

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

REPLY BRIEF OF APPELLANT ELIZABETH A. HOLMES

JOHN D. CLINE
LAW OFFICE OF JOHN D. CLINE
*600 Stewart Street
Suite 400
Seattle, WA 98101
(360) 320-6435*

KEVIN M. DOWNEY
LANCE A. WADE
AMY MASON SAHARIA
Counsel of Record
KATHERINE A. TREFZ
WILLIAMS & CONNOLLY LLP
*680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000
asaharia@wc.com*

TABLE OF CONTENTS

	Page
I. The Court Erroneously Admitted Das’ Expert Testimony, the CMS Report, and Voiding Evidence	2
A. The Court Impermissibly Admitted Unnoticed and Unreliable Scientific Opinion	2
B. The Court Erred in Admitting the CMS Report for Holmes’ State of Mind	7
C. Admission of Theranos’ Voiding of Test Results Was Error	10
II. The Court Unconstitutionally Restricted Holmes’ Cross-Examination of Rosendorff.....	14
A. <i>De Novo</i> Review Applies	14
B. The Court Violated Holmes’ Confrontation Right.....	15
1. Rosendorff’s post-Theranos employment was highly relevant	15
2. No legitimate interests outweighed Holmes’ interest in examining Rosendorff	17
3. The jury could not fairly assess Rosendorff’s credibility, competence, or bias	19
III. The Court Abused Its Discretion in Excluding Balwani’s Testimony ..	23
IV. The Court’s Errors Were Not Harmless	27
A. Holmes’ Representations about the Technology Were the Foundation of the Case.....	28
B. The Case Was Close.....	32
1. Representations regarding pharmaceutical companies.....	32
2. Representations regarding the Department of Defense ...	34
3. Representations regarding Walgreens	35
4. Financial projections	36
5. Representations regarding third-party devices.....	37
C. The Court’s Errors Infected the Key Issues in the Case	39

V. The Court Erroneously Applied the Preponderance-of-the-Evidence
Standard at Sentencing42

CONCLUSION.....45

CERTIFICATE OF COMPLIANCE47

CERTIFICATE OF SERVICE.....48

ADDENDUM OF CONSTITUTIONAL PROVISIONS, STATUTES, AND
RULES..... A-1

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re Aircrash in Bali</i> , 871 F.2d 812 (9th Cir. 1989)	10
<i>Kotteakos v. United States</i> , 328 U.S. 750 (1946)	39
<i>Rodriguez v. Gen. Dynamics Armament & Tech. Prod.</i> , 510 F. App'x 675 (9th Cir. 2013).....	4
<i>SEC v. Jasper</i> , 678 F.3d 1116 (9th Cir. 2012)	3, 4
<i>United States v. Armstead</i> , 552 F.3d 769 (9th Cir. 2008).....	43
<i>United States v. Bowen</i> , 2023 WL 3300518 (9th Cir. 2023)	18
<i>United States v. Bruce</i> , 394 F.3d 1215 (9th Cir. 2005)	27
<i>United States v. Cardenas-Mendoza</i> , 579 F.3d 1024 (9th Cir. 2011).....	15
<i>United States v. Durham</i> , 464 F.3d 976 (9th Cir. 2006).....	3, 5
<i>United States v. Gadson</i> , 763 F.3d 1189 (9th Cir. 2014).....	4
<i>United States v. Garrido</i> , 596 F.3d 613 (9th Cir. 2010).....	5
<i>United States v. Gay</i> , 967 F.2d 322 (9th Cir. 1992).....	17
<i>United States v. Haischer</i> , 780 F.3d 1277 (9th Cir. 2015).....	18
<i>United States v. Hymas</i> , 780 F.3d 1285 (9th Cir. 2015).....	45
<i>United States v. Jannuzzio</i> , 184 F. Supp. 460 (D. Del. 1960).....	9
<i>United States v. Larson</i> , 495 F.3d 1094 (9th Cir. 2007)	14, 15, 19
<i>United States v. Lonich</i> , 23 F.4th 881 (9th Cir. 2002).....	42
<i>United States v. Lucas</i> , 70 F.4th 1218 (9th Cir. 2023).....	44

Cases—continued:

<i>United States v. McElmurry</i> , 776 F.3d 1061 (9th Cir. 2015).....	3
<i>United States v. Pac. Gas & Elec.</i> , 178 F. Supp. 3d 927 (N.D. Cal. 2016).....	12
<i>United States v. Paguio</i> , 114 F.3d 928 (9th Cir. 1997)	23, 25
<i>United States v. Perez</i> , 962 F.3d 420 (9th Cir. 2020)	5
<i>United States v. Pineda-Torres</i> , 287 F.3d 860 (9th Cir. 2002)	8
<i>United States v. Ray</i> , 731 F.2d 1361 (9th Cir. 1984).....	17
<i>United States v. Shih</i> , 73 F.4th 1077 (9th Cir. 2023)	20, 21, 22
<i>United States v. Valenzuela</i> , 2023 WL 6276280 (9th Cir. 2023).....	9
<i>United States v. Voorhies</i> , 658 F.2d 710 (9th Cir. 1981)	8, 9
<i>United States v. Wolf</i> , 820 F.2d 1499 (9th Cir. 1987).....	9
<i>United States v. Ziegler</i> , 583 F.2d 77 (2d Cir. 1978).....	9
<i>Williamson v. United States</i> , 512 U.S. 594 (1994)	25, 26

Rules

Fed. R. Crim. P. 16 (2021).....	2, 6
Fed. R. Evid. 104.....	9
Fed. R. Evid. 403.....	<i>passim</i>
Fed. R. Evid. 404.....	17
Fed. R. Evid. 407.....	10, 11, 12
Fed. R. Evid. 608.....	17, 18
Fed. R. Evid. 701.....	2, 3

	Page(s)
Fed. R. Evid. 702.....	2, 3, 6
Fed. R. Evid. 804.....	25
Other Authority	
U.S.S.G. § 2B1.1	43, 44

The public narrative regarding the spectacle of Theranos' downfall is that the company's technology simply did not work and Holmes knew it. The government rooted its entire case in this narrative by making Holmes' representations regarding the capabilities of Theranos' technology the "thread" tying together the alleged investor fraud scheme. 44-ER-12538 (government closing). But Holmes' intent and knowledge on this central question were intensely contested at trial.

Substantial evidence showed that Holmes and Theranos' scientists believed in good faith that Theranos had developed technology that could accurately run virtually any blood test. And this is what Holmes told investors. Holmes Br. 4-7. Faced with this evidence, to prove its case, it was paramount for the government to show the technology did not work (and Holmes knew it). But the government lacked the data to conduct a reliable scientific analysis, and, for this reason or another, jettisoned its retained expert at trial.

To plug this massive hole, the government successfully urged the court to bend the Rules of Evidence and ignore the Confrontation Clause. The government does little to justify these errors on appeal and often does not even defend the court's reasoning. Instead, it leans on harmlessness and tries a new tack: it asks the Court to uphold the convictions by arguing that certain

allegations are unrelated to the effectiveness of Theranos' technology and independently merit affirmance. All the government's allegations, however, rose and fell on whether Holmes believed the technology worked. And the government's presentation of these allegations also was plagued by error and contested (and sometimes definitively disproven) to such an extent that this Court cannot reasonably rely on them to affirm.

The end result was a miscarriage of justice. The Court should reverse.

I. THE COURT ERRONEOUSLY ADMITTED DAS' EXPERT TESTIMONY, THE CMS REPORT, AND VOIDING EVIDENCE

Das' expert opinions, the CMS report, and the voiding evidence enabled the jury to find that the government's technology case rested on comprehensive scientific analysis, regulatory findings, and Theranos' (supposed) admission. None of this evidence was reliable or admissible.

