. Holmes moved to exclude most of Master's opinions as unreliable. 12-ER-3381. The court held that Master's opinion regarding the Vitamin D assay was reliable but that it could not assess the reliability of his opinions about the remaining nine assays. 9-ER-2344. The court therefore ordered a *Daubert* hearing. *Id.*

Before the scheduled hearing, in June 2021, the government served a supplement to Master's report introducing new opinions. 9-ER-2304. The supplement purported to employ a new "sigma metrics" methodology, using data in validation reports and quality-control data provided to CMS. 9-ER-2305-07. The supplement stated that Master had reviewed a draft document prepared by Das estimating sigma metrics and concluded that Das' results were "similar" to Master's. 9-ER-2312.

Holmes moved to strike the supplemental opinions. 9-ER-2293. The court vacated the *Daubert* hearing to be rescheduled before the government

called Master. 9-ER-2268-70. But there would be no *Daubert* hearing. The government never called Master.

c. On July 29, 2021, five weeks before trial, the government disclosed for the first time its intent to call Das, Theranos' full-time clinical laboratory director from March 2016 until June 2018, as an expert. 33-ER-9409-10; 8-ER-2227. The government's "disclosure" was a four-sentence email. 8-ER-2231. The email stated that Das' anticipated testimony and the "bases for his opinions, to the extent they constitute expert opinion testimony," were contained in FBI interview memoranda, a draft Theranos document produced in discovery, and documents listed in Master's supplemental report. *Id.*

When Das became Theranos' lab director in March 2016, Theranos was no longer using the Edison for patient testing. 8-ER-2227; 47-ER-13682. In FBI interviews, Das described conducting or overseeing two retrospective analyses of the Edison while at Theranos. One was a "six sigma" data analysis that led him to conclude "the Edison devices did not perform well, and the accuracy and precision did not meet the level needed for clinical testing." 8-ER-2228. The second was a Patient Impact Assessment, involving a "retrospective analysis" of quality-control data, validation reports, and "test result distributions and calculations." 47-ER-13707-08; 33-ER-9421; *see* 8-ER-2222.

Das concluded there was a "possible patient impact for every test reported from the laboratory's [Edison] instruments." 33-ER-9457. Das told the government before trial he no longer had access to the underlying data from "Theranos' share drives" or the "LIS … data dumps on his computer." 8-ER-2229.

Holmes moved to strike the late disclosure. 9-ER-2236. The government argued that, even though Das' testimony "may sound scientific to [the court] or others in the courtroom, … he was doing the job he was hired to do" and therefore offering lay testimony. 13-ER-3507-08. The court ruled that the government's "representations" "persuaded [it] that Dr. Das may proceed" as a lay witness. 1-ER-184.

The court cautioned that "details of particular scientific procedures or analyses that would require specialized knowledge to understand and interpret—including the Six Sigma analysis—would move Dr. Das's testimony from percipient to expert," but deferred ruling "unless and until Dr. Das offers expert witness testimony at trial." 1-ER-184. The court held that "[a] *Daubert* hearing will be sufficient to address any prejudice to Holmes." *Id.*

4. Das' trial testimony

The government called Das without requesting a *Daubert* hearing. Before Das' testimony, the court heard argument regarding the admissibility of (1) the CMS report absent a sponsoring CMS witness, (2) Das' expert opinions and Patient Impact Assessment, and (3) evidence of the voiding of test results. *See* 8-ER-2123, 2117; 33-ER-9300-48. The court deferred ruling. 33-ER-9332-33, 9348.

Das then took the stand. Over Holmes' objection, 33-ER-9426, the government introduced excerpts of the CMS report. 33-ER-9422-27, 9477. Apparently compensating for its failure to produce the report's authors, the government offered, and the court admitted, the report for the non-hearsay purpose of Holmes' "knowledge and intent." 33-ER-9436; *see also, e.g.*, 33-ER-9317-18, 9435, 9438, 9477. The government read portions of the report to Das and asked what he understood them to mean. *See* 33-ER-9428-47, 9469-84. The government similarly elicited opinions on the report's findings. 33-ER-9472-73; *see also, e.g.*, 33-ER-9445-46, 9474.

The court permitted questioning about, and admitted, the Patient Impact Assessment over Holmes' Rule 702 objection. 33-ER-9339, 9452; *see* 47-ER-13707-08. Das explained that he performed "patient impact assessments

… [using] validation reports for the tests performed … quality control results and reports … [and] patient test result distributions and calculations from those." 33-ER-9421. According to Das, the Patient Impact Assessment reflected a "retrospective analysis for 2014 and 2015 [quality-control] data." 33-ER-9455. As a result of the assessment, he explained, "the laboratory … concluded that there is a possible patient impact for every test reported from the [Edison]." 33-ER-9457; *see* 47-ER-13708. Das further testified that he never resumed testing on Edison devices because he found them "unsuitable for clinical use." 33-ER-9460.

In response to questions whether he "detect[ed] errors in the patient reported test results," and whether he felt "required to take certain action pursuant to [42 C.F.R. § 493.1291(k)] and [his] professional responsibilities," Das answered yes. 33-ER-9450-51. The court then overruled Holmes' objections to the voiding evidence. 33-ER-9452.

Despite representing before trial that Holmes would be able to cross-examine the CMS report's authors, *see, e.g.*, 11-ER-2936, 2938, 2942, 2962; 10-ER-2562, 2567—the government never called them. At the close of the government's case, Holmes moved to strike the admitted excerpts of the CMS report and Das' related testimony under Rule 403, citing two concerns: (1)

the government never called the CMS witnesses and (2) the report related to Holmes' state of mind only as of January 2016, after any proven representations to investors or patients. 37-ER-10715-18.

The court denied the motion, holding that the report "revealed knowledge by Ms. Holmes[] of the state of the [clinical] Lab in late 2015 (when the CMS inspection was ongoing) and early 2016 … [which made] it more likely that Ms. Holmes also knew about the condition of the lab during the charging period." 1-ER-169. The court instructed the jury that "Trial Exhibit 4621, which contains excerpts of the January 25, 2016 CMS report was admitted for … the limited purpose of Ms. Holmes's state of mind and not for the truth of the matter asserted." 43-ER-12485.

B. Das' Testimony and Patient Impact Assessment Were Inadmissible as Lay Testimony

Das' testimony and Patient Impact Assessment were expert opinions admitted in violation of Rules 701 and 702, and were unfairly prejudicial under Rule 403. Whether those opinions fall within Rules 701 or 702 is reviewed *de novo*. *Supra* p. 26.

1. Rule 701 barred Das' testimony

a. Rules 701 and 702 govern admissibility of opinions. Under Rule 701, a lay witness may provide opinions "rationally based on the witness's

perception" only if the opinions are "not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. Rule 702, in turn, "governs admission of *expert* opinion testimony concerning '*specialized* knowledge.'" *Figueroa-Lopez*, 125 F.3d at 1246. Together, the two rules "eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing." Fed. R. Evid. 701 advisory comm.'s note to 2000 amend.; *see United States v. Cabrera*, 13 F.4th 140, 149-50 (2d Cir. 2021).

Rules 701 and 702 apply the same way to fact witnesses and retained expert witnesses. In *Figueroa-Lopez*, this Court rejected a contrary argument from the government, holding that "[t]he mere percipience of a witness to the facts on which he wishes to tender an opinion does not trump Rule 702." 125 F.3d at 1246. As the Court observed, any other conclusion would "blur[] the distinction" between Rules 701 and 702 and "subvert[]" the expert disclosure requirements in Federal Rule of Criminal Procedure 16. *Id.*; *see United States v. Millan*, 730 F. App'x 488 (9th Cir. 2018).

A party thus cannot evade Rule 702 by claiming an expert is simply "talk[ing] about his job." *Rodriguez v. Gen. Dynamics Armament & Tech. Prods.*, 510 F. App'x 675, 676 (9th Cir. 2013). In *Rodriguez*, as here, the party

disclosed retained expert opinions before trial but called at trial a "lay witness" to offer "specialized and highly technical testimony." *Id.* This Court reversed, holding that Rule 702 governed "any part of a witness' testimony that is based upon scientific, technical, or other specialized knowledge … even when the expertise involved is specialized knowledge gained as part of a witness's job." *Id.* (internal quotation marks omitted). Other circuits agree. *See, e.g.*, *United States v. Garcia*, 413 F.3d 201, 217 (2d Cir. 2005); *In re: Taxotere (Docetaxel) Prods. Liab. Litig.*, 26 F.4th 256, 264, 266 (5th Cir. 2022); *United States v. Ramirez*, 491 F. App'x 65, 74 (11th Cir. 2012).

b. The government's examination of Das was an "end-run around Rule 702 and *Daubert*." *In re: Taxotere*, 26 F.4th at 264. Jettisoning its retained expert who purported to conduct the same analysis as Das, *supra* pp. 15-16, 30-32, the government simply pivoted to a different expert in lay witness' clothing—thus avoiding *Daubert* scrutiny.

The Patient Impact Assessment, and Das' opinions that flowed from it (*see* 33-ER-9421, 9457-60; 47-ER-13707-08), reflected opinions about Theranos' technology "based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701(c). As Das explained, the assessment constituted a "comprehensive retrospective analysis."

33-ER-9457; 47-ER-13707-08. It assessed "the magnitude of [quality-control] deviations from target means." 47-ER-13708. Notably, the government's retained expert also offered retrospective expert opinions based on quality-control data. 9-ER-2312.

The court recognized before trial that Das' retrospective "sigma" data analysis would be expert testimony. 1-ER-184. But the Patient Impact Assessment was no different. That assessment, and Das' resulting opinion that the Edison was not suitable for clinical use, rested on sophisticated data analysis based on extensive scientific training—far more than rational perception of lay witnesses. This evidence far exceeded what other courts have deemed "specialized." *See, e.g.*, *United States v. Natal*, 849 F.3d 530, 536 (2d Cir. 2017) ("how cell phone towers operate"); *United States v. Haynes*, 729 F.3d 178, 194 (2d Cir. 2013) ("how [a] fuel tank functions"); *United States v. Farrad*, 895 F.3d 859, 882 (6th Cir. 2018) ("how criminals behave on social media").

The district court never offered a reasoned explanation for permitting these opinions. The government's pre-trial argument that Das would testify only to "the job he was hired to do," 13-ER-3507-08, misunderstood Rules 701 and 702. The government may not present scientific opinions without

complying with Rules 16 and 702, whether or not the opinions are part of the witness' "job." *Supra* pp. 37-38. Rule 702 applied to Das' testimony.

