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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

In re: No. CV

Arizona THERANOS, INC. Litigation,

No. CV-16-02138-PHX-DGC

(Consolidated with)

No. 2:16-cv-2373-HRH

No. 2:16-cv-2660-HRH

No. 2:16-cv-2775-DGC

-and-

No. 2:16-cv-3599-DGC

ORDER

Defendants Walgreens Boots Alliance, Inc. and Walgreen Arizona Drug Co. (collectively, "Walgreens") move for summary judgment on Plaintiffs' remaining class claims. Doc. 521. Walgreens brings a *Celotex* motion, arguing that there is "no evidence from which a jury could conclude that Walgreens knew about or recklessly disregarded indications of Theranos's[] fraud at the time." *Id.* at 7.

Plaintiffs respond that Walgreens knew, deliberately ignored, or recklessly disregarded that the new Theranos blood testing method lacked reliable results, was not market-ready, and received only minimal regulatory scrutiny. Doc. 538. Plaintiffs cite deposition testimony, emails, and documents. Walgreens argues that Plaintiffs mischaracterize the evidence. Doc. 555.

The Court must determine whether Plaintiffs have produced sufficient evidence to create triable issues of fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). Reviewing the evidence without making credibility determinations, the Court concludes that summary judgment must be denied on Plaintiffs' remaining counts and granted on Plaintiffs' request for punitive damages.

I. Background.

This case arises from Theranos's claim that it had developed a revolutionary blood testing technique that could evaluate hundreds of blood characteristics from a single finger prick. The claim, promoted by Theranos executives Elizabeth Holmes and Ramesh "Sunny" Balwani (who are Defendants in this case), received worldwide attention and attracted millions of dollars in investments. Walgreens partnered with Theranos to introduce the simple blood tests in Walgreens retail pharmacy stores. Plaintiffs represent class members who received blood tests in Walgreens stores in Arizona and California.

Walgreens now acknowledges that the Theranos product was not a legitimate and accurate new blood testing method, but asserts that Walgreens – like many others – was defrauded by Theranos, Holmes, and Balwani. The facts that follow in this section of the order are taken largely from the Walgreens motion for summary judgment. Doc. 521 at 6-15. They provide the basic chronology of the Walgreens-Theranos relationship and illustrate Walgreens's argument that it was diligent in its investigation of Theranos and is not liable for Theranos's fraud.¹

Theranos represented to Walgreens that its technology – the Theranos Systems, also known as the "Edison" – had been validated over the course of the previous seven years by 10 of the 15 largest pharmaceutical companies, had been validated by the FDA, and had been shown highly accurate by correlation data (comparisons of Theranos test results to results from a commercially available machine). Theranos claimed that its clients included

¹ Defendant Theranos is now defunct. Defendants Homes and Balwani did not participate in the summary judgment briefing or argument, and the Court's recitation of evidence in this order is not intended to be a finding of fact against either of them.

major pharmaceutical and biopharmaceutical companies, research institutions, and U.S. and foreign health and military organizations. Theranos told Walgreens about notable investors and board members, including Donald Lucas, Larry Ellison, and Bob Shapiro (former CEO of Pfizer).

In April 2010, Holmes sent Walgreens three independent due diligence reports on the Theranos technology from GlaxoSmithKline, Pfizer, and Schering-Plough, which she said were based on the pharmaceutical companies' own technical validations and experiences with Theranos products in the field. Walgreens also engaged a team from Johns Hopkins School of Medicine to review testing data and observe a demonstration of the Theranos technology, leading Johns Hopkins to report that the technology was novel and sound, could accurately run a wide range of routine and special assays, and would be useful in the retail clinic setting.

Walgreens engaged Kevin Hunter, the CEO and Managing Partner of Colaborate, a laboratory management consulting firm, to assist in evaluating a potential partnership with Theranos. Hunter expressed excitement about Theranos and concluded that its technology could be a game changer for the lab industry. Walgreens visited Theranos's headquarters and laboratory, discussed business models, reviewed patents, and discussed regulatory strategy.

Walgreens entered into a Master Purchase Agreement with Theranos on July 30, 2010. The contract was not a commitment to go to market, but secured the opportunity for Walgreens to work exclusively with Theranos on a potential partnership.

In June 2011, Walgreens postponed the launch of Theranos testing in its stores until appropriate regulatory approval was in place, even though this meant that Theranos might go to market with a competitor.

In June 2012, the parties signed an Amended and Restated Theranos Master Services Agreement. Instead of Theranos testing devices being located inside Walgreens stores, the devices would be located at a stand-alone Theranos laboratory where testing

would occur. Walgreens would act as a patient service center. Walgreens or Theranos employees would collect blood samples using Theranos finger-stick technology in "Theranos Wellness Centers" in Walgreens stores, and the blood would be sent to a certified laboratory owned and operated by Theranos. Theranos would be responsible for running tests and sending results to the requesting physician or patient. Walgreens purchased a \$40 million convertible note from Theranos and agreed to pay another \$100 million "Innovation Fee" in installments, based on reaching certain milestones (which Walgreens paid in full by December 2013).