A. The Court Impermissibly Admitted Unnoticed and Unreliable Scientific Opinion

Das' testimony contravened Rules 16 and 701-702.

1. The government's argument (at 31-32) that plain-error review governs this issue is meritless. The government acknowledges (at 31-32) that "Holmes repeatedly objected" "before and during Das' testimony," but argues that plain-error review applies to one question and answer regarding Das' opinion about the Edison device's suitability for clinical use. The government

thus concedes that the remainder of Das' opinions are not subject to plain-error review. This lone question occurred after the court had repeatedly overruled Holmes' objections, including to the Patient Impact Assessment on which Das based his ultimate opinion. 33-ER-9422-27, 9435-39, 9446, 9452, 9477, 9481; *see* Holmes Br. 34-35. Once the court overruled Holmes' objections, repeatedly objecting to the same line of testimony was not required. *United States v. McElmurry*, 776 F.3d 1061, 1066-67 (9th Cir. 2015).

The government also errs in arguing (at 30) that review is for abuse of discretion. Whether testimony qualifies as expert opinion is reviewed *de novo*. *United States v. Durham*, 464 F.3d 976, 981 (9th Cir. 2006). In any event, Holmes should prevail under either standard.

2. Das' scientific opinions and the Patient Impact Assessment were inadmissible under Rules 701-702.

First, the rules contain no "company-prepared" exception (*see* U.S. Br. 33-34), and *SEC v. Jasper*, 678 F.3d 1116 (9th Cir. 2012), does not articulate one. *Jasper* addressed whether the court erred in admitting a company's 10-K even though the 10-K reflected accounting judgments. *Id.* at 1124. This Court found the 10-K admissible as a business record, and observed that the defendant did not object to the failure to disclose the 10-K's authors as experts.

Id. Here, Holmes objected vigorously to the government’s failure to disclose Das as an expert.

Second, Das testified to expert opinions, and the government’s minimization (at 35)—embraced by the district court—that his opinions were just “observations during the job he was hired to do” is unavailing. 1-ER-184; 13-ER-3510, 3512-13, 3522. This Court and others have rejected that argument. *E.g., Rodriguez v. Gen. Dynamics Armament & Tech. Prod.*, 510 F. App’x 675, 676 (9th Cir. 2013); *see* Holmes Br. 37-38; NACDL Amicus Br. 13-15.¹ Das’ testimony was expert analysis, not his “observations.” Das retrospectively analyzed data that predated his hiring.² Theranos stopped using the Edison for patient testing half a year *before* Das was hired. 8-ER-2228; 11-ER-3037-38; 33-ER-9525-26; 47-ER-13683. Likewise, Das’ opinions at trial about the CMS report were based on the observations of absent CMS inspectors. The

¹ The government focuses on *United States v. Gadson*, 763 F.3d 1189 (9th Cir. 2014), but the cited portion of the case does not involve an argument about expert testimony. The government likewise errs in suggesting (at 33 n.7) that Holmes relies on Second Circuit cases rejected in *Gadson*. *Gadson* disagreed with Second Circuit law on the admissibility of agent testimony construing phone conversations. *See* 763 F.3d at 1208. Holmes did not cite that Second Circuit case law.

² The government claims (at 35 n.8) that the “most technical topics” such as the “Sigma metric” were elicited by Holmes. But Das volunteered the Sigma metric information, and Holmes’ counsel immediately requested that Das “stay out of the complexity” when answering. 34-ER-9559-70.

government's claim that Das simply recounted "observations" is belied by the fact that the government's retained-but-abandoned expert disclosed the same opinion, purportedly using the same methodology.³ *Compare* 22-ER-2313 *with* 33-ER-9460.

Third, contrary to the government's claim (at 36), Holmes does not seek to exclude observations of witnesses working in technical fields. If the government wanted to elicit expert opinions from Das, it could have timely disclosed Das as an expert, as it did for other hybrid fact/expert witnesses, 12-ER-3224, and provided the data and methodology underlying those opinions. Or the government could have limited Das' testimony to non-scientific observations.

Finally, the government's cited cases (at 36-37) only underscore the impropriety of Das' expert testimony. In *United States v. Garrido*, 596 F.3d 613, 616-17 (9th Cir. 2010), and *Durham*, 464 F.3d at 982, the witnesses testified to their sensory perceptions. And in *United States v. Perez*, 962 F.3d 420, 436-37 (9th Cir. 2020), the testimony—which included decoding "XVIII" as "18"—"required no technical or specialized knowledge." Das, by contrast, testified

³ The government's statement (at 40) that Holmes pushed off the *Daubert* hearing is misleading. Before the scheduled hearing, the government served a "supplemental" report introducing new opinions under a new methodology. 9-ER-2304-07. Holmes moved to strike the supplemental opinions, and the court vacated the hearing to be rescheduled during trial. 9-ER-2268-70.

that his “sophisticated analysis” was not something a person “without knowledge and training would be in a position to do.” 34-ER-9565.

3. The government attempts (at 37) to sweep away the Rule 702 violation because Das “could have qualified as an expert.” Possessing expert qualifications is only one part of Rule 702. Expert testimony must also 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. *Figueroa-Lopez* is not to the contrary. There, the witness testified that a defendant’s actions were consistent with narcotics trafficking, 125 F.3d at 1244-45, which, unlike here, required no scientific methodology or data. The required gatekeeping analysis never occurred below—and could not occur because the data on which Das based his expert opinion were unavailable. Holmes Br. 34-35, 41; NACDL Amicus Br. 15-16.

4. Attempting to defend its Rule 16 violation, the government asserts (at 39-40) that Holmes was aware of Das’ testimony since February 2021—almost a year *after* the expert disclosure deadline. All the government provided in February 2021 was an FBI interview memorandum. It was not an expert disclosure and did not disclose the required data or opinions. 8-ER-2227.

The government next claims (at 40) that its “disclosure” in the weeks before trial complied with the “parties’ agreed-upon deadline” for supplemental expert disclosures. That is just plain false. The agreed-upon deadline was for physicians whose expert disclosures the government had *initially produced in 2020*. See 1-FER-7. The government agreed to supplement those disclosures after the court held *in limine* that “the disclosures are lacking in information necessary for [Holmes] to adequately prepare for trial.” 1-ER-244-45. That ruling did not apply to Das because the government had not disclosed any expert opinions for him.

B. The Court Erred in Admitting the CMS Report for Holmes’ State of Mind

The government only half-heartedly defends the theory on which the court admitted the CMS report—that it evidenced Holmes’ earlier state of mind—for good reason. None of the government’s current arguments supports the report’s admission.

1. The government’s “lulling” theory (at 42) was never raised below and is improper bootstrapping. Evidence that Holmes supposedly downplayed knowledge gained from the report (by repeating Das’ contemporaneous affirmation that the CMS deficiencies did *not* relate to “the fundamental integrity of the technologies,” 1-FER-168) is irrelevant to what she believed

before the report, when the alleged offense conduct took place. The government cannot admit irrelevant evidence for the purpose of showing that a defendant supposedly “downplayed” that irrelevant evidence.

The government next asserts (at 43-44) that the CMS report responded to Holmes’ evidence concerning her good faith in 2016. This argument has the chronology backwards. Holmes’ 2016 evidence responded to the government’s. As one example, after Secretary Mattis testified that the accuracy of Theranos’ technology was not “proven to the Board’s satisfaction” following the October 2015 *Wall Street Journal* article, 19-ER-5297-98, Holmes presented evidence showing steps taken to demonstrate the technology worked. 19-ER-5344, 5347-49; 20-ER-5352-56; 1-FER-103-09. And after the government obtained admission of the CMS report before trial and referenced CMS’ findings (and later events) in its opening statement, 16-ER-4235, 4237, 4241-42, Holmes was entitled to respond without waiving her objection. *See United States v. Pineda-Torres*, 287 F.3d 860, 885-86 (9th Cir. 2002).