2. Rules 16 and 702 barred Das' expert opinions

Das' untimely expert opinions were inadmissible under Federal Rule of Criminal Procedure 16 and Rule 702.

a. Under Rule 16, the government must provide "a written summary" of expert testimony it intends to present. Fed. R. Crim. P. 16(a)(1)(G) (2021). Under the then-applicable version of Rule 16, the summary must "describe the witness's opinions [and] the bases and reasons for those opinions." *Id.*

The government's disclosure, provided nearly 17 months after the court-ordered deadline, was untimely. The four-sentence email did not summarize any opinions, and neither the email nor the cited documents disclosed the bases for Das' opinions. 8-ER-2231. The most Das said about the bases for his opinions (in an interview memorandum) was that he used no-longer-accessible Theranos data. 8-ER-2229. Without an adequate disclosure or the underlying data, Holmes could not prepare a *Daubert* attack or a substantive defense. Rule 16 barred the government from presenting Das' expert opinions. *See United States v. Lloyd*, 807 F.3d 1128, 1157 (9th Cir. 2015).

b. In all events, Das' opinions were inadmissible. Expert testimony must be based on "sufficient facts or data" and the expert must "reliably appl[y] the principles and methods" to the data. Fed. R. Evid. 702(b), (d). A court cannot test the sufficiency of *missing* data or ask whether the expert reliably applied valid methods to the data. *See, e.g.*, *United States v. Sheppard*, 2021 WL 1700356, at *4-5 (W.D. Ky. Apr. 29, 2021); *Am. & Foreign Ins. Co. v. Gen. Elec. Co.*, 45 F.3d 135, 139 (6th Cir. 1995). Nor could Holmes offer a rebuttal expert to conduct the same analysis. The court abused its discretion in admitting Das' expert opinions based on now-missing data.

C. The CMS Report and Associated Testimony Were Irrelevant and Unduly Prejudicial

1. The court abused its discretion in admitting excerpts of the CMS report and Das' related testimony. This evidence was doubly irrelevant. *See* Fed. R. Evid. 401.

First, the report was irrelevant to Holmes' state of mind at the time of the offenses. But the court admitted excerpts of the report, and expected the jury to consider them, for this purpose. 1-ER-169-70. Holmes received the CMS report in January 2016. 41-ER-11653. The government proved no representations to patients after that date. And the charged investor conspiracy concluded in 2015, with all three C-2 wires in 2014. 13-ER-3534-35 (¶¶ 20, 24).

Accordingly, the "state of mind" theory of relevance is invalid. Any notice to Holmes in 2016 cannot be transported backwards to 2014. In *Phillips v. United States*, this Court found error in the admission of documents to show knowledge of an alleged scheme to defraud, because the government had not "independently shown that [the] defendant had actual knowledge of the documents while the asserted scheme was in progress." 356 F.2d 297, 306 (9th Cir. 1965). As the Third Circuit put it, "[t]he logic of showing prior intent or knowledge by proof of subsequent activity escapes us." *United States v. Boyd*, 595 F.2d 120, 126 (3d Cir. 1978) (reversing conviction where court admitted evidence that post-dated conspiracy's conclusion to prove intent or knowledge during conspiracy).

The evidence is irrelevant for a second reason: CMS' inspection determined only whether Theranos was following the company's procedures—CMS did not assess the performance of Theranos' technology. Had the government called a CMS witness, as it promised, this would have been clear. As CMS inspector Sarah Bennett explained in deposition testimony, "[i]t's not [CMS'] job to determine whether a result is accurate." 11-ER-3013. She told the government that CMS only "looks at a laboratory's procedures" and not at "the

patient data." 11-ER-2985-86. The CMS report at most put Holmes on notice of regulatory violations, not that Theranos' technology did not work.

2. The CMS report's purported evidentiary value was substantially outweighed by the danger of unfair prejudice, confusion, or misleading the jury. *See* Fed. R. Evid. 403.

The CMS report almost certainly misled the jury. Injecting civil regulatory violations into criminal trials always risks inviting convictions on an improper basis. *See, e.g.*, *United States v. Wolf*, 820 F.2d 1499, 1505 (9th Cir. 1987); *United States v. Christo*, 614 F.2d 486, 492 (5th Cir. 1980). Before trial, the government maintained that any Rule 403 concerns were tempered because Holmes "remains free to cross-examine CMS witnesses and attempt to undercut their observations." 11-ER-2942. But the government never called the report's authors. The jury thus never heard that surveyors may "have differences of opinion." 11-ER-3009. The government's failure to call the report's authors both decreased the report's probative value and increased its unfair prejudice.

The court's holding that the report was not unduly prejudicial because it was admitted "only for state of mind" was incorrect. 1-ER-169. Das' expert testimony discussing the report was not so limited. *See, e.g.*, 33-ER-9445-46.

And, as already discussed, the court erroneously permitted the government to use the report to *retroactively* prove Holmes' state of mind with the benefit of hindsight. According to the court, even if the report were a "post-charging period event[]," it still "tend[ed] to make it more likely that Ms. Holmes also knew about the condition of the lab during the charging period." 1-ER-169. As discussed in more detail below, the government ran with that prejudicial theory, repeatedly invoking the after-the-fact CMS findings to bolster its claim that earlier-in-time anecdotes gave Holmes knowledge that the technology did not work. *See infra* pp. 49-50.

D. Theranos' Voiding of Test Results Was an Inadmissible Remedial Measure

Finally, the court abused its discretion in admitting evidence that Theranos voided test results.

1. Under Rule 407, "[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, *inter alia*, "culpable conduct" or "a defect in a product or its design." The Rule allows parties to "remedy hazardous conditions without fear that subsequent measures will be used as evidence against them." *Gauthier v. AMF, Inc.*, 788 F.2d 634, 637 (9th Cir. 1986). Where, however, a party is "legally obligated" to act, Rule 407 does not apply.

In re Aircrash in Bali, 871 F.2d 812, 817 (9th Cir. 1989). Acts are "involuntary" under Rule 407 only when legally required or mandated by a superior governmental authority. *See id.*; *see also O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir. 1990) (an "exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority"); *Herndon v. Seven Bar Flying Serv., Inc.*, 716 F.2d 1322, 1331 (10th Cir. 1983).

The government never claimed that CMS required Theranos to void tests. Nor could it: CMS inspector Bennett told the government that "Theranos made the decision to void the test results; CMS didn't tell them to do that." 11-ER-2987.

The government instead argued that two CMS regulations required the voiding: (1) 42 C.F.R. § 493.1812, which provides that "[i]f a laboratory's deficiencies pose immediate jeopardy … CMS requires the laboratory to take immediate action to remove the jeopardy"; and (2) 42 C.F.R. § 493.1291(k), which provides that "[w]hen errors in the reported patient test results are detected, the laboratory must … [i]ssue corrected reports promptly." Whether these regulations required the voiding was a question of law—not a matter of Das' personal beliefs. *See supra* pp. 44-45. But the court never answered this question.

Neither regulation rendered the voiding involuntary. Section 493.1812 required Theranos to take "immediate action" upon an immediate-jeopardy finding. But it left open what kind (and how drastic) of an action to take.

Section 493.1291(k) mandated "corrected reports" only when "errors in the reported patient test results are detected." Neither CMS nor Das detected error in *all* Edison test results. CMS inspector Bennett explained: "CMS doesn't look to the patient data. If the [quality control] is problematic, there is no way to assess whether the patient data is accurate and reliable." 11-ER-2986. And the Patient Impact Assessment found that "[t]he fraction of patient results truly impacted, and the nature and magnitude of any effect, are unknown." 47-ER-13708. Voiding *all* Edison tests thus was a remedial measure taken, as Das said contemporaneously, "out of an extreme abundance of caution." 11-ER-3057. Rule 407 barred the evidence.

2. The court also should have excluded the voiding evidence under Rule 403. Because the court failed to perform any Rule 403 balancing, 2-ER-461, this Court's review is *de novo*. *Supra* p. 26.

As the court acknowledged before trial, 1-ER-226-27, the risk of unfair prejudice was significant. Because the voiding occurred in 2016, it was irrelevant to Holmes' intent and knowledge. But the jury may well have been

confused into thinking that the company's prophylactic decision to void tests was an admission that the technology did not work. Indeed, the government specifically urged that unfair, unsupported conclusion in closing. *See infra* p. 50. The Rule 403 balance tipped sharply toward exclusion.

E. Admission of This Evidence Prejudiced Holmes

The district court did not defend any of the foregoing rulings in its order denying release pending appeal—concluding, instead, they were unlikely to result in reversal. 55-ER-15886. But the government cannot show "it is more probable than not that the error[s] [were] harmless." *United States v. Espinoza*, 880 F.3d 506, 518 (9th Cir. 2018) (citation omitted); *see also United States v. Frederick*, 78 F.3d 1370, 1381 (9th Cir. 1996) (harmlessness inquiry considers "the overall effect of all the errors in the context of the evidence introduced at trial against the defendant").

1. Absent this evidence, the government's case that Holmes knowingly and intentionally misrepresented the capabilities of Theranos' technology was extraordinarily weak. Theranos' patient testing data was gone. The government had no statistically significant way to compare Theranos' error rate to expected error rates. The government did not call its retained expert. Nor did it call Daniel Young, head of R&D—no doubt because Young's

testimony would be unfavorable to it, as Holmes' defense exhibits showed. *See, e.g.*, 48-ER-13880; 52-ER-14982. And the government presented at trial only three patient witnesses who thought their results were incorrect, out of at least eight million test results. 19-ER-5133; 36-ER-10373; 37-ER-10514.

The government thus had to rest its case about the capabilities of Theranos' technology on the testimony of three former employees: Rosendorff, Cheung, and Gangakhedkar. *Supra* pp. 18-20. The unscientific nature of this evidence (which relied on scattered vignettes and lacked comprehensive data) was a key aspect of Holmes' anticipated defense. *See* 16-ER-4293-95 (Holmes opening: "What is the evidentiary significance of 20 results in the face of 8 million results performed? How does that compare to typical error rates within a lab? Is that really meaningful evidence of fraud?").

2. The government used the late-disclosed 2016 evidence to plug this hole—highlighting the 2016 evidence in opening and closing and on cross-examination. *See Arnold v. Runnels*, 421 F.3d 859, 868 (9th Cir. 2005) ("prosecutor's emphasis on [an erroneously admitted] tape in both his opening statement and his closing argument" compelled finding of prejudice).

Critically, Das' Patient Impact Assessment constituted the *only* "comprehensive" and "retrospective" opinion on Theranos' technology in the case.

33-ER-9452; 47-ER-13707-08. It provided the scientific analysis the government otherwise lacked. The government highlighted Das' opinions in opening, telling the jury that Das "will tell, I expect, about what he saw of the miniature blood analyzer and what he told the defendant." 16-ER-4242. In closing, the government argued that Das' Assessment proved "the problems with the tests that occurred when [Theranos was] testing patients using Theranos devices," even while conceding that it did not "prove knowledge earlier on." 44-ER-12578. And it reminded the jury about Das' "conclusion" that "there were instances when the device was fundamentally flawed" and that the device was "unsuitable for … clinical use." 43-ER-12511; 44-ER-12579.

The government invoked the CMS report to bolster and vindicate its anecdotal case that Holmes knew of problems with the technology. In opening, the government emphasized that "CMS … saw firsthand the problems that Erika Cheung was raising and that Dr. Rosendorff had been raising … all along." 16-ER-4235. Cross-examining Holmes, the government asked: "Erika Cheung was right when she was raising issues about the [Edison], wasn't she? … You don't think the CMS report vindicates her in any way?" 40-ER-11538. Given the court's ruling admitting the report for Holmes' "state of

mind," the jury undoubtedly used the report to retroactively assess Holmes' knowledge at the time of the at-issue representations. *See supra* pp. 41-45.