The government cites (at 42) *United States v. Voorhies*, 658 F.2d 710 (9th Cir. 1981), for the proposition that “acts both prior and subsequent to the indictment period may be probative of the defendant’s state of mind.” *Id.* at 715. But the relevant acts in *Voorhies* occurred during the indictment period.

And the case *Voorhies* cited for this proposition, *United States v. Jannuzzio*, 184 F. Supp. 460 (D. Del. 1960), cautioned that subsequent acts are “admissible” only if they “establish the existence of the specific wrongful intent at the time the purported criminal act transpired.” *Id.* at 470 n.46. Holmes’ receipt of the CMS report in January 2016 says nothing about her earlier beliefs. *See United States v. Valenzuela*, 2023 WL 6276280, at *1 (9th Cir. 2023).

Finally, the government’s observation (at 42-43) that it alleged a patient conspiracy into 2016 does not render the report relevant. At best, this argument is one of conditional relevance under Rule 104(b). Once the government closed its case without proof of representations to patients in 2016, the report lacked relevance and the court was required to grant Holmes’ motion to “strike the insufficiently connected item.” *United States v. Ziegler*, 583 F.2d 77, 80 (2d Cir. 1978); *see* 37-ER-10716-17; Holmes Br. 35-36.

2. The government’s Rule 403 arguments are no better. The government contends (at 44) that the jury instruction cured any prejudice. *See* 6-ER-1506. But instructions will not necessarily cure the prejudice associated with evidence of regulatory violations. *See United States v. Wolf*, 820 F.2d 1499, 1505 (9th Cir. 1987). And the instruction could not prevent the prejudice

arising from the court's explicit instruction to consider the report for Holmes' state of mind.

That only 20 pages of the CMS report were admitted does not tilt the Rule 403 analysis. *Contra* U.S. Br. 41. The government admitted the most prejudicial sections, including the immediate-jeopardy finding. 47-ER-13683.

Nor does Das' testimony fix the Rule 403 problem. *Contra* U.S. Br. 45. Das' agreement with the report's findings amplified the prejudice. Just as the government used Das to introduce its retained-but-abandoned expert's opinions, it used Das to inject the CMS report into the case on a bogus "notice" theory without calling the report's authors.

C. Admission of Theranos' Voiding of Test Results Was Error

1. Rule 407 barred evidence of voiding. The government did not prove that the decision to void test results was involuntary. *See In re Aircrash in Bali*, 871 F.2d 812, 817 (9th Cir. 1989).

The record contradicts the government's claim (at 47) that Das "consistently stated that the regulations required" voiding in "pretrial interviews available to the court." Neither the February 2021 nor June 2021 interview memoranda indicate that Das ascribed the voiding decision to CMS regulations. 8-ER-2222-28. And though the government does not cite it, an interview

memorandum disclosed the night before Das' testimony stated that "Das initially said that his decision to void the test was voluntary, but clarified that it would have been incorrect not to do so." 33-ER-9331-32. Before his testimony, Das appeared to characterize his voiding recommendation as a professional obligation or best practice.

Holmes requested to *voir dire* Das. 8-ER-2119-20. The court recognized that whether Das "was required to ... void" or whether he "did it because [he] thought it was the right thing" was the dispositive question under Rule 407. 33-ER-9314. Yet the court denied *voir dire* after the government pledged to ask whether there was "a legal obligation or was it a voluntary discretionary act that he took to be conservative in an abundance of caution." 33-ER-9332-33.

The government never asked that question, and Das never testified that voiding was legally required. Instead, the government asked a vague compound question: "Did you feel that you were required to take *certain action* pursuant to [42 C.F.R. § 493.1291(k)] *and your professional responsibilities?*" 33-ER-9451 (emphases added). Das' affirmative answer did not clarify whether the required "action" was voiding the test results (as opposed to conducting patient impact assessments, *see* 8-ER-2228). Nor did it answer

whether CMS rules compelled voiding. The court nevertheless overruled Holmes' Rule 407 objection. 33-ER-9452. Das never testified that the regulations mandated that Theranos void all Edison test results. *Contra* U.S. Br. 46.

The government (like the court) overlooks evidence that no one contemporaneously viewed voiding as legally required. CMS inspector Sarah 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. And Das endorsed company communications describing the voiding decision as "aggressive" and made in an "abundance of caution." 11-ER-3057.

The government next argues (at 48) that Rule 407 does not apply to measures that, "while not directly compelled by government regulators, were undertaken to comply with a regulatory regime." Neither of the authorities the government cites supports this view. *Wright & Miller* refers to "conduct required by a government agency." U.S. Br. 48. And in *United States v. Pac. Gas & Elec.*, 178 F. Supp. 3d 927 (N.D. Cal. 2016), the court held that the agency "was heavily involved in requiring" the corrective actions. *Id.* at 952. The government omits the "requiring" part of the quotation.

2. Rule 403 also mandated exclusion. The government cannot dispute that the court failed to conduct Rule 403 balancing at trial, *see* 33-ER-

9452, but suggests (at 46) that the ruling nevertheless fits within the court’s “expressed Rule 403 calculus” in its *in limine* order. It is unclear what that even means. The court *deferred* ruling on Rule 403 before trial, 1-ER-227, and identified the substantial risk that admission of the company’s 2016 decision could confuse the jury in evaluating Holmes’ intent “during 2010-2015—the years that are the subject of the indictment.” 1-ER-226-27. The court’s failure to weigh that risk against the evidence’s probative value at trial requires *de novo* review.

The unfairly prejudicial nature of the evidence vastly outweighed any relevance. The government’s principal relevance argument (at 45-46)—that the voiding “amounted to Theranos conceding the unreliability of its blood tests despite years of Holmes’ misleading statements to the contrary”—merely reaffirms the inflammatory nature of this evidence. The prophylactic voiding decision was not an admission of unreliability and could not inform Holmes’ earlier state of mind. *See* Holmes Br. 46; 11-ER-3057, 3069; 47-ER-13708.

The government’s argument (at 46) that Holmes’ purported “attempt to minimize [the voiding’s] significance” rendered the voiding evidence relevant is the same improper bootstrapping argument it advances with respect to the

CMS report. *See supra* pp.7-8. Holmes was not charged with misleading anyone about the voiding or CMS report.

II. THE COURT UNCONSTITUTIONALLY RESTRICTED HOLMES' CROSS-EXAMINATION OF ROSENDORFF

Rosendorff was central to the government's case about Holmes' knowledge of the technology's capabilities and accuracy, as he led the company's laboratory when Holmes was making representations to investors. To prove its case, the government had to present him as a highly competent, unblemished truth-teller. The reality showed a different picture: other laboratories directed by Rosendorff experienced serious issues mirroring ones at Theranos. Two of them were under federal investigation at the time of trial. The court unconstitutionally shielded the jury from this damaging evidence of Rosendorff's incompetence, motive to foist his failures on Holmes and Theranos' technology, and pattern of shifting blame to others.

A. *De Novo* Review Applies

The government summarily asserts (at 54) that abuse-of-discretion review applies. But it never explains why the total ban on cross-examination about Invitae and uBiome, and the material restriction as to PerkinElmer, do not necessitate *de novo* review. Nor could it—because these were whole “area[s] of inquiry,” their exclusion requires *de novo* review. *United States v.*

Larson, 495 F.3d 1094, 1101 (9th Cir. 2007) (en banc); see *United States v. Cardenas-Mendoza*, 579 F.3d 1024, 1030 (9th Cir. 2011). Given the obvious deficiencies in the court’s analysis—several of which the government does not even defend—Holmes prevails under any standard of review.