In closing, the government invoked the voiding evidence together with the Patient Impact Assessment as proving "the problems" with the tests. 44-ER-12577-78; 43-ER-12511. Cross-examining Holmes, the government cited Theranos' 2016 voiding of Vitamin D tests as evidence that an employee "was right about problems with the Edison" in an April 2014 email. 40-ER-11557. Cross-examining another defense witness, it asked, "[Y]ou also know that the reason that the tests were voided had to do with concerns about whether those tests were accurate …?" 38-ER-10860-62.

3. In denying Holmes' motion for release pending appeal, the district court suggested, bafflingly, that none of these rulings "directly pertain[ed]" to the investor-related counts. 55-ER-15890. The indictment squarely accuses Holmes of lying to investors about the capabilities of "Theranos's proprietary analyzer," including its "accuracy and reliability problems." 13-ER-3530 (¶12(A)). The court's after-the-fact attempt to downplay the relevance of this erroneously admitted evidence was just plain wrong.

The court also stated that its rulings were harmless because "Holmes had also made several misrepresentations that do *not* turn on whether the

technology worked." 55-ER-15891.[5] But an error's harmlessness is not measured by "whether there was enough to support the result, apart from the phase affected by the error." *Kotteakos v. United States*, 328 U.S. 750, 765 (1946). Even where the remaining evidence sufficed to support the conviction, a court may be unable to "say, with fair assurance, … that the judgment was not substantially swayed by the error." *Id.* In that event, "the conviction cannot stand." *Id.*; *see United States v. Bruce*, 394 F.3d 1215, 1229 (9th Cir. 2005).

When juries render general guilty verdicts, and the indictment charges multiple means of committing the offense, evidentiary errors affecting some but not all of those means may well be prejudicial. *See, e.g.*, *United States v. Safavian*, 528 F.3d 957, 968 (D.C. Cir. 2008) (exclusion of evidence that would have "gone at least part of the way to convincing the jury" that defendant did not make false statements not harmless); *United States v. Alexius*, 76 F.3d 642, 647 & n.11 (5th Cir. 1996) (restriction of cross-examination affecting one alleged false statement not harmless where jury returned general verdict).

[5] Notably, although the court pointed to alleged misrepresentations about pharmaceutical companies in denying release pending appeal, 55-ER-15891-94, the court declined to decide whether the government had proven those misrepresentations when it denied Holmes' acquittal motion. 5-ER-1344 n.1; *see supra* p. 22 n.3.

Here, the case for prejudice is overwhelming. This Court cannot be sure about the basis for the jury's general verdict. Holmes vigorously defended against all of the government's allegations. Critically, the alleged misrepresentations regarding the capabilities of Theranos' technology were the core of the case. As the government said in closing, "[t]he whole point of the company was to develop and use this technology." 45-ER-12852. The government told the jury that these alleged misrepresentations were "sort of the underlying false statement in the case." 44-ER-12538. The government stressed that the alleged misrepresentation "about the capabilities of the analyzer, and in particular its accuracy" was "a thread through this scheme." *Id.* The government cannot walk back these statements on appeal.

Echoing this "thread" argument, the government tied other alleged misrepresentations back to the core allegation about the technology's capabilities. For example, it argued that Holmes knew she was making misrepresentations about the Walgreens relationship because she supposedly knew "the [Walgreens] relationship is destined to fail because the technology can't do what Walgreens thinks it can do." 43-ER-12498. In opening, the government said that Holmes "deceived" investors about Theranos' use of third-party testing devices because the technology didn't work. 16-ER-4223. And the

government suggested that other alleged misrepresentations served to legitimize Theranos' technology. *See, e.g.*, 44-ER-12547 (closing: Holmes made alleged misrepresentations about the military "for investors to believe that the technology worked"); 29-ER-8294 (testimony of C-2 investor: alleged representation that Pfizer validated Theranos' technology important because "we thought [Pfizer] was saying that the results were accurate"). This evidence tainted the whole case because the *government* tied the whole case to the underlying "thread" of the technology's capabilities. The district court was wrong to dismiss this as merely *Holmes'* "suggestion." 55-ER-15890.

In the end, the case was close: the jury convicted on only four of eleven counts, a classic "indicator of prejudice." *Vega v. Ryan*, 757 F.3d 960, 974 (9th Cir. 2014). The government cannot fairly assure the Court that the jury would have convicted Holmes on a record lacking the 2016 evidence.

II. THE COURT ERRED IN RESTRICTING HOLMES' CROSS-EXAMINATION OF DR. ROSENDORFF

Also critical to the government's case that Holmes knowingly and intentionally misrepresented the capabilities of Theranos' technology was the testimony of Theranos lab director Rosendorff. *Supra* pp. 18-19. The government leaned heavily on Rosendorff's testimony to persuade the jury that Holmes knew Theranos' technology did not work. The court permitted the

government to portray Rosendorff as a competent, truth-telling professional with an unblemished record. At the government's urging, the court shielded the jury from devastating evidence regarding Rosendorff's post-Theranos employment demonstrating his lack of credibility, incompetence, and bias. The court's restrictions on Holmes' cross-examination of Rosendorff prevented her from correcting the government's misleading presentation and violated Holmes' confrontation right.

A. Background

1. Rosendorff was the "highest authority under the federal regulations" in Theranos' clinical laboratory. 21-ER-5689. He was responsible for ensuring that results were accurate and reliable, and verifying and validating tests offered in the laboratory. 21-ER-5691-92, 5743-45. He approved the offering of numerous tests on the Edison.[6]

Before trial, over Holmes' objection, the court held that Rosendorff could testify to scientific issues based on his lay "background as a laboratory director." 1-ER-265; *see also* 1-ER-266 ("judgment and experience as a certified laboratory director"). Nevertheless, the court emphasized that Holmes was "entitled to explore these issues on cross-examination." 1-ER-265.

[6] *See, e.g.*, 50-ER-14529-14622; 51-ER-14625-14922; 52-ER-14925-47.

At trial, Rosendorff invoked his laboratory-director experience to opine on the technology used in Theranos' clinical laboratory. He testified that third-party analyzers had "superior performance" to Theranos analyzers, 20-ER-5461, and that he "came to believe that the Theranos results were wrong," 20-ER-5584; *see also, e.g.*, 20-ER-5458-59. As the government highlighted in closing, Rosendorff testified that he asked Holmes to delay the "commercial launch" in 2013 because he found certain tests "unreliable." 20-ER-5428-33; 45-ER-12854-85 (closing); 6-ER-1456. Rosendorff claimed he left Theranos in 2014 because, among other things, "the equipment and reagents, the platform was not allowing [him] to function effectively as a lab director" and he "felt pressured to vouch for tests that [he] did not have confidence in." 20-ER-5405; *see* 16-ER-4234 (opening); 43-ER-12495, 12504 (closing).

On direct examination, the government elicited testimony comparing Theranos to other laboratories. Rosendorff claimed that "questions about test results" were "much more frequent at Theranos" than at the University of Pittsburgh, where he previously worked. 20-ER-5480-81. Rosendorff asserted that at Theranos, unlike the University of Pittsburgh, he "felt pressured to defend the company's results to physicians." 20-ER-5480. More broadly, Rosendorff testified that, in contrast to Theranos, in his "other lab

director positions" he did not "routinely" "discuss[] taking an assay off of a particular piece of equipment because it wasn't working properly." 23-ER-6479-80.

2. Holmes sought to cross-examine Rosendorff concerning his post-Theranos tenure at three laboratories—Invitae, uBiome, and PerkinElmer.

After leaving Theranos, Rosendorff was laboratory director at Invitae. During Rosendorff's tenure, Invitae "determined that the genetic tests for 50,000 patients were subject to [a] systemic testing error, ... likely a record high for such an error," informed physicians of that error, and offered to re-test patients. 8-ER-2162; *see* 23-ER-6298. The laboratory's "quality control program"—within the purview of the laboratory director, 42 C.F.R. § 493.1407—failed to detect this "systemic error." 8-ER-2163-64.

Rosendorff next served as laboratory director at uBiome. [redacted], 56-ER-16054 (sealed), and he omitted uBiome from the resume he gave the government before trial, 8-ER-2175-78. [redacted]. 56-ER-16050, 16052 (sealed). Rosendorff told them [redacted] 56-ER-16054 (sealed). Rosendorff also said

that he had [redacted] *Id.* A grand jury indicted uBiome's founders for health-care fraud several months later—a case pending while Rosendorff testified at trial. *United States v. Apte*, Crim. No. 21-116 (N.D. Cal.).

During trial, Rosendorff was laboratory director at PerkinElmer. Months before trial, state and federal investigators found "deficient practices" in Rosendorff's lab; concluded (as CMS had with respect to Theranos) that those practices "pose[d] immediate jeopardy to patient health and safety"; and proposed sanctioning the laboratory. 8-ER-2157, 2150, 2139. Two months before trial, Rosendorff called a CMS investigator noticed as a government witness in this case and asked about the sanctions' implications for him personally; the investigator responded that Rosendorff could lose the ability to direct laboratories. 8-ER-2135, 2200; 23-ER-6467.

3. At the government's urging, the court precluded Holmes from examining Rosendorff about Invitae and uBiome. 23-ER-6454-56. As for PerkinElmer, the court permitted "limited, limited" questioning only on the issue of bias. 23-ER-6456-57, 6464-67. The court forbade PerkinElmer-related

questioning regarding "the nature of any investigation, the quality of the investigation, [or] [Rosendorff's] specific role in it." 23-ER-6457. This ruling precluded examination about the immediate-jeopardy finding or specific deficiencies. 23-ER-6458-59. The court permitted Holmes to elicit only the fact of the investigation, the overlap in CMS investigators, and testimony regarding whether those facts caused Rosendorff to skew his testimony. 23-ER-6456-63, 6467-68. According to the court, "what is really involved here is the CMS characters are the same as in Theranos." 23-ER-6462.

4. On redirect examination, the government elicited testimony that the problems Rosendorff experienced at Theranos were worse than expected based on his experience at other laboratories. 24-ER-6616. Holmes argued the government had opened the door to the excluded testimony. 24-ER-6617-18. The court bailed out the government by instructing the jury to disregard the questions and answers. 24-ER-6640. But the damage had already been done in direct examination, when Rosendorff offered similar testimony. *Supra* pp. 55-56.

B. The Court's Limitations Violated Holmes' Confrontation Right

The Confrontation Clause secures a defendant's right to cross-examine government witnesses. U.S. Const. Amend. VI; *Davis v. Alaska*, 415 U.S. 308,

316 (1974); *Delaware v. Van Arsdall*, 475 U.S. 673, 679 (1986). When it comes to defense questioning of government witnesses, "[f]ull disclosure of all relevant information concerning their past record and activities through cross-examination and otherwise is indisputably in the interests of justice." *United States v. Brooke*, 4 F.3d 1480, 1489 (9th Cir. 1993).

The court violated Holmes' confrontation right by excluding "area[s] of inquiry" highly relevant to Rosendorff's credibility, competence, and bias, requiring *de novo* review. *Larson*, 495 F.3d at 1101; *supra* pp. 53-58. "Because the trial court's rulings unnecessarily limited relevant, probative, and perhaps crucial evidence concerning the credibility of a key government witness," they violated Holmes' confrontation right. *United States v. Adamson*, 291 F.3d 606, 612 (9th Cir. 2002). That was reversible error.