B. The Court Violated Holmes’ Confrontation Right

The government focuses (at 59-60) on the factors in *Larson*, 495 F.3d at 1103—“(1) [whether] the excluded evidence was relevant; (2) [whether] there were other legitimate interests outweighing [Holmes’] interest in presenting the evidence; and (3) [whether] the exclusion of evidence left the jury with sufficient information to assess the credibility of the witness.” The court’s ban on Holmes’ cross-examination of Rosendorff satisfies each factor in spades.

1. *Rosendorff’s post-Theranos employment was highly relevant*

Rosendorff’s post-Theranos career was marred by repeated, serious, and scandalous failures. When he testified at trial, Rosendorff was a subject in federal investigations relating to two post-Theranos laboratories. This was extraordinarily probative evidence of Rosendorff’s incompetence and pro-government bias—and it exculpated Holmes, who relied on Rosendorff’s expertise as laboratory director. The jury heard almost none of this.

The government’s attempts to dispute relevance fall flat. First, the government preposterously invokes witness Erika Cheung (at 60) for the proposition that post-employment evidence was categorically irrelevant. The government sought to admit evidence of Cheung’s post-Theranos employment at an *ethics* organization to show the “impact” of Theranos on Cheung’s “state of mind.” 17-ER-4678-79. That irrelevant, inflammatory evidence was properly excluded.

Second, the government claims (at 60) that Holmes has not argued that the excluded Invitae evidence related to bias. Not so. Holmes cited (at 62) “Invitae’s public scrutiny” as a source of pro-government bias. Invitae’s publicly reported quality-control failure provided a motive to blame Holmes for Theranos’ quality-control issues. 8-ER-2162; 20-ER-5444-49, 5467-73; 23-ER-6512-13.⁴

Third, the government insinuates (at 60) that Holmes argued below that Rosendorff’s employment history was relevant only to bias, before changing tack on appeal. But Holmes argued that the evidence also went to Rosendorff’s competence. 23-ER-6301-03, 6306-11, 6320-21.

⁴ Rosendorff understands that this case has put his professional reputation at risk, as he sued a TV developer for defamation. *Rosendorff v. Hulu LLC*, No. 152734/2023 (Sup. Ct. N.Y.).

Fourth, that Holmes was allowed to cross-examine Rosendorff on his tenure at the University of Pittsburgh (which he claimed did not experience the same severity of problems as Theranos, *see* Holmes Br. 55) only highlights the need to undermine that testimony by reference to his problematic experiences elsewhere.

Lastly, the court's instruction to ignore the government's redirect examination about Rosendorff's experience at other laboratories does not cure the violation, when the government had already asked Rosendorff to compare Theranos with other laboratories in direct examination. Holmes Br. 55-56.

2. *No legitimate interests outweighed Holmes' interest in examining Rosendorff*

The government provides no reason to affirm the court's exclusion of evidence concerning Invitae. That ruling relied solely on Rule 404, which "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); *see* Holmes Br. 63.

The government similarly runs from the court's reliance on Rule 608(b) to bar the PerkinElmer evidence. The government does not acknowledge the black-letter law that Rule 608(b) does not bar impeachment evidence to show bias. *United States v. Ray*, 731 F.2d 1361, 1364 (9th Cir. 1984). Instead, the

government cites (at 61) a case affirming application of Rule 608(b) to exclude impeachment evidence intended to “contradict” testimony elicited on *cross-examination*. *United States v. Bowen*, 2023 WL 3300518, at *1 & n.1 (9th Cir. 2023). Here, the government put at issue Rosendorff’s competence on *direct examination*.

Finally, the government does not engage with Holmes’ Rule 403 arguments. Specifically, the government does not try to defend the court’s reasoning that the uBiome investigation had nothing to do with the laboratory—because the investigation *did* relate to the laboratory. Holmes Br. 65.

More generally, the government does not acknowledge that Rule 403 should “be used sparingly” to exclude evidence offered by criminal defendants. *United States v. Haischer*, 780 F.3d 1277, 1281-82 (9th Cir. 2015) (citation omitted). It vaguely invokes (at 61) the prospect of “mini-trials.” The government conducted a broad direct examination (that raised *Napue* concerns, *see infra* pp.21-22); Rosendorff’s later employment was highly relevant; and the government (not Holmes) “open[ed] the door” to Rosendorff’s competence and experience at other laboratories. U.S. Br. 61. The government’s desire to avoid a “mini-trial” on this critical evidence cannot overcome the confrontation right.

3. *The jury could not fairly assess Rosendorff's credibility, competence, or bias*

As for the final *Larson* factor, Rosendorff's checkered tenure after Theranos cast into doubt his credibility and furnished a strong motive to favor the government.

The government again ignores the *Invitae* evidence in discussing this factor. The jury could not fairly evaluate Rosendorff's credibility—for example, about the supposed uniqueness of problems at Theranos—while in the dark about the systemic quality-control failures at Rosendorff's next laboratory.

As to uBiome, the government says only (at 62) that Rosendorff was not a “target” of the investigation. But Rosendorff still had a motive to lie. The government does not dispute that Rosendorff was a “subject” and therefore in the “zone of danger.” 23-ER-6319.

Rosendorff's tenure at uBiome also undermined specific claims by the government in closing—including attempts to pit Rosendorff's credibility against Holmes'. The government claimed that Rosendorff's departure from Theranos evidenced a cover-up by Holmes and Balwani. 43-ER-12530-44-ER-12533. [REDACTED] undercuts that claim, and bolsters Holmes' contrary testimony concerning Rosendorff's departure.

Holmes Br. 56, 66-67; 39-ER-11107-09; 40-ER-11397-98. The government pointed to Rosendorff's testimony about his communications with Holmes about quality-control issues as evidence of Holmes' knowledge. 44-ER-12554, 12584-85. [REDACTED]

[REDACTED]—and bolsters Holmes' testimony that, when she learned of issues, she made resources available and deferred to Rosendorff and others to resolve the issues. *Compare* 56-ER-16054 (under seal) *with* 20-ER-5433-35; 39-ER-11107, 11113-14; 40-ER-11397-99; 1-FER-44-46.

As for PerkinElmer, the government notes (at 63) that some examination was allowed. But it does not dispute the fundamental point that the jury was unable to assess the risk of the PerkinElmer investigation to Rosendorff—and therefore his bias—without knowing about the immediate-jeopardy finding. Holmes Br. 61.⁵ The government cites (at 63) *United States v.*

⁵ Improperly citing (and including in its record excerpts) Balwani's record, the government notes (at 58) CMS' eventual finding that PerkinElmer corrected deficiencies. This *post-trial* event says nothing about Rosendorff's bias at Holmes' trial. Related documents the government produced following trial show that shortly after these findings, Rosendorff's employment ended, the laboratory closed, and Rosendorff's blame-shifting persisted, as he told a federal investigator that his superior had obstructed justice.

Shih, 73 F.4th 1077 (9th Cir. 2023), but there the court restricted cross-examination where defense counsel had already “asked the question repeatedly.” *Id.* at 1095. Here, the court barred all questioning about the PerkinElmer immediate-jeopardy finding, while admitting evidence that CMS deemed Theranos in immediate jeopardy in 2016.

The government (at 63) also invites this Court to disregard Rosendorff’s bias on the ground that Rosendorff provided testimony before the uBiome and PerkinElmer investigations consistent with his trial testimony. But, even before formal investigations began, Rosendorff had motive to deflect blame to preserve his reputation given percolating issues at his post-Theranos laboratories.

Finally, the government argues that the jury was able to assess Rosendorff’s bias, credibility, and competence even without the excluded evidence because he was cross-examined for four days. The length of Rosendorff’s cross-examination, however, reflects his importance to the case and the misleading nature of his direct examination.