1. The excluded evidence bore directly on Rosendorff's credibility and competence. Given the raft of problems that followed Rosendorff from laboratory to laboratory, one of two things must be correct. One, Rosendorff was an incompetent laboratory director. Or, two, systemic testing errors at laboratories are common. Both of those scenarios tend to exonerate Holmes. But neither was fully before the jury. Instead, exclusion of this evidence

allowed the government to hold out Rosendorff as a truth-telling, competent laboratory director who thought Theranos was uniquely problematic.

The court permitted Rosendorff to testify about the accuracy and reliability of Theranos' tests based on his experience. 1-ER-265-66. But the court's ruling hid critical parts of that experience from the jury. For example, Rosendorff criticized Theranos' quality-control testing, 20-ER-5459, but the jury did not hear that Invitae suffered a "systemic error" involving quality control that affected 50,000 results. *See supra* p. 56.

The jury also did not know that Rosendorff [redacted] 56-ER-16054 (sealed). This fact would have bolstered the notion that Rosendorff's absences from the laboratory in fall 2014 explained why Balwani told Holmes in November 2014 that the lab was a "disaster zone." 23-ER-6443-46; 47-ER-13715; *see* 40-ER-11398-11402.

PerkinElmer presents an especially glaring illustration. The jury never learned that CMS concluded, among other things, that "[t]he Laboratory Director," *i.e.*, Rosendorff, "failed to ensure that … [t]esting systems [for the COVID-19 test] provided quality laboratory results for all aspects of the testing performed; … Quality Assessment (QA) programs are maintained; …

[and] Test systems are functioning properly." 8-ER-2153. The jury also did not know that CMS' PerkinElmer investigation produced an immediate-jeopardy finding, and was unable to assess the likelihood that CMS might sanction Rosendorff personally. *Supra* pp. 57-58.

At the same time, the court permitted the government to introduce CMS' Theranos findings, including its immediate-jeopardy finding.[7] *See supra* pp. 28-29. Either Rosendorff's lab management puts patients in immediate jeopardy, or immediate-jeopardy findings are more common than the court's conflicting rulings led the jury to think. Either alternative would have materially advanced Holmes' defense.

In sum, this evidence would have cast Theranos' problems in a far different light: the jury might well have found that problems in Theranos' laboratory arose not from pressure from Holmes, as Rosendorff claimed, but from Rosendorff's incompetence. Rosendorff, after all, was the person who validated the Edison tests for clinical laboratory use, *supra* p. 54—which Das later concluded should not have occurred. 34-ER-9570. The evidence would have bolstered Holmes' defense that Rosendorff's incompetence obscured any

[7] The CMS report relied on testing data from 2014, when Rosendorff was lab director, and 2015, when Theranos continued to rely on Rosendorff's prior validation decisions. *See* 47-ER-13683; 26-ER-7323, 7334-35, 7348, 7386; 52-ER-14984-90.

problems from her. And Holmes was entitled to confront Rosendorff with this evidence to undermine his testimony comparing Theranos negatively to other laboratories.

2. Additionally, the excluded evidence was highly relevant to Rosendorff's bias. Invitae's public scrutiny, Rosendorff's firing at uBiome, and PerkinElmer's immediate-jeopardy finding provided Rosendorff with "possible motivation to falsify [his] testimony" against Holmes to shore up his professional reputation. *United States v. Harris*, 185 F.3d 999, 1008 (9th Cir. 1999). By faulting Holmes, Rosendorff deflected from his own mismanagement, both at Theranos and other laboratories. *See, e.g.*, 20-ER-5405; 22-ER-5520, 5585; 21-ER-5655-56.

Similarly, the pending investigations of uBiome and PerkinElmer gave Rosendorff powerful reason to favor the government. A defendant "must be permitted" to examine a witness concerning the "benefit or detriment to flow to a witness as a result of his testimony." *United States v. Schoneberg*, 396 F.3d 1036, 1042 (9th Cir. 2005). Any reasonable person in Rosendorff's position would believe that providing the government helpful testimony could yield benefits in the pending investigations—conducted by the same U.S. Attorney's

Office (uBiome) and a CMS inspector whom the government disclosed as a witness (PerkinElmer).

Finally, Rosendorff's material omission of his uBiome employment opened him to potential criminal liability under 18 U.S.C. § 1001. *Supra* p. 56. That action provided another reason to curry favor with the government and bore on Rosendorff's character for truthfulness. *See* Fed. R. Evid. 608.

3. The court's contrary ruling was erroneous.

First, the court stated that it excluded the Invitae evidence because it constituted "inappropriate character evidence." 23-ER-6456. But Rule 404 "does not proscribe the use of other act evidence as an impeachment tool during cross-examination." *United States v. Gay*, 967 F.2d 322, 328 (9th Cir. 1992).[8]

Second, the court appeared to invoke Rule 608(b) to bar the PerkinElmer evidence. 23-ER-6457-58. Rule 608(b) bars extrinsic evidence "to prove specific instances of a witness's conduct in order to attack or support the witness's character for truthfulness." The PerkinElmer evidence had nothing to do with Rosendorff's character for truthfulness, and Rule 608(b) has no

[8] The government ironically argued that Invitae's "deci[sion] to retest 50,000 patients" was inadmissible because it was a remedial measure under Rule 407. 23-ER-6312; *see supra* Part I.D. The court did not rely on this ground.

application to impeachment by bias or contradiction. *See* Fed. R. Evid. 608 advisory comm.'s note to 2003 amend.; *United States v. Castillo*, 181 F.3d 1129, 1132 (9th Cir. 1999) (contradiction); *United States v. Ray*, 731 F.2d 1361, 1364 (9th Cir. 1984) (bias). And the court's ruling barred more than just *extrinsic* evidence; it barred *all* evidence relevant to whole areas of inquiry. The court erred in invoking Rule 608(b).

The court alluded generally to Rule 403 considerations (which it reiterated post-sentencing, 55-ER-15893), highlighting "some cumulative nature … in all of this" and "the additional time that would be required to probe into other matters." 23-ER-6460. The use of Rule 403 to exclude evidence offered by a criminal defendant must be "cautious and sparing." *United States v. Haischer*, 780 F.3d 1277, 1281-82 (9th Cir. 2015) (citation omitted). The court threw caution to the wind.

The court's vague Rule 403 observations did not substantially outweigh the probative value of this evidence. *See* Fed. R. Evid. 403. The evidence was not cumulative: defense counsel attempted to attack Rosendorff's competence and credibility in other ways, but lacked this powerful evidence.[9] And the

[9] The court referenced the duration of Holmes' cross-examination of Rosendorff. 23-ER-6460. But "the breadth of the [cross-]examination" was driven

small amount of additional time required to present this evidence (in the context of a four-month trial) is insufficient reason to exclude highly probative evidence impeaching the credibility of a government star witness.

The court more specifically invoked Rule 403 to exclude the uBiome evidence, reasoning that the criminal investigation "did not have anything to do with the operation of the lab per se." 23-ER-6455. That was incorrect. [redacted] 56-ER-16052-53 (sealed). And Rosendorff [redacted] 56-ER-16054 (sealed). Given those facts, anyone in Rosendorff's position would be motivated to stay in the government's good graces.

C. The Ruling Prejudiced Holmes

The government cannot carry its hefty burden to show the court's unconstitutional ban on cross-examination was harmless beyond a reasonable doubt. *Larson*, 495 F.3d at 1107; *see Chapman v. California*, 386 U.S. 18, 24 (1967). The government put Holmes' representations to investors about the

by "substantial concerns about what was [elicited] in direct under *Napue* [*v. Illinois*, 360 U.S. 264 (1959)]." 23-ER-6461. For example, the government elicited on direct that "there was no formal proficiency testing process" at Theranos. 20-ER-5615; *see also* 21-ER-5664-65 (similar). On cross, Rosendorff agreed that this testimony was "inaccurate." 22-ER-5964-66.

capabilities of Theranos' technology front and center. *Supra* pp. 52-53. The government viewed Rosendorff's testimony as central to Holmes' knowledge and intent on this issue.

The government referenced Rosendorff more than any other government witness (65 times collectively) during opening and closing statements. 16-ER-4217-44; 43-ER-12486-12530; 44-ER-12533-12609; 44-ER-12817-30; 45-ER-12833-12904. In closing, the government tied Rosendorff to Holmes' "knowledge" of the truth of her statements about Theranos' technology, 44-ER-12554, and her "intent" in making those statements, 44-ER-12590; *see, e.g.*, 43-ER-12530; 44-ER-12533, 12579-80, 12585-89, 12592-93, 12602-03, 12607-08; 45-ER-12850-56, 12902-03.

In closing, the government defended Rosendorff's competence and impugned Holmes' concerns with his performance. According to the government, Holmes' "complaints with Dr. Rosendorff [were] not about inattention and a lack of diligence," but instead "that [Rosendorff] kept sounding the alarm about these unreliable tests made it inconvenient," 45-ER-12855. But had the jury known the full story, it may have viewed evidence that Holmes considered firing Rosendorff as responsible corporate stewardship—not as

evidence of guilt, as the government argued. 43-ER-12530-44-ER-12533 (closing); 16-ER-4234 (opening).

At first, the court too recognized Rosendorff's importance to the investor-related counts. In denying Holmes' acquittal motion, the court invoked Rosendorff's testimony in concluding that Holmes and Balwani "lied to investors about the capabilities, and financial security, of Theranos." 5-ER-1343. Rosendorff was the *only* Theranos witness the court named in that order. The government invoked him throughout its opposition to Holmes' acquittal motion and at oral argument. 6-ER-1456, 1462-64, 1402-03. After Holmes previewed her appellate arguments, the court pivoted, attempting to dismiss Rosendorff's testimony as "substantially attenuated" from "Holmes' varied misrepresentations to investors." 55-ER-15893. That pivot cannot undo the court's prior (correct) recognition of Rosendorff's significance to the counts of conviction. Reversal is required.

III. THE COURT ABUSED ITS DISCRETION IN EXCLUDING CRITICAL TESTIMONY FROM BALWANI

The government also emphasized a related allegation: that Holmes provided misleading revenue projections to C-2 investors. But the jury never heard that Balwani admitted under oath that he, not Holmes, was responsible

for the model that generated the projections. The court's erroneous exclusion of Balwani's statement against interest severely harmed Holmes' defense.

A. Background

1. The indictment alleged in relevant part that Holmes misrepresented that Theranos (1) "would generate over $100 million in revenues" in 2014 and (2) "expected to generate approximately $1 billion in revenues in 2015." 13-ER-3530 (¶ 12(B)).

The first half of the allegation fell apart at trial. Theranos had over $160 million in revenue in 2014. 46-ER-13158; *see* 16-ER-4429-31, 4460. Theranos recorded that revenue as "deferred" revenue, but it was still revenue. 46-ER-13158; *see* 16-ER-4429-31, 4460. C-2 investors knew that Theranos recorded revenue in 2014 as deferred revenue. 31-ER-8893-94; 30-ER-8632.

The government thus relied heavily on the second half of this allegation: that Holmes misrepresented expected 2015 revenue in projections provided to C-2 investors. Each of the three C-2 investor witnesses testified about these projections. 29-ER-8298-8300; 31-ER-8730-31, 8747, 8750; 35-ER-10080-82.

The projections resulted from a financial model based on various assumptions, including related to Walgreens. 35-ER-10041-42; 36-ER-10290,

10303-04, 10365. Holmes defended this allegation at trial in large part on the ground that Balwani created and handled the financial model. 39-ER-11225-26 (Holmes' testimony that Balwani generated projections from model and shared both with investors); 44-ER-12763 (defense closing: "preparing these financial projections … was not Ms. Holmes's province. [That] was done by Mr. Balwani").

2. A critical piece of Holmes' defense was Balwani's sworn deposition testimony that he, not Holmes, bore sole responsibility for the financial model. Holmes moved under Rule 804(b)(3) to introduce testimony that Balwani gave to the SEC in August 2017.[10] Holmes sought to admit Balwani's testimony that he "started building a financial model [in 2010] … that he owned," and that he was "responsible for," 6-ER-1625; that no one "else from Theranos … was working on the model" and "[no]body else modified it," 6-ER-1618; that he was "revving the model and adding so many assumptions that [Holmes] may not [have been] familiar with all of [the assumptions] or even most of them," 6-ER-1619; and that Holmes did not "ever edit the model," *id.*

[10] Holmes also moved under Rule 804(b)(1) but is not renewing that argument on appeal.

The court found that Balwani was "unavailable" under Rule 804(a) because he would invoke his Fifth-Amendment privilege. 1-ER-173. But the court nonetheless denied the motion, concluding that Balwani's statements were not sufficiently inculpatory and the record did not contain corroborating circumstances indicating the trustworthiness of his statements. 1-ER-177-80.

B. The Court Erroneously Excluded Balwani's Statements Under Rule 804(b)(3)

A hearsay statement is admissible under Rule 804(b)(3) if (1) the declarant is unavailable; (2) "a reasonable person in the declarant's position would have made [the statement] only if the person believed it to be true because, when made it … had so great a tendency to … expose the declarant to civil or criminal liability;" and (3) it is "supported by corroborating circumstances that clearly indicate its trustworthiness." Fed. R. Evid. 804(b)(3). The court abused its discretion in concluding the statements were insufficiently inculpatory or trustworthy under elements (2) and (3).

1. Balwani's statements were inculpatory

The court's ruling that Balwani's statements were insufficiently inculpatory misconstrued Rule 804(b)(3). In determining whether a statement is against the declarant's interest, courts consider the perspective of a "reasonable person in the declarant's position." Fed. R. Evid. 804(b)(3)(A); *United*

States v. Magana-Olvera, 917 F.2d 401, 407 (9th Cir. 1990). "Rule 804(b)(3) is founded on the commonsense notion that reasonable people, even reasonable people who are not especially honest, tend not to make self-inculpatory statements unless they believe them to be true." *Williamson v. United States*, 512 U.S. 594, 599 (1994). "The word 'tending' broadens the phrase, so that the statement need not be a plain confession making the difference between guilty and not guilty." *United States v. Paguio*, 114 F.3d 928, 933 (9th Cir. 1997).

Any reasonable person in Balwani's shoes would understand that his statements to the SEC "tended to" subject him to civil or criminal liability. Balwani had ample notice that the U.S. Attorney's Office and SEC were then investigating Theranos' financial projections. In November 2015 and February 2016, while Balwani was still at Theranos, the SEC subpoenaed Theranos for, among other things, "all communications with Theranos Series C-2 investors," information regarding "projected revenues," Theranos' financial statements, and certain of Balwani's communications. 6-ER-1603-04; 6-ER-1573-74. In January 2016, Theranos learned that a grand jury was investigating possible fraud-based offenses. 6-ER-1539. The grand jury subpoenaed "[w]ith respect to any securities offering, a copy of the prospectus and any other offering materials used," 6-ER-1540, which would have included the projections.

On these facts, any reasonable person in Balwani's shoes would appreciate that Theranos' financial projections were in the grand jury's and SEC's crosshairs. Indeed, the mere fact that the SEC was asking about the financial model would alert any reasonable person that taking responsibility for the model could subject him to liability. Under these circumstances, a reasonable person would not have made these statements unless he believed them to be true.

So too, a reasonable person would not have testified that Holmes did not edit the model or understand many of its assumptions unless that were true. *Paguio* is instructive. There, the defendant's father admitted to preparing false tax returns and engineering a fraudulent loan application and added that his son had "nothing to do with it." 114 F.3d at 933. The district court admitted under Rule 804(b)(3) the father's admission to the crimes but excluded his exoneration of his son. *Id.* at 931-32. This Court reversed, holding that the entire statement was against interest. As the Court explained, by stating that his son was not involved, "[t]he father admitted not only participation but leadership," which "has always been seen as especially bad." *Id.* at 933-34. Here, Balwani took sole leadership responsibility for Theranos' financial model, rather than trying to "shift blame" to Holmes. *Id.* at 934 (citation omitted).

The court held that Balwani's statements were not against interest because it is "not a crime to create a financial model [or] to take ownership over the creation of a financial model." 1-ER-179. But a declarant need not confess to a crime for a statement to be against interest; "remarks that 'tend to subject' the declarant to criminal [or civil] liability" suffice. *Magana-Olvera*, 917 F.2d at 407 (citation omitted).

2. The record corroborates Balwani's statements

The court also abused its discretion in determining that the record does not contain corroborating circumstances that "clearly indicate" the trustworthiness of Balwani's testimony. 1-ER-180. The court based this conclusion on two pieces of evidence: a May 2012 text message from Holmes to Balwani stating "they needed to 'work together on the rev piece'" and Balwani's SEC testimony that "he gave Ms. Holmes access to the models and asked her to make edits." *Id.* Neither supports the court's conclusion.

First, an ambiguous text message about the "rev piece," sent years before the at-issue projections, in no way suggests that Holmes accessed or understood the financial models. To be sure, on cross-examination Holmes said it could mean "revenue," even though she thought it meant technology "revision." 40-ER-11595-96. But working on "revenue" does not connote working

on a financial model to *project* future revenue. No evidence suggests Holmes contributed to the at-issue model or projections.

Second, the court's invocation of Balwani's testimony that he gave Holmes access to the model ignores the rest of his testimony. Balwani's full statement was that he once made a version of the model for Holmes to edit but he "[did not] think she ever did because [he] continued with [his] assumptions and [he] never even looked at that model." 6-ER-1619. When the SEC asked Balwani whether Holmes edited the model, he answered no. *Id.*

Other evidence the court ignored suggested that Balwani was responsible for the model. Grossman, a C-2 investor, emailed Balwani for access to the model. 46-ER-13389. Mosley, another C-2 investor, told the government he discussed his questions about the 2015 projections with Balwani. 31-ER-8891-92. A Theranos Board member testified that Balwani reviewed "financial forecasts" during Board meetings. 19-ER-5254, 5318-19.

Balwani's testimony had other indicia of trustworthiness. He had personal knowledge of the information, gave the statements voluntarily and under oath, and accepted responsibility. These facts corroborate the trustworthiness of his testimony. *See United States v. Johnson*, 767 F.3d 815, 825 (9th Cir.

2014) (declarant's statements trustworthy when made with personal knowledge and provided voluntarily).

C. Exclusion of Balwani's Statements Prejudiced Holmes

The government cannot carry its "burden of persuasion with respect to proving that the error was harmless." *United States v. Mitchell*, 172 F.3d 1104, 1111 (9th Cir. 1999). The 2015 financial projections were key to the government's case and the counts of conviction. The government highlighted them in opening, 16-ER-4243, closing, 44-ER-12565, and rebuttal, 45-ER-12902. The district court had to recognize in denying release pending appeal the "pertinen[ce]" of this evidence to the investor counts of conviction. 55-ER-15892.

The court nevertheless brushed aside any error as harmless, reasoning that this alleged misrepresentation "was not a necessary element of the government's case, given the other misrepresentations [Holmes] had made to investors." *Id.* That improperly morphs harmlessness review into a sufficiency-of-the-evidence test. *See supra* p. 51. The Court cannot know which representations the jury found false or misleading. *See supra* pp. 50-53. The C-2 investor witnesses received the projections, *see supra* p. 68, whereas the C-1 investor witnesses (who invested earlier in time) did not. And the jury

convicted Holmes of wire fraud with respect to the C-2 investors but hung with respect to the C-1 investors. That fact by itself should defeat a conclusion of harmlessness. *See Paguio*, 114 F.3d at 935.

Balwani's testimony is compelling evidence corroborating Holmes' defense that she did not intend to defraud investors with the financial projections or conspire with Balwani to do so. No other evidence before the jury on this issue had similar evidentiary weight.[11] The jury surely would have deemed Balwani's *inculpatory* testimony more persuasive than Holmes' *exculpatory* testimony. *See United States v. Benveniste*, 564 F.2d 335, 342 (9th Cir. 1977) (reversing conviction where exclusion of statement against interest rendered entrapment defense "far less persuasive than it might have been"). The Court should reverse.

* * *

Even if the foregoing errors and restrictions on cross-examination were harmless in isolation, their cumulative and compounding effect was prejudicial. *See Frederick*, 78 F.3d at 1381. The Court should reverse for this reason as well.

[11] The government in closing acknowledged it was "fair" to say Balwani handled the finances "more than Ms. Holmes," 43-ER-12521, but claimed "the division [in roles] wasn't a clear line," 43-ER-12520-21. Balwani's testimony contradicted this assertion.

IV. AT A MINIMUM, THE COURT SHOULD REMAND FOR RESENTENCING

At sentencing, the district court applied a 26-level Guidelines enhancement, adding more than 10 years to what otherwise would have been a 0-7 month range. It did so by making factual findings about the number of victims and the amount of loss by a mere preponderance of the evidence, based in large part on extra-record and untested evidence such as government interview memoranda. That was error: under this Court's precedent, the court needed to find the facts supporting its severe enhancement by clear-and-convincing evidence. The result of this error is an excessive 135-month term of imprisonment. That is 27 months *higher* than what the Probation Office recommended, for a woman who—unlike other white-collar defendants—neither sought nor gained any profit from the purported loss and was trying to improve patient health. At a minimum, this Court should remand for resentencing.

A. Background

1. Under the Guidelines, a defendant convicted of wire fraud and wire-fraud conspiracy begins with a base offense level of 7. United States Sentencing Guidelines ("U.S.S.G.") § 2B1.1(a)(1). The court may then apply an enhancement for "actual loss"—that is, the "reasonably foreseeable pecuniary harm that resulted from the offense." *Id.* § 2B1.1(b)(1) & cmt. n.3(A)(i). To

prove actual loss, the government must show that a defendant's alleged misrepresentations were both the but-for and proximate cause of each investor's loss. *See United States v. Lonich*, 23 F.4th 881, 916 (9th Cir. 2022); *United States v. Hicks*, 217 F.3d 1038, 1048-49 (9th Cir. 2000). The government must also quantify the loss; in cases involving an "otherwise legitimate company" such as Theranos, actual loss is not simply the value of investors' stock, but the "inflation of that value due to the fraud." *United States v. Zolp*, 479 F.3d 715, 719 (9th Cir. 2007). The court may also add an enhancement for the number of "victims," defined as anyone who suffered actual loss. U.S.S.G. § 2B1.1(b)(2) & cmt.1.