Holmes provided one example of the misleading nature of Rosendorff’s direct testimony in her opening brief (at 64-65 n.9). As another example, Rosendorff testified on direct that he discussed with Holmes that no one could

enter the “Normandy lab” (containing the Edison devices) during an inspection. 20-ER-5638. This testimony rested on an incomplete email chain that the government showed to Rosendorff. *See id.*; 46-ER-13387. After defense counsel showed Rosendorff the complete chain, 53-ER-15342-43, he testified that the full exchange showed a Theranos employee “suggesting a path to the Normandy lab”—the opposite of his direct testimony. 21-ER-5843-50. Incredibly, the government features Rosendorff’s direct testimony on appeal (at 14) without acknowledging the cross-examination.

Holmes had to do similar work on cross-examination concerning numerous other topics of testimony. *See, e.g., infra* n.8 (Walgreens launch); 21-ER-5715-16, 5732-39; 23-ER-6366-89, 6441-43; 24-ER-6657-58 (electrolytes); Holmes Br. 64-65 n.9, 22-ER-6142-86 (proficiency testing); 23-ER-6338-66 (HDL); 23-ER-6395-6407 (bicarbonate); 24-ER-6666-84 (HCG); *see also* 44-ER-12778-83 (defense closing summarizing HCG chronology as example).

Rosendorff’s cross-examination, though lengthy, could not reveal the bias resulting from his criminal, regulatory, and reputational exposure, or the incompetence evidenced by repeated problems at laboratories he directed after Theranos. The court unconstitutionally put those topics off limits.

III. THE COURT ABUSED ITS DISCRETION IN EXCLUDING BALWANI'S TESTIMONY

1. Balwani's SEC testimony taking responsibility for Theranos' financial model was inculpatory. This Court should reject the government's strained arguments to the contrary.

The government's argument that Balwani's statements were not self-inculpatory because "it 'is not a crime' 'to take ownership over the creation of a financial model,'" U.S. Br. 68 (citing 1-ER-179-80), ignores that a statement against interest "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). Balwani was on notice that the U.S. Attorney's Office and SEC were investigating Theranos' financial projections. *See* 6-ER-1539-40, 1573-74, 1603-04. He nonetheless testified that he "started building a financial model ... that he owned," and 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; and that Holmes did not "ever edit the model," 6-ER-1619. The model generated and contained the at-issue financial projections. Any reasonable person in Balwani's shoes, knowing that he shared the model and resulting projections with investors, would understand his testimony tended to expose him to civil or criminal liability.

The government argues (at 67-68) that Balwani accepted responsibility only for Theranos' financial model but not for its financial projections. That is an artificial distinction of the government's creation. The "financial model" and "financial forecast" or projection were one and the same. 35-ER-10041-42; 36-ER-10189. Balwani explained this fact to the SEC, testifying that the spreadsheet model "spit out" certain tabs "as the end result." 6-ER-1625-26; *see also* 35-ER-10076-80 (Grossman testimony that model he received from Balwani contained "projected statement of income" tab); 1-FER-93-94. The government acknowledged this fact in Balwani's separate appeal: "In January 2014, Balwani provided PFM with a financial *model projecting* Theranos would earn hundreds of millions of dollars in 2014 and 2015 revenue" U.S. Br. 6, *United States v. Balwani*, No. 22-10338 (Sept. 20, 2023) (emphasis added).

The government claims (at 67) that Balwani deflected blame to Theranos' controller Danise Yam and potential investor BDT. He did not. Balwani testified that "early on" Yam was in charge of Theranos' financials, but that "around 2010" he "started building a financial model with help initially from Safeway and Walgreens *that [he] owned until [he] left the company.*" 6-ER-1625 (emphasis added). And Balwani testified only that "consultants at

BDT” made “[f]ormatting,” “typo[]” corrections, and other changes to “clean the model up.” 6-ER-1617.

The government’s cited cases (at 68-69) are inapposite. None involved a statement inculcating the declarant. Balwani’s inculpatory testimony is analogous to the statements in *Paguió* taking sole responsibility for the at-issue action. *See* 114 F.3d at 933.

2. The government (at 70-71) limits its argument on Rule 804(b)(3)’s corroborating-circumstances element to Balwani’s statement that Holmes did not edit the model. The government does not argue that the remainder of Balwani’s testimony—including the statement that he owned the model—lacks corroboration. Nor could it. *See* Holmes Br. 73-75.

The government fails to undermine Balwani’s testimony that Holmes did not edit the model. The government (at 70) points to Balwani’s testimony that he “put a model with her name on it so she could edit,” but ignores Balwani’s related testimony that he did not “think she ever did [edit the model] because he continued with [his] assumptions” to his model and “never even looked at that model [sent to Holmes].” 6-ER-1619.⁶

⁶ The government selectively quotes (at 70-71) *Williamson v. United States*, 512 U.S. 594 (1994), for the supposed proposition that a codefendant’s

The cited text messages (at 71) likewise are irrelevant. The 2012 text message stating that “80k will be basically mostly throwaway when we move to Oracle later in [the] year once we get revenue flowing in,” 4-SER-643, has nothing to do with Balwani’s model. An April 2013 text referencing the “hospital model,” 4-SER-645, does not contradict Balwani’s testimony that Holmes did not edit the model. And Holmes’ November 2013 text stating that she would “get [] comfortable” with “financial models” in case she needed to present it while Balwani was abroad and asking him “what file to use,” 4-SER-650, does not undermine Balwani’s testimony that she never edited the model. As Holmes proffered below, Balwani told the SEC that he ended up doing the presentation referenced in the text. 39-ER-11296-97. No evidence showed that Holmes ever got comfortable with or edited the model.

Finally, the government’s argument (at 71-72) that Balwani’s supposed “motive of love might be a reason to lie” is belied both because Balwani’s SEC testimony postdates the relationship, 40-ER-11440-42, and because the record

statements are less credible than ordinary hearsay evidence. But *Williamson* involved a situation where the government sought to admit portions of an out-of-court statement *exculpating the declarant* and *implicating the defendant*. *Id.* at 597-601. Balwani, by contrast, implicated himself and exculpated Holmes.

shows (without dispute) Balwani's extensive abuse of Holmes, 40-ER-11414-39.

IV. THE COURT'S ERRORS WERE NOT HARMLESS

The court's errors made it impossible for the jury fairly to assess Holmes' intent and knowledge, and the credibility of her trial testimony, with respect to the key issues: the accuracy and capabilities of Theranos' technology and the financial projections provided to C-2 investors (but not C-1 investors).

The government devotes significant attention to harmlessness, claiming (at 51-53, 64-65) that any errors related to Holmes' representations about Theranos' technology were harmless because the government supposedly proved that Holmes made other misrepresentations. The relevant question, however, is *not* whether, after removing the error-affected evidence, the remaining evidence in the light most favorable to the government sufficed to sustain a conviction. *See* Holmes Br. 51; *United States v. Bruce*, 394 F.3d 1215, 1228-29 (9th Cir. 2005). The question is whether the government has sustained its burden to convince the Court "that the error did not influence the jury, or had but very slight effect." *Bruce*, 394 F.3d at 1229 (citation omitted). When

it comes to the court's Confrontation Clause violation, the government bears this burden beyond a reasonable doubt. Holmes Br. 65.

The government cannot prove harmlessness—beyond a reasonable doubt or otherwise. The government's attempts to walk back its assertions that Holmes' representations about Theranos' technology were foundational to the case, and to all the other alleged representations, lack credibility. And the Das/CMS/voiding evidence and Rosendorff's testimony were the twin pillars of the government's case about the technology's effectiveness.

A. Holmes' Representations about the Technology Were the Foundation of the Case

Holmes' statements to investors concerning Theranos' technology—and thus her knowledge and belief about the technology—were the heart of this case. The government repeatedly said so below to the jury and the court:

- Closing: “There are certain kinds of statements, though, I think that are a thread through this scheme, especially this first one about the capabilities of the analyzer, and in particular its accuracy.” 44-ER-12538.
- Closing: “The accuracy of the testing ... [is] sort of the underlying false statement in the case” 44-ER-12538.
- Sentencing: “[A] large portion of both trials in this case focussed [*sic*] on not only the problems with Theranos's technology and the way that those problems had an adverse impact on the accuracy of the test, but also specifically the defendant's knowledge of those problems, both Ms. Holmes and Mr. Balwani.” 1-ER-43.

- Briefing: “Defendants’ fraud centered on misleading the public regarding the capabilities of Theranos’s technology.” 1-FER-18.
- Briefing: “Central to the alleged fraud in this case is the fact that Defendant led victims to believe that Theranos had developed a small proprietary analyzer device that could conduct the full range of blood tests using a drop of blood from a finger-stick.” 1-FER-9.

Reiterating these statements, the government claims on appeal (at 4) that “Holmes’s fraud centered on the company she founded, Theranos, *and the false statements she made about Theranos’s blood testing technology*” (emphasis added). Theranos’ technology underlies all the government’s allegations, which explains why the government references the company’s “technology” or “device” (or similar terms) 101 times in its 20-page factual background on appeal.

The government protests (at 52-53) that in closing it merely identified “the capabilities of Theranos’s device as the underlying theme between the two fraud schemes”—*i.e.*, the alleged investor and patient schemes. That is not what the government told the jury. The government made these assertions in the portion of its closing argument “focussing [*sic*] on the counts related to investors.” 44-ER-12536. The government claimed that “there are different kinds of false statements that Ms. Holmes made in order to defraud investors,” and acknowledged that “it’s not the case that every investor heard

every statement.” 44-ER-12537-38. The government then said: “There are certain kinds of statements, though, I think that are a thread through this scheme, especially this first one about the capabilities of the analyzer, and in particular its accuracy.” 44-ER-12538. The government then asserted, merely as an aside, that Holmes made the same representation to patients. 44-ER-12538.

When the government highlighted other alleged misrepresentations below, it argued that Holmes made those alleged misrepresentations *to prove that the technology worked* or that she knew other representations were false *because the technology didn’t work*:

- Closing: “She’s making false statement after false statement about work that Theranos had done, was doing with the Department of Defense in order to get investors to invest, for investors to believe that the technology worked wasn’t just validated by its work with pharmaceutical companies, but also through its work with the Department of Defense.” 44-ER-12547.
- Closing: “She knows that the relationship is destined to fail because the technology can’t do what Walgreens thinks it can do.” 43-ER-12498.
- Briefing: “To support her bold claims [about the technology], Holmes repeatedly told potential investors that Theranos’ technology had been comprehensively validated by multiple major pharmaceutical companies” 3-ER-577; 6-ER-1452.

The government reprises these arguments on appeal:

- “To support these claims [about the technology], Holmes repeatedly told potential investors that major pharmaceutical companies had validated Theranos’s device, and the U.S. military was using it in the battlefield to treat wounded soldiers.” U.S. Br. 4.
- The government quotes an investor as stating that “[t]he most extensive evidence supplied regarding the reliability of the Theranos technology and its application is a study report prepared by Pfizer.” U.S. Br. 8 (quoting 4-SER-649); *see also, e.g.*, 29-ER-8294; 31-ER-8717-18, 8742.
- “Fundamentally, Theranos’s device never worked, yet Holmes either entirely fabricated or grossly exaggerated endorsements from pharmaceutical companies, the military, Walgreens, and others in order to deceive and cheat investors.” U.S. Br. 29.

These are the government’s own words. The pivotal issue always was Holmes’ knowledge about whether Theranos’ technology worked. If the jury found that Holmes knew Theranos’ technology didn’t work, it could find she had reason to misrepresent various aspects of Theranos’ business to create a perception that the technology worked—as the government argued below. But the converse is equally true and powerful: if the jury found that Holmes genuinely believed the technology worked, it was more likely to find that she made statements regarding other aspects of the company’s business in good faith and not as a fraudulent effort to legitimize the technology.

The Court thus cannot confidently conclude that the jury would have convicted Holmes on the other alleged misrepresentations alone. Notably, the jury rendered a general verdict, meaning that the Court cannot know which

alleged representations the jury found false or why. *See* Holmes Br. 51 (citing cases). The government does not address this point at all.

B. The Case Was Close

Holmes vigorously defended against *all* the alleged misrepresentations. The government's *ipse dixit* notwithstanding (at 50), this was a close case. The government prevailed on only 4 of 12 counts, after 7 days of deliberations.

In discussing the other categories of alleged misrepresentations, the government's brief predictably selects and presents the evidence in the light most favorable to the government. But the evidence was in conflict, and substantial evidence showed Holmes' good-faith belief in the accuracy of all her representations, including the fact that she held her Theranos shares until the very end. *See* Holmes Br. 4-13, 18-20. Holmes briefly summarizes here the most prominent examples:

1. *Representations regarding pharmaceutical companies*

The indictment alleged that Holmes knowingly misrepresented “that Theranos’s technology had been examined, used, and validated by several national or multinational pharmaceutical companies and research institutions.” 13-ER-3531 (¶ 12(H)). Several pharmaceutical companies and research institutions did examine, use, and validate Theranos’ technology. 49-ER-14266-67

(various companies); 45-ER-13003 (GSK); 45-ER-13004-05 (Johns Hopkins); 49-ER-14314-25 (Celgene); 1-FER-31 (UCSF); 1-FER-174-75 (Mayo Clinic); *see also* 49-ER-14274-327, 50-ER-14330-467. Theranos employees believed and told Holmes that Theranos' work with pharmaceutical companies was successful and comprehensive. *E.g.*, 18-ER-4962; 49-ER-14261 ("Great feedback; Home run"; "Great correlation with Merck data"); 49-ER-14266 ("Completed Successes"); 1-FER-218 (slide sent to GSK stating that GSK had "completed a comprehensive validation of Theranos Systems"). Conspicuously, none of the pharmaceutical-company witnesses invoked by the government shared unfavorable evaluations of the technology with Holmes or Theranos. 22-ER-8654, 8680-81, 8685 (Schering-Plough); 28-ER-7997-8004, 8029, 8034-35 (Pfizer); *see also* 44-ER-12613-20 (defense closing highlighting this fact). Indeed, those companies later expressed interest in working with Theranos again. 38-ER-10969-71, 10980-87; 1-FER-169, 178-83.

Given these problems with the indictment allegations, the government pivoted below to the unpleaded allegation that Holmes "doctored" reports by affixing the logos of Pfizer, Schering-Plough, and GSK. In ruling on the sufficiency of the evidence after trial, the court declined to rely on the government's evidence regarding pharmaceutical companies following Holmes'

argument that this new theory amended and/or varied from the indictment. 5-ER-1344 n.1.

This allegation too had significant weakness. Contemporaneous evidence showed that Holmes did not believe she did anything wrong, because she freely shared the supposedly “doctored” reports with those companies themselves. 39 ER-11040-43; 1-FER-181, 186, 213, 252, 288-89. Holmes shared the GSK report with the GSK logo with Schering-Plough in 2008, 1-FER-110, 119—well before the government argued a motive to deceive investors arose. Holmes testified at trial—consistent with these documents—that she meant only to convey that the work described in the reports occurred in partnership with the companies. 39-ER-11039-40.

2. Representations regarding the Department of Defense

The government’s case relating to the Department of Defense was hotly contested. Contemporaneous recordings showed Holmes speaking only about potential, promising applications of Theranos’ technology in the military context. *See* 29-ER-8118 (“the *ability* to take a technology like this and put it in flight, specifically on a medevac, has the *potential* to change survival rates”); *see also* 1-FER-100.