2. In calculating Holmes' Guidelines range, the Presentence Report ("PSR") relied on a spreadsheet produced by the government listing twenty-nine C-1 and C-2 investors. PSR add. ¶ 7. The PSR assumed that their loss was the entire value of their investments—$730 million—and counted all twenty-nine investors as victims. *Id.* The government urged the same approach. Alternatively, the government offered the report of an expert named Carl Saba who calculated investors' net loss by subtracting various estimates of Theranos' value from their investments, and urged the court to use Saba's estimates for all 29 investors. 3-ER-779-80, 596.

At sentencing, the court rejected the all-or-nothing approach, concluding that it needed to find loss causation on an investor-by-investor basis. 1-ER-103-04. The court identified 10 investors whom it believed, based on a review of interview memoranda and other documents provided by the government, had "relied on or reviewed the Theranos misrepresentations propagated by Defendant's conspiratorial conduct": Hall Group, Richard Kovacevich, Lucas Venture Group (LVG), Mendenhall TF Partners, Black Diamond Ventures (BDV), Peer Ventures Group (PVP), PFM Funds, Mosley Family Holdings, RDV Corporation, and Rupert Murdoch. 1-ER-14.

By selecting exactly 10 "victims," the court was able to impose a 2-level enhancement for 10 or more victims under section 2B1.1(b)(2). Of these 10 "victims," only 3 related to the wire-fraud counts of conviction—PFM (Count 6), Mosley (Count 8), and RDV (Count 7). Two were investors with respect to whom the jury hung—BDV (Count 4) and Hall Group (Count 5). 6-ER-1471-72. The remaining five were not the subject of any wire-fraud count.

To calculate the loss amount, the court offset the 10 victims' investments by the value of their stock as estimated by Saba. 1-ER-19. The court thus found by a preponderance of the evidence a total loss amount of $120,146,247. *Id.* This yielded an additional 24-point enhancement.

Based on a total offense level of 33 and a criminal history category of I, the court determined a Guidelines range of 135-168 months' imprisonment and imposed a sentence of 135 months. 1-ER-30, 118, 163.

B. The Court Was Required To Find the Facts Supporting Its 26-Level Sentencing Enhancement by Clear-and-Convincing-Evidence

The court's 26-level sentencing enhancement turned almost entirely on its loss calculation, which accounted for 24 points. Over Holmes' objection, the court ruled that the government need only prove loss by a preponderance of the evidence.[12] 1-ER-103-04, 13. In doing so, the court violated Holmes' due process rights and this Court's precedent.

1. Although courts ordinarily must find facts supporting a sentencing enhancement by a preponderance of evidence, this Court requires a clear-and-convincing standard when the disputed enhancements would have an "extremely disproportionate effect on the sentence relative to the offense of conviction." *United States v. Jordan*, 256 F.3d 922, 926 (9th Cir. 2001); *see also United States v. Garro*, 517 F.3d 1163, 1168-69 (9th Cir. 2008). To determine whether enhancements' effect is "extremely disproportionate," this Court

[12] The court's ruling also affected the 2-level victim-count enhancement, because a "victim" is anyone who sustained actual loss. § 2B1.1 cmt. n.1.

considers six non-exhaustive ("*Valensia*") factors. *Jordan*, 256 F.3d at 928 (listing factors).

In practice, the analysis turns primarily on factors five and six—whether the enhancement is four or more levels and whether it more than doubles the length of the sentence, respectively. *See United States v. Valle*, 940 F.3d 473, 479 (9th Cir. 2019). Here, without the enhancements, an offense level of 7 yielded a Guidelines range of 0-7 months. The loss enhancement alone increased Holmes' offense level by 24 points and the lower end of her sentencing range by 108 months. Thus, factors five and six straightforwardly require application of the clear-and-convincing standard.

2. Contrary to the court's conclusion, *Valensia* factor four does not change this analysis. Under this factor, "[t]he fact that an enhancement is based on the extent of a conspiracy for which the defendant was convicted weighs heavily against the application of the clear and convincing evidence standard of proof." *United States v. Riley*, 335 F.3d 919, 926 (9th Cir. 2003). As this Court recently explained, this factor "is just an example of another broader principle: if a defendant has already been convicted of certain conduct … enhancements that are based on the conduct of conviction do not require proof by clear and convincing evidence." *Lonich*, 23 F.4th at 913.

The defendants in *Lonich* were convicted of conspiracy to commit bank fraud after they (1) fraudulently induced a bank to approve excessive loans, and (2) induced the bank to approve loans to a sham company. *Id.* at 889. Federal and state regulators later gave the bank the lowest possible rating short of closing it. *Id.* at 890. Shortly thereafter, the bank failed and its assets were transferred to federal regulators. *Id.* At sentencing, the government argued, and the district court agreed, that the defendants' crimes caused the bank's collapse. *Id.* at 908. There, as here, the defendants' Guidelines ranges were driven primarily by the court's loss calculation, representing losses to the federal government because the bank collapsed. *Id.* Invoking *Valensia* factor four, the government argued that the preponderance standard sufficed because the enhancement reflected the extent of the defendants' conspiracy. *Id.* at 915.

This Court rejected that argument for two reasons. First, the loss calculation included losses related to uncharged and acquitted conduct. *Id.* Second, the case involved a "substantial intermediate causation question," as the loss calculation rested on the theory that the defendants caused the bank's collapse. *Id.* Yet, "[t]he jury's guilty verdicts [did] not compel [that] conclusion," as the jury did not hear evidence regarding why the bank failed. *Id.*

Thus, it could not be said that the defendants had "ample opportunity at trial to challenge the government's evidence of the extent of losses caused by the conspiracy." *Id.* (quoting *United States v. Treadwell*, 593 F.3d 990, 1001 (9th Cir. 2010)).

The point of factor four, the Court explained, is that due process concerns associated with disproportionately large sentencing enhancements are diminished when those enhancements are grounded in conduct for which a jury convicted the defendant beyond a reasonable doubt. *See id.* at 913. Which losses fall within the scope of a conspiracy, for purposes of this factor, is necessarily limited by the indictment allegations, the trial evidence, and the jury's verdict. *Cf. Garro*, 517 F.3d at 1169 (preponderance standard was appropriate because the indictment charged defendant with raising $37.5 million dollars through fraud); *Treadwell*, 593 F.3d at 1001 (preponderance standard sufficed because the amount-of-loss finding was "based on the evidence presented at trial"), *overruled in part on other grounds by United States v. Miller*, 953 F.3d 1095 (9th Cir. 2020).

3. *Lonich* requires application of the clear-and-convincing standard here. For two reasons, the jury's conspiracy verdict does not establish that Holmes caused the loss found by the court at sentencing.

First, the government did not prove at trial that all Theranos investors received the same information from defendants or that they invested in reliance on the same information. In fact, the evidence showed the opposite was true: Theranos was a closely held corporation, and investors had varying levels of access to and information about the company—both from the different investment processes used by different investors and from their roles. For example, Kovacevich, one of the ten investor "victims," was a member of Theranos' Board of Directors. 19-ER-5284; 28-ER-10839.

The government introduced *no evidence* at trial as to the reasons why five of the ten "victim" investors—Mendenhall TF Partners, Kovacevich, PVP, LVG, and Murdoch—purchased Theranos shares. That is why the court had to rely at sentencing on extra-record statements (such as testimony from other proceedings or FBI interview memoranda) that were not subject to cross-examination by Holmes, 1-ER-21 (Mendenhall); 1-ER-23 (Kovacevich); 1-ER-22 (PVP, LVG, Murdoch). Because none of this evidence was introduced at trial, Holmes lacked "ample opportunity" to challenge it. *Treadwell*, 593 F.3d at 1001.

In rejecting the clear-and-convincing standard, the court reasoned that this case bears closer resemblance to *United States v. Laurienti*, where the

preponderance standard sufficed for the losses caused by the defendants' pump-and-dump scheme. 611 F.3d 530 (9th Cir. 2010). But the "mass-marketing" scheme in *Laurienti* affected all victims equally: the defendants "artificially inflated" the price of stocks through a pump-and-dump scheme and the brokers failed to disclose bonus commissions. *Id.* at 537, 553-54. Under those circumstances, "it [was] reasonable to infer that all clients of Defendants who purchased the house stocks were duped by the conspiracy." *Id.* at 557. The record here does not permit such an inference.

Second, as in *Lonich*, the reasons each investor invested in Theranos is a causal inquiry "thoroughly disconnected from the jury's verdict." 23 F.4th at 915. To prove wire fraud, the government did not need to show that any victims relied on Holmes' alleged misrepresentations. *See Neder v. United States*, 527 U.S. 1, 25 (1999). In fact, the government moved *in limine* to preclude Holmes from arguing that "the victims did not in fact rely" on her alleged misrepresentations. 11-ER-2955; *see also* 29-ER-8224 (government mid-trial argument: "We don't need to prove reliance."). The district court agreed in a pre-trial ruling: "[R]eliance upon the defendant's misrepresentations has no place in criminal fraud cases." 1-ER-270. Having successfully argued that

investor reliance was irrelevant, the government cannot now suggest investor reliance is within the scope of the jury's verdict.

What is more, two other "victims" found by the court—BDV and Hall Group—were investors with respect to whom the jury hung. *See supra* p. 21. The verdict by definition does not establish loss causation for these investors.

In short, *Valensia* factor four is inapplicable on these facts. Given the dramatic increase in Holmes' offense level and Guidelines range resulting from the loss and victim-count enhancements, the Due Process Clause requires the clear-and-convincing standard. U.S. Const. Amend. V.

C. The Court's Application of the Wrong Standard Requires Resentencing

The court's error undoubtedly affected the sentence. The Guidelines calculation drove the court's sentencing decision. The court ignored Holmes' argument that the Guidelines' excessive focus on loss produces sentences unmoored from the objectives of section 3553(a). *See* SENT-00133 (sealed); *see, e.g.*, *United States v. Corsey*, 723 F.3d 366, 380 (2d Cir. 2013) (Underhill, J., concurring) ("The higher the loss amount, the more distorted is the guideline's advice to sentencing judges."). And the court barely engaged with Holmes' argument that the Guidelines, as applied by the court, produced an excessive sentence on the facts of this case—where Holmes, unlike most fraud

defendants, was not motivated by greed; where Holmes led serious efforts to root out and correct problems; where Holmes suffered substantial trauma throughout the relevant time period; and where Theranos' sophisticated investors acknowledged significant uncertainty in their investments. SENT-00083-91, 00117-20 (sealed). Once the court calculated a 26-level enhancement and the resulting Guidelines range, the work it did was basically done.

When district courts apply the wrong evidentiary standard at sentencing, this Court does not engage in "guesswork" as to what the district court might have found by clear-and-convincing evidence. *United States v. Hymas*, 780 F.3d 1285, 1292 (9th Cir. 2015). Remand is required.