Emails from the U.S. Africa Command confirmed that Theranos' device was "deploy[ed]" to Cameroon, South Sudan, and Uganda. 53-ER-15491-92 ("[t]his is what we usually use when we *deploy* for most equipment" (emphasis added)); *see also* 52-ER-14949-50; 53-ER-15489; Holmes Br. 8. The government called no Department of Defense witness to contradict the documentary record. *See* 44-ER-12744 (defense closing highlighting this gap).⁷

As it did in closing, 43-ER-12504, the government asserts on appeal (at 8-9) that the military did not use the technology *to treat patients*. 43-ER-12504. But the indictment did not charge Holmes with representing that it did. The court thus appropriately declined to rely on evidence relating to the Department of Defense in assessing evidentiary sufficiency after trial. 5-ER-1344 n.1.

3. Representations regarding Walgreens

The Walgreens-Theranos 2013 agreement charted expansion to 3,000 stores in 24 months. 55-ER-15898.⁸ The parties' Program Charter—dated

⁷ The government (at 9) neglects to mention that Board Member James Mattis recused himself from Theranos' military work. 19-ER-5305-06; *see also* 44-ER-12744.

⁸ The government's account of the Walgreens launch (at 11-12) is incorrect, and was an issue requiring correction during Holmes' cross-examination of Rosendorff. Holmes Br. 64-65 n.9. Theranos validated each test before offering it to the public, 21-ER-5750-51, and, when informed of concerns with

March 2014—set a goal of 2,500 stores by August 2016. *See* 26-ER-7256; 46-ER-13359.

The government claims (at 18-19) that in August 2014 Walgreens “decreased its 2015 goal for stores with Theranos testing from 500 to 200” because venous draws were not “used for less than 10% of patients.” No evidence showed that anyone communicated to Holmes an August 2014 decision to reduce the planned rollout to 200 stores.⁹ Balwani managed the day-to-day relationship, not Holmes. 26-ER-7184. The following month, a Walgreens employee told Holmes that “we are making great progress in our relationship.” 49-ER-14123. And Holmes met with a Walgreens senior executive in December 2014 to continue planning the national rollout. 39-ER-11157-58, 42-ER-12154-55.

4. Financial projections

The government did not prove that Theranos generated “only modest revenues” in 2014, as the indictment alleged. 13-ER-3530. The government incorrectly claims (at 10) that Theranos “earn[ed] just \$150,000 in 2014.” The

certain fingerstick tests before the launch, Holmes told Rosendorff that Theranos should use venous testing—which it did, 21-ER-5739.

⁹ Balwani’s November 11, 2014 text to Holmes that “We can’t scale with wag,” read in context, shows Balwani’s belief that the company should focus its efforts on “swy” (Safeway) and “cvs.” 4-SER-657.

cited testimony states only that Theranos “recorded” \$150,000 as income in 2014. 16-ER-4393. Theranos *received* more than \$160 million in revenue in 2014 but ultimately “recorded” the revenue as deferred revenue. 46-ER-13158; *see* 16-ER-4429-31, 4460; Holmes Br. 68.

Investors testified that the 2015 projection assumed that Theranos would substantially increase the number of Walgreens locations. 29-ER-8263-64; 31-ER-8750-51; 46-ER-13157. As discussed, the jury could have found that Holmes had reason to believe that assumption, in part because she believed the technology worked. And Holmes further defended her belief on the ground that Balwani was responsible for the company’s financial projections. 39-ER-11225-26; 44-ER-12763.¹⁰

5. *Representations regarding third-party devices*

Substantial evidence showed that Holmes did not intend to mislead investors about Theranos’ use of third-party devices during Phase 1 of its operations (*see* Holmes Br. 9-11). In many instances Theranos used third-party devices in conjunction with its own proprietary small-sample (*i.e.*, fingerstick)

¹⁰ The government also claims (at 10, 51) that in 2013 Holmes orally misrepresented to an investor that Theranos had \$200 million in past revenue from pharmaceutical and military work. The indictment allegations, however, were tied only to 2014 revenue and 2015 projected revenue. 13-ER-3530. And that investor’s own projections contradicted his testimony on this issue. 1-FER-91-92.

assay technology—a methodology it viewed and protected as a trade secret. Holmes Br. 10; *see* 38-ER-10869. And, although it also used third-party devices to conduct traditional venous (non-fingerstick) testing, Holmes told Theranos personnel that “we need to own” venous draws on the company’s website. 48-ER-13937. She told Fortune journalist Roger Parloff about venous testing. 1-FER-99. Both Theranos and Walgreens disclosed venous testing. Holmes Br. 10; *see* 18-ER-4817; 45-ER-13120; 46-ER-13383; 53-ER-15509, 15512; 1-FER-42. Investors knew that Theranos conducted venous testing. 31-ER-8881-82; 36-ER-10164; 47-ER-13659-61; 1-FER-101.

Holmes’ representations about the ability of Theranos’ technology to conduct any blood test were not knowingly false: Theranos developed a device, the 4-series miniLab, that Theranos employees, including Holmes, believed could accurately run virtually any blood test. Holmes Br. 6-7; *see* U.S. Br. 11 n.2.¹¹ To be sure, the company was not using the miniLab to test patient samples in Phase 1 while it sought FDA approval to use the miniLab outside Theranos. Holmes Br. 9. But Theranos validated assays on the miniLab and

¹¹ The government’s claim (at 11 n.2) that Holmes testified the miniLab never worked is false and is not supported by the government’s citations.

submitted that data in good faith to FDA. 39-ER-11121-26; 48-ER-13944-49-ER-14124; 54-ER-15537-752; 54-ER-15761-55-ER-15883; Holmes Br. 7.

C. The Court's Errors Infected the Key Issues in the Case

The court's errors made it impossible for the jury fairly to assess Holmes' intent and knowledge with respect to the key issues.

1. Unsurprisingly, the government features the testimony of Rosen-dorff and Das prominently in its factual background (at 14-19, 22-23). These witnesses, and the CMS and voiding evidence the government admitted through Das, were the centerpiece of the government's case on Holmes' intent and knowledge as it related to Theranos' technology.

In an attempt to prove the harmlessness of Das' testimony and the evidence admitted through his testimony, the government (at 50) highlights the length of his testimony and the number of references to him in closing. But harmlessness review "transcend[s] confinement by formula or precise rule." *Kotteakos v. United States*, 328 U.S. 750, 761 (1946). Das' testimony was different in kind than every other witness'. In a case about science, he presented the *only* expert scientific analysis of Theranos' technology. And his analysis enabled the government to prop up what was otherwise an exceptionally weak

scientific case. The government disputes none of the points at pages 47-48 of Holmes' brief outlining the glaring weaknesses in its case.

The government likewise used the CMS report and voiding evidence, which it linked together (*see* 43-ER-12510-11), to fill this hole. Holmes defended the case in large part by pointing to all the evidence that she and others at Theranos contemporaneously believed in the technology. Holmes Br. 4-7. The court's direction to consider the later-in-time CMS report as evidence of Holmes' state of mind devastated this defense. So too with the voiding evidence, which the government claims (at 45-46) the jury could have viewed as an admission that the technology did not work. No other such "admission" existed.

2. As for Rosendorff, the government does not even acknowledge its burden to prove harmlessness beyond a reasonable doubt. Holmes Br. 65-67. That burden is insurmountable on these facts. Rosendorff was *the* central government witness. The government does not dispute that it referenced Rosendorff more than any other government witness in opening, closing, and rebuttal argument. And the government cannot relegate Rosendorff's importance to the patient counts: both the government and the court, in denying judgment

of acquittal, invoked Rosendorff's testimony as supporting the investor counts. Holmes Br. 66-67.

Contrary to the government's suggestion (at 64), no other witness was a substitute for Rosendorff. None commanded anywhere near the attention that Rosendorff did, and none could have established notice to Holmes that the Edison did not work at the time of representations to C-2 investors. Cheung was an entry-level employee with no direct contact with Holmes during her employment. 17-ER-4664; 40-ER-11385-86, 11538. Gangakehdkar departed in summer 2013, before the Edison device was deployed in the clinical laboratory and before representations to C-2 investors. 18-ER-4844.