The clear-and-convincing standard would have made a significant difference. The court could not possibly have found that the alleged misrepresentations were the but-for and proximate cause of each investor's loss by clear-and-convincing evidence. For example, the court counted as victims investors who "relied on *or reviewed*" the alleged misrepresentations. 1-ER-14 (emphasis added). But evidence of reliance—not mere review—is required to prove but-for causation. *See United States v. Stein*, 846 F.3d 1135, 1153 (11th Cir. 2017).

Three additional examples—Rupert Murdoch, RDV, and Black Diamond Ventures—illustrate the evidentiary gaps in the government's proof:

Murdoch invested $124,999,997. 4-ER-844. The only evidence the court cited regarding the cause of this investment is the 2017 SEC testimony of Murdoch's chief of staff, Natalie Ravitz. But Ravitz testified that Murdoch "had already, basically, agreed to invest before [she and Murdoch] even were able to sit down with [Holmes and Balwani] personally." 4-ER-821. Ravitz guessed the two "most important factors" in Murdoch's decision were: (1) his interest in "the area" of health and wellness and (2) the involvement of other investors he "respected." 4-ER-825. And the government produced no statement from Murdoch himself.

RDV, an investment vehicle owned by the DeVos family, invested $99,999,984. 4-ER-844. The court relied exclusively on Lisa Peterson's trial testimony for its loss causation finding. But Peterson, a manager at RDV, had no investment decision-making authority and was not privy to discussions among those who did. 29-ER-8325; 46-ER-13214, 13225, 13230, 53-ER-15353.

[redacted] SENT-00161-62 (sealed). But

it was signed by an attorney with no personal knowledge and failed to identify any specific misrepresentation RDV relied upon or the circumstances of its reliance—hardly clear-and-convincing evidence.

Black Diamond Ventures invested $5,349,900. 4-ER-844. Evidence regarding this investment came from the trial testimony of its founder and managing director, Chris Lucas (nephew of Theranos' chairman Don Lucas). 1-ER-22. The court relied on Lucas' statement that a *Wall Street Journal* article touting Theranos' blood-testing processes was "important" to his investment decision. 32-ER-9028-31. But Lucas testified that Holmes' positive characteristics and vision also were important to his investment decision. 32-ER-9069. So too, the involvement of Lucas' "very successful" uncle mattered to his investment. 32-ER-9068, 9077. The jury's inability to return a verdict on this count, *supra* p. 21, underscores the paucity of the government's evidence.

Nor does the Saba report clearly and convincingly establish the *amount* of loss. *See* 3-ER-596. Among other issues, the report's income-based valuation method, adopted by the court, does not appropriately address Theranos' most valuable asset: its intellectual property. By 2016, Theranos owned almost 150 U.S. patents and many more patent assets worldwide. 53-ER-15333; 4-ER-977. By one estimate, these assets could have yielded more than $700

million in licensing opportunities—an estimate not addressed by Saba at all. 4-ER-893. The Saba report contains no explanation regarding why it did not consider this valuation, or why it did not include potential licensing income as part of the income method.

In its sentencing order, the court assumed without a basis in the Saba report that Theranos' patent assets added nothing to its value because Theranos was not licensing its patents in 2015. 1-ER-18-19. But an estimate of Theranos' value necessarily includes its unrealized business capabilities. Indeed, investors were aware of Theranos' extensive patent portfolio and considered it in their assessment of the company. *See, e.g.*, 29-ER-8177-78 (Tolbert); 31-ER-8878-79 (Mosley). A sentencing court bound by a higher standard of proof would have done the same.

For these reasons, this Court should remand for resentencing under the correct standard of proof.

CONCLUSION

For the foregoing reasons, both individually and cumulatively, the Court should reverse the conviction and remand for a new trial or, alternatively, remand for resentencing.

DATED: APRIL 17, 2023

Respectfully submitted,

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STATEMENT OF RELATED CASES

Appellant is aware of the following related appeal pending in this Court:

United States v. Balwani, No. 22-10338

/s/ Amy Mason Saharia
AMY MASON SAHARIA

DATED: APRIL 17, 2023

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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9th Cir. Case Number(s) 22-10312

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on April 17, 2023. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/Amy Mason Saharia
AMY MASON SAHARIA

DATED: APRIL 17, 2023

ADDENDUM OF CONSTITUTIONAL PROVISIONS, STATUTES, AND RULES

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U.S. Constitution, Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

U.S. Constitution, Amendment VI

In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defence.

18 U.S.C. § 1343. Fraud by wire, radio, or television

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation occurs in relation to, or involving any benefit authorized, transported, transmitted, transferred, disbursed, or paid in connection with, a presidentially declared major disaster or emergency (as those terms are defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122)), or affects a financial institution, such person shall be fined not more than $1,000,000 or imprisoned not more than 30 years, or both.

18 U.S.C. § 1349. Attempt and conspiracy

Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

42 C.F.R. § 493.2. Definitions

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by CMS in accordance with this part.

Adverse action means the imposition of a principal or alternative sanction by CMS.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with "intermediate sanctions" as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received CMS's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received CMS approval based on the State's compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Calibration means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by CMS or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with § 493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the expiration date,

pending an appeal, in accordance with § 493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in § 493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by CMS (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with § 493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by CMS or its agent; or in accordance with § 493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.37, to a laboratory to perform only the waived tests listed at § 493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where CMS has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by CMS in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as "conditions" in § 493.41 and subparts G through Q of this part.

Confirmatory testing means testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;
(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and
(3) Indicates that the problem has been resolved.

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Distributive testing means laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by CMS, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as

(1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and

(2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

CMS agent means an entity with which CMS arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component CMS approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the CMS agent.

FDA-cleared or approved test system means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

Nonwaived test means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the

safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by CMS or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where CMS, the State survey agency or other CMS agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the

deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

Example: Assume the State survey agency, CMS or other CMS agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. CMS reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Reflex testing means confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other preestablished criteria for additional testing.

Repeat proficiency testing referral means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization).

Reportable range means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State licensure program means a State laboratory licensure or approval program.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group)

may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.
(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.
(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.
(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which CMS conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

42 C.F.R. § 493.5. Categories of tests by complexity

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

42 C.F.R. § 493.20. Laboratories performing tests of moderate complexity

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1777.

(c) If the laboratory also performs waived tests, compliance with § 493.801(a) and (b)(7) and subparts J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.801(b)(1) through (6), 493.1771, 493.1773, and 493.1775.

42 C.F.R. § 493.1291. Standard: Test report

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

(1) Results reported from calculated data.

(2) Results and patient-specific data electronically reported to network or interfaced systems.

(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

(c) The test report must indicate the following:

(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.

(2) The name and address of the laboratory location where the test was performed.

(3) The test report date.

(4) The test performed.

(5) Specimen source, when appropriate.

(6) The test result and, if applicable, the units of measurement or interpretation, or both.

(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in § 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(f) Except as provided in § 493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

(i) If a laboratory refers patient specimens for testing—

(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and

(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

(3) Maintain duplicates of the original report, as well as the corrected report.

(l) Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

42 C.F.R. § 493.1407. Standard; Laboratory director responsibilities

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§ 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

42 C.F.R. § 493.1812. Action when deficiencies pose immediate jeopardy

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) CMS requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, CMS suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. CMS may later revoke the certificate.

(c) In addition, if CMS has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, CMS may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

Federal Rule of Criminal Procedure 16(a)(1)(G): Discovery and Inspection (2021)

(a) Government's Disclosure.

(1)*Information Subject to Disclosure.*

* * *

(G) *Expert Witnesses.* At the defendant's request, the government must give to the defendant a written summary of any testimony that the government intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence during its case-in-chief at trial. If the government requests discovery under subdivision (b)(1)(C)(ii) and the defendant complies, the government must, at the defendant's request, give to the defendant a written summary of testimony that the government intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence as evidence at trial on the issue of the defendant's mental condition. The summary provided

under this subparagraph must describe the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications.

* * *

Federal Rule of Evidence 401. Test for Relevant Evidence

Evidence is relevant if:

(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and

(b) the fact is of consequence in determining the action.

Federal Rule of Evidence 402. General Admissibility of Relevant Evidence

Relevant evidence is admissible unless any of the following provides otherwise:

- the United States Constitution;
- a federal statute;
- these rules; or
- other rules prescribed by the Supreme Court.

Irrelevant evidence is not admissible.

Federal Rule of Evidence 403. Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons

The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

Federal Rule of Evidence 404. Character Evidence; Other Crimes, Wrongs or Acts

(a) Character Evidence.

(1) Prohibited Uses. Evidence of a person's character or character trait is not admissible to prove that on a particular occasion the person acted in accordance with the character or trait.

(2) Exceptions for a Defendant or Victim in a Criminal Case. The following exceptions apply in a criminal case:

(A) a defendant may offer evidence of the defendant's pertinent trait, and if the evidence is admitted, the prosecutor may offer evidence to rebut it;

(B) subject to the limitations in Rule 412, a defendant may offer evidence of an alleged victim's pertinent trait, and if the evidence is admitted, the prosecutor may:

(i) offer evidence to rebut it; and

(ii) offer evidence of the defendant's same trait; and

(C) in a homicide case, the prosecutor may offer evidence of the alleged victim's trait of peacefulness to rebut evidence that the victim was the first aggressor.

(3) Exceptions for a Witness. Evidence of a witness's character may be admitted under Rules 607, 608, and 609.

(b) Other Crimes, Wrongs, or Acts.

(1) Prohibited Uses. Evidence of any other crime, wrong, or act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character.

(2) Permitted Uses. This evidence may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.

(3) Notice in a Criminal Case. In a criminal case, the prosecutor must:

(A) provide reasonable notice of any such evidence that the prosecutor intends to offer at trial, so that the defendant has a fair opportunity to meet it;

(B) articulate in the notice the permitted purpose for which the prosecutor intends to offer the evidence and the reasoning that supports the purpose; and

(C) do so in writing before trial—or in any form during trial if the court, for good cause, excuses lack of pretrial notice.

Federal Rule of Evidence 407. Subsequent Remedial Measures

When 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:

- negligence;
- culpable conduct;
- a defect in a product or its design; or
- a need for a warning or instruction.

But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

Federal Rule of Evidence 608. A Witness's Character for Truthfulness or Untruthfulness

(a) Reputation or Opinion Evidence. A witness's credibility may be attacked or supported by testimony about the witness's reputation for having a character for truthfulness or untruthfulness, or by testimony in the form of an opinion about that character. But evidence of truthful character is admissible only after the witness's character for truthfulness has been attacked.

(b) Specific Instances of Conduct. Except for a criminal conviction under Rule 609, extrinsic evidence is not admissible to prove specific instances of a witness's conduct in order to attack or support the witness's character for truthfulness. But the court may, on cross-examination, allow them to be inquired into if they are probative of the character for truthfulness or untruthfulness of:

(1) the witness; or

(2) another witness whose character the witness being cross-examined has testified about.

By testifying on another matter, a witness does not waive any privilege against self-incrimination for testimony that relates only to the witness's character for truthfulness.

Federal Rule of Evidence 701. Opinion Testimony by Lay Witness

If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that 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.