3. Balwani's SEC testimony was critical evidence of Holmes' intent as to the financial projections. The government claims (at 72) that it was not contested at trial that Balwani largely handled the financials, but it argued in closing that "the division [in roles] wasn't a clear line." 43-ER-12520-21. Balwani's inculpatory testimony directly contradicted this assertion and would have bolstered Holmes' exculpatory trial testimony.

The government argues (at 73) that Balwani's testimony did not matter because, the government claims, Holmes knew that Theranos had only "modest revenues" in 2014. That is incorrect. *See supra* p.37. The government

next argues (at 73-74) that Theranos' deferred revenue did not match the "detailed breakdown of sources of projected revenue" provided to investors. This claim appears nowhere in the indictment, *see* 13-ER-3530, and the government did not even argue it in closing.

Finally, the projection-related allegations were potentially dispositive. The government has no answer for the facts that (1) only the C-2 investors received the projections and (2) the jury convicted Holmes of wire fraud with respect to the C-2 investors but not the C-1 investors.

V. THE COURT ERRONEOUSLY APPLIED THE PREPONDERANCE-OF-THE-EVIDENCE STANDARD AT SENTENCING

The Court should vacate Holmes' 11.25-year sentence and remand for resentencing under a clear-and-convincing standard.

1. The parties agree that courts consult the non-exhaustive *Valensia* factors to determine the standard of proof for sentencing enhancements. The government's primary argument (at 76) is that the 26-level increase was "based on the extent of the conspiracy," and therefore the fourth *Valensia* factor favors a preponderance standard. That argument is incorrect.

The fourth *Valensia* factor recognizes that when "[t]he defendants had the opportunity at trial to challenge the evidence," "a clear and convincing standard of proof is not warranted." *United States v. Lonich*, 23 F.4th 881,

910-11 (9th Cir. 2002) (cleaned up). The government focuses on the fact Count 1 alleged a conspiracy from 2010 to 2015, but the government did not prove that every investment in that period resulted from the alleged scheme. The government ignores that (1) the jury obviously did not convict Holmes of defrauding every investor from 2010 to 2015 because the jury hung on the three counts related to investments in 2013; (2) investors in Theranos, a private company, invested at different times and had access to different information;¹² and (3) the trial evidence did not address the majority of the investments on the court's list of ten victims. Holmes Br. 83-86.

Moreover, as to all investors, the fact of the conspiracy conviction does not prove loss under § 2B1.1(b). Loss causation is not an element of wire fraud. Holmes Br. 85-86. That Holmes did not challenge the investment *amounts* at trial says nothing about what caused those investments. Evidence that an investment occurred does not prove loss *causation* (reliance) or amount of loss. See Holmes Br. 85 (citing 1-ER-270; 11-ER-2955; 29-ER-8224).¹³

¹² The government suggests (at 81 n.17) that the court found there were “likely” “many more” victims, but the court said only that “the reality may be” there were more victims. 1-ER-24. The court rightly “declined to expand” “the scope of victims to all investors.” 1-ER-24-25.

¹³ *United States v. Armstead*, 552 F.3d 769 (9th Cir. 2008), does not help the government. There, the totality of the *Valensia* factors weighed in favor of the preponderance standard: the disputed enhancements resulted in a total 4-

2. In a footnote, the government notes that this Court may revisit the standard to be used in Guidelines-related factfinding when it rehears *United States v. Lucas*, No. 22-50064, in January 2024. Even more so than in *Lucas*, the circumstances here underscore the importance of heightened scrutiny of the quality and volume of sentencing-related evidence when judicial factfinding will dramatically increase the Guidelines range. In *Lucas*, the at-issue enhancement produced a 6-level increase, which increased the Guidelines range by 2.5 to 3 years. *United States v. Lucas*, 70 F.4th 1218, 1221 (9th Cir. 2023). After finding the enhancement applied, the court sentenced the defendant to a *below*-Guidelines sentence. *Id.* Here, application of § 2B1.1 increased the offense level by 26 levels, and the Guidelines range by more than a decade, and the court gave a within-Guidelines sentence. Without the current due process check on the Guidelines calculation, the government would have a strong incentive to prove the minimum necessary to secure a conviction, and then ratchet up the Guidelines calculation based on evidence that a defendant has no real opportunity to challenge.

level increase, while the jury found the largest enhancement beyond a reasonable doubt. *Id.* at 776-77. Neither circumstance exists here.

If this Court alters its longstanding precedent in *Lucas*, Holmes requests the opportunity to provide supplemental briefing addressing whether and how those changes affect her case.

3. Because this Court does not engage in “guesswork” regarding what courts might have found by clear-and-convincing evidence, *United States v. Hymas*, 780 F.3d 1285, 1292 (9th Cir. 2015), remand is required.¹⁴

CONCLUSION

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

¹⁴ The government cites (at 80-81) a comment by the court suggesting it might reach the same result under a clear-and-convincing standard, but that comment was specific to Balwani.

DATED: NOVEMBER 13, 2023

Respectfully submitted,

/s/Amy Mason Saharia

KEVIN M. DOWNEY

LANCE A. WADE

AMY MASON SAHARIA

KATHERINE A. TREFZ

WILLIAMS & CONNOLLY LLP

680 Maine Avenue SW

Washington, DC 20024

(202) 434-5000

asaharia@wc.com

JOHN D. CLINE

LAW OFFICE OF JOHN D. CLINE

600 Stewart Street

Suite 400

Seattle, WA 98101

(360) 320-6435

Attorneys for Appellant

Elizabeth A. Holmes

CERTIFICATE OF COMPLIANCE

This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5)(A) and Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14-point font.

This brief contains 8964 words, including 0 words manually counting in any visual images, and excluding the parts exempted by Fed. R. App. P. 32(f). I certify that this brief is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

/s/ Amy Mason Saharia
AMY MASON SAHARIA

DATED: NOVEMBER 13, 2023

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: <http://www.ca9.uscourts.gov/forms/form08instructions.pdf>

9th Cir. Case Number(s)

I am the attorney or self-represented party.

This brief contains words, including words

manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

I certify that this brief (*select only one*):

- complies with the word limit of Cir. R. 32-1.
- is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- is an **amicus** brief and complies with the word limit of FRAP 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- complies with the longer length limit permitted by Cir. R. 32-2(b) because (*select only one*):
 - it is a joint brief submitted by separately represented parties.
 - a party or parties are filing a single brief in response to multiple briefs.
 - a party or parties are filing a single brief in response to a longer joint brief.
- complies with the length limit designated by court order dated
- is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature

Date

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

ADDENDUM OF CONSTITUTIONAL PROVISIONS, STATUTES, AND RULES

Except for the following, all applicable Constitutional provisions, statutes and rules are contained in the Addendum of Constitutional Provisions, Statutes, and Rules attached to Holmes' Opening Brief.

Federal Rule of Evidence 104. Preliminary Questions

- (a) **In General.** The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege.
- (b) **Relevance That Depends on a Fact.** When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist. The court may admit the proposed evidence on the condition that the proof be introduced later.
- (c) **Conducting a Hearing So That the Jury Cannot Hear It.** The court must conduct any hearing on a preliminary question so that the jury cannot hear it if:
 - (1) the hearing involves the admissibility of a confession;
 - (2) a defendant in a criminal case is a witness and so requests; or
 - (3) justice so requires.
- (d) **Cross-Examining a Defendant in a Criminal Case.** By testifying on a preliminary question, a defendant in a criminal case does not become subject to cross-examination on other issues in the case.
- (e) **Evidence Relevant to Weight and Credibility.** This rule does not limit a party's right to introduce before the jury evidence that is relevant to the weight or credibility of other evidence.