Federal Rule of Evidence 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Federal Rule of Evidence 804. Exceptions to the Rule Against Hearsay—When the Declarant Is Unavailable as a Witness

(a) Criteria for Being Unavailable. A declarant is considered to be unavailable as a witness if the declarant:

(1) is exempted from testifying about the subject matter of the declarant's statement because the court rules that a privilege applies;

(2) refuses to testify about the subject matter despite a court order to do so;

(3) testifies to not remembering the subject matter;

(4) cannot be present or testify at the trial or hearing because of death or a then-existing infirmity, physical illness, or mental illness; or

(5) is absent from the trial or hearing and the statement's proponent has not been able, by process or other reasonable means, to procure:

(A) the declarant's attendance, in the case of a hearsay exception under Rule 804(b)(1) or (6); or

(B) the declarant's attendance or testimony, in the case of a hearsay exception under Rule 804(b)(2), (3), or (4).

But this subdivision (a) does not apply if the statement's proponent procured or wrongfully caused the declarant's unavailability as a witness in order to prevent the declarant from attending or testifying.

(b) The Exceptions. The following are not excluded by the rule against hearsay if the declarant is unavailable as a witness:

(1) Former Testimony. Testimony that:

(A) was given as a witness at a trial, hearing, or lawful deposition, whether given during the current proceeding or a different one; and

(B) is now offered against a party who had—or, in a civil case, whose predecessor in interest had—an opportunity and similar motive to develop it by direct, cross-, or redirect examination.

(2) Statement Under the Belief of Imminent Death. In a prosecution for homicide or in a civil case, a statement that the declarant, while believing the declarant's death to be imminent, made about its cause or circumstances.

(3) Statement Against Interest. A statement that:

(A) a reasonable person in the declarant's position would have made only if the person believed it to be true because, when made, it was so contrary to the declarant's proprietary or pecuniary interest or had so great a tendency to invalidate the declarant's claim against someone else or to expose the declarant to civil or criminal liability; and

(B) is supported by corroborating circumstances that clearly indicate its trustworthiness, if it is offered in a criminal case as one that tends to expose the declarant to criminal liability.

(4) Statement of Personal or Family History. A statement about:

(A) the declarant's own birth, adoption, legitimacy, ancestry, marriage, divorce, relationship by blood, adoption, or marriage, or similar facts of personal or family history, even though the declarant had no way of acquiring personal knowledge about that fact; or

(B) another person concerning any of these facts, as well as death, if the declarant was related to the person by blood, adoption, or marriage or was so intimately associated with the person's family that the declarant's information is likely to be accurate.

(5) [Other Exceptions.] [Transferred to Rule 807.]

(6) Statement Offered Against a Party That Wrongfully Caused the Declarant's Unavailability. A statement offered against a party that wrongfully caused—or acquiesced in wrongfully causing—the declarant's unavailability as a witness, and did so intending that result.

United States Sentencing Guideline § 2B1.1

§2Bl.1. Larceny, Embezzlement, and Other Forms of Theft; Offenses Involving Stolen Property; Property Damage or Destruction; Fraud and Deceit; Forgery; Offenses Involving Altered or Counterfeit Instruments Other than Counterfeit Bearer Obligations of the United States

(a) Base Offense Level:

(1) 7, if (A) the defendant was convicted of an offense referenced to this guideline; and (B) that offense of conviction has a statutory maximum term of imprisonment of 20 years or more; or

(2) 6, otherwise.

(b) Specific Offense Characteristics

(1) If the loss exceeded $6,500, increase the offense level as follows:

Loss (Apply the Greatest)	Increase in Level
(A) $6,500 or less	no increase
(B) More than $6,500	add **2**
(C) More than $15,000	add **4**
(D) More than $40,000	add **6**

(E) More than $95,000	add 8
(F) More than $150,000	add **10**
(G) More than $250,000	add **12**
(H) More than $550,000	add **14**
(I) More than $1,500,000	add **16**
(J) More than $3,500,000	add **18**
(K) More than $9,500,000	add **20**
(L) More than $25,000,000	add **22**
(M) More than $65,000,000	add **24**
(N) More than $150,000,000	add **26**
(O) More than $250,000,000	add **28**
(P) More than $550,000,000	add **30**

(2) (Apply the greatest) If the offense—

(A) (i) involved 10 or more victims; (ii) was committed through mass-marketing; or (iii) resulted in substantial financial hardship to one or more victims, increase by 2 levels;

(B) resulted in substantial financial hardship to five or more victims, increase by 4 levels; or

(C) resulted in substantial financial hardship to 25 or more victims, increase by 6 levels.

(3) If the offense involved a theft from the person of another, increase by **2** levels.

(4) If the offense involved receiving stolen property, and the defendant was a person in the business of receiving and selling stolen property, increase by **2** levels.

(5) If the offense involved theft of, damage to, destruction of, or trafficking in, property from a national cemetery or veterans' memorial, increase by **2** levels.

(6) If (A) the defendant was convicted of an offense under 18 U.S.C. § 1037; and (B) the offense involved obtaining electronic mail addresses through improper means, increase by **2** levels.

(7) If (A) the defendant was convicted of a Federal health care offense involving a Government health care program; and (B) the loss under

subsection (b)(1) to the Government health care program was (i) more than $1,000,000, increase by **2** levels; (ii) more than $7,000,000, increase by **3** levels; or (iii) more than $20,000,000, increase by **4** levels.

(8) (Apply the greater) If—

(A) the offense involved conduct described in 18 U.S.C. § 670, increase by **2** levels; or

(B) the offense involved conduct described in 18 U.S.C. § 670, and the defendant was employed by, or was an agent of, an organization in the supply chain for the pre-retail medical product, increase by **4** levels.

(9) If the offense involved (A) a misrepresentation that the defendant was acting on behalf of a charitable, educational, religious, or political organization, or a government agency; (B) a misrepresentation or other fraudulent action during the course of a bankruptcy proceeding; (C) a violation of any prior, specific judicial or administrative order, injunction, decree, or process not addressed elsewhere in the guidelines; or (D) a misrepresentation to a consumer in connection with obtaining, providing, or furnishing financial assistance for an institution of higher education, increase by **2** levels. If the resulting offense level is less than level **10,** increase to level **10.**

(10) If (A) the defendant relocated, or participated in relocating, a fraudulent scheme to another jurisdiction to evade law enforcement or regulatory officials; (B) a substantial part of a fraudulent scheme was committed from outside the United States; or (C) the offense otherwise involved sophisticated means and the defendant intentionally engaged in or caused the conduct constituting sophisticated means, increase by **2** levels. If the resulting offense level is less than level **12,** increase to level **12.**

(11) If the offense involved (A) the possession or use of any (i) device-making equipment, or (ii) authentication feature; (B) the production or trafficking of any (i) unauthorized access device or counterfeit access device, or (ii) authentication feature; or (C)(i) the unauthorized transfer or use of any means of identification unlawfully to produce or obtain any other means of identification, or (ii) the possession of 5 or more means of identification that unlawfully were produced from, or obtained by the use of,

another means of identification, increase by **2** levels. If the resulting offense level is less than level **12,** increase to level **12.**

(12) If the offense involved conduct described in 18 U.S.C. § 1040, increase by **2** levels. If the resulting offense level is less than level **12,** increase to level **12.**

(13) (Apply the greater) If the offense involved misappropriation of a trade secret and the defendant knew or intended—

(A) that the trade secret would be transported or transmitted out of the United States, increase by **2** levels; or

(B) that the offense would benefit a foreign government, foreign instrumentality, or foreign agent, increase by **4** levels.

If subparagraph (B) applies and the resulting offense level is less than level **14,** increase to level **14.**

(14) If the offense involved an organized scheme to steal or to receive stolen (A) vehicles or vehicle parts; or (B) goods or chattels that are part of a cargo shipment, increase by **2** levels. If the resulting offense level is less than level **14,** increase to level **14.**

(15) If the offense involved (A) the conscious or reckless risk of death or serious bodily injury; or (B) possession of a dangerous weapon (including a firearm) in connection with the offense, increase by **2** levels. If the resulting offense level is less than level **14,** increase to level **14.**

(16) (Apply the greater) If—

(A) the defendant derived more than $1,000,000 in gross receipts from one or more financial institutions as a result of the offense, increase by **2** levels; or

(B) the offense (i) substantially jeopardized the safety and soundness of a financial institution; or (ii) substantially endangered the solvency or financial security of an organization that, at any time during the offense, (I) was a publicly traded company; or (II) had 1,000 or more employees, increase by **4** levels.

(C) The cumulative adjustments from application of both subsections (b)(2) and (b)(16)(B) shall not exceed 8 levels, except as provided in subdivision (D).

(D) If the resulting offense level determined under subdivision (A) or (B) is less than level **24,** increase to level **24.**

(17) If (A) the defendant was convicted of an offense under 18 U.S.C. § 1030, and the offense involved an intent to obtain personal information, or (B) the offense involved the unauthorized public dissemination of personal information, increase by **2** levels.

(18) (A) (Apply the greatest) If the defendant was convicted of an offense under:

(i) 18 U.S.C. § 1030, and the offense involved a computer system used to maintain or operate a critical infrastructure, or used by or for a government entity in furtherance of the administration of justice, national defense, or national security, increase by **2** levels.

(ii) 18 U.S.C. § 1030(a)(5)(A), increase by **4** levels.

(iii) 18 U.S.C. § 1030, and the offense caused a substantial disruption of a critical infrastructure, increase by **6** levels.

(B) If subdivision (A)(iii) applies, and the offense level is less than level **24,** increase to level **24.**

(19) If the offense involved—

(A) a violation of securities law and, at the time of the offense, the defendant was (i) an officer or a director of a publicly traded company; (ii) a registered broker or dealer, or a person associated with a broker or dealer; or (iii) an investment adviser, or a person associated with an investment adviser; or

(B) a violation of commodities law and, at the time of the offense, the defendant was (i) an officer or a director of a futures commission merchant or an introducing broker; (ii) a commodities trading advisor; or (iii) a commodity pool operator, increase by **4** levels.

(c) Cross References

(1) If (A) a firearm, destructive device, explosive material, or controlled substance was taken, or the taking of any such item was an object of the offense; or (B) the stolen property received, transported, transferred, transmitted, or possessed was a firearm, destructive device, explosive material, or controlled substance, apply §2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with

Intent to Commit These Offenses); Attempt or Conspiracy), §2D2.1 (Unlawful Possession; Attempt or Conspiracy), §2K1.3 (Unlawful Receipt, Possession, or Transportation of Explosive Materials; Prohibited Transactions Involving Explosive Materials), or §2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition), as appropriate.

(2) If the offense involved arson, or property damage by use of explosives, apply §2K1.4 (Arson; Property Damage by Use of Explosives), if the resulting offense level is greater than that determined above.

(3) If (A) neither subdivision (1) nor (2) of this subsection applies; (B) the defendant was convicted under a statute proscribing false, fictitious, or fraudulent statements or representations generally (e.g., 18 U.S.C. § 1001, § 1341, § 1342, or § 1343); and (C) the conduct set forth in the count of conviction establishes an offense specifically covered by another guideline in Chapter Two (Offense Conduct), apply that other guideline.

(4) If the offense involved a cultural heritage resource or a paleontological resource, apply §2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources or Paleontological Resources; Unlawful Sale, Purchase, Exchange, Transportation, or Receipt of Cultural Heritage Resources or Paleontological Resources), if the resulting offense level is greater than that determined above.