The Amended Agreement required all Theranos laboratories to receive a Certificate of Compliance under the Clinical Laboratory Improvement Amendments of 1998 ("CLIA"). CLIA regulations are overseen by the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services, and establish quality standards for laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results. Shortly after signing the 2012 Agreement, Theranos provided Walgreens a copy of its CLIA Certificate of Compliance and associated inspection report.

Ken Finnegan, Walgreens's Vice President of New Product Development and Innovation and a former Quest Diagnostics executive, reviewed Theranos's proficiency reports and correlation studies and was satisfied with the results. Dr. Jeffrey Kang, Walgreens's Senior Vice President of Pharmacy, Health, and Wellness Services and Solutions, and the former Chief Medical Officer of CMS, visited Theranos and performed his own review of its proficiency data, correlation studies, and inspection reports. Dr. Harry Leider, Walgreens's Chief Medical Officer, and Dr. Patrick Carroll, Chief Medical Officer of the Healthcare Clinics, also reviewed Theranos's correlation studies.

Walgreens retained another independent third-party consultant, Paul Rust, also a former Quest Diagnostics executive, to further review Theranos's correlation and

proficiency test results. Rust visited Theranos in October 2012, reviewed data, and concluded that the results documented excellent performance.

In March 2013, Walgreens and Theranos began a controlled "soft launch" with paid clinical trial patients in one Phoenix Walgreens store. In September 2013, the parties launched a pilot in a Palo Alto Walgreens store. Over the next year, Theranos Wellness Centers opened in 40 Walgreens stores in the Phoenix area.

In late 2013 and early 2014, nurse practitioners who worked at the health clinics requested additional information about the accuracy of Theranos testing before they would recommend Theranos testing to patients. In response, Walgreens requested, received, and shared with the nurse practitioners Theranos's clinical correlation information, which Dr. Kang reviewed and found acceptable.

On January 9, 2014, the government renewed Theranos's California laboratory's CLIA Certificate of Compliance after an inspection and review of proficiency testing results. Theranos opened a second laboratory in Arizona, which also received a CLIA Certificate of Compliance in May 2015.

On July 2, 2015, Theranos publicly announced that it had received FDA clearance of its test system and herpes simplex 1 virus IgG (HSV-1) test for both finger stick and venous blood testing, explaining that with FDA approval it could use the test system in locations outside of traditional clinical laboratories.

In October 2015, The Wall Street Journal published an article accusing Theranos of not using its own technology to conduct the majority of its blood tests and suggesting that Theranos cheated on the proficiency tests required for CLIA certification. In January 2016, CMS issued a letter to Theranos identifying deficiencies at its California laboratory. On May 18, 2016, Theranos voided two years of Edison test results. On June 12, 2016, Walgreens terminated the Amended Agreement for cause. A month later, CMS revoked the CLIA Certificate for Theranos's California lab. In February 2017, CMS revoked the CLIA Certificate for Theranos's Arizona lab.

Theranos, Holmes, and Balwani were subsequently charged with fraud by the U.S. Securities and Exchange Commission and the U.S. Department of Justice. Theranos is now defunct, and separate juries convicted Holmes and Balwani of multiple counts of wire fraud and conspiracy. Each has been sentenced to more than a decade in federal prison. The Arizona Attorney General entered into a Consent Decree with Theranos which required full refunds for Arizona consumers who purchased any Theranos blood test.

II. Legal Standards for Walgreens's State of Mind.

Plaintiffs assert claims under the Racketeer Influenced and Corrupt Organization Act ("RICO"), 18 U.S.C. § 1962(c), Arizona Consumer Fraud Act ("ACFA"), Ariz. Rev. Stat. § 44-1522, California False Advertising Law ("FAL"), Cal. Bus. & Prof. Code § 17250, and California Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code. § 17200. Plaintiffs also assert claims for common law battery and medical battery.

Walgreens argues that it is entitled to summary judgment on all these claims because no reasonable jury could find that it knew about or intentionally disregarded Theranos's fraud. Plaintiffs claim they have ample evidence for a jury to find that Walgreens knew of or intentionally disregarded the fraud. The Court begins by determining the level of knowledge and intent necessary for each of Plaintiffs' claims.

A. RICO.

Plaintiffs base their RICO claim on violations of the federal wire fraud statute, 18 U.S.C. § 1343. Plaintiffs therefore must prove each element of wire fraud. *See Nutrition Distrib. LLC v. Custom Nutraceuticals LLC*, 194 F. Supp. 3d 952, 957 (D. Ariz. 2016).

Walgreens notes that the "intent to defraud" required for wire fraud exists when "the defendant either knew it was making false representations or acted with reckless indifference to their truth or falsity." Doc. 521 at 18 (citing *United States v. Cusino*, 694 F.2d 185, 187 (9th Cir. 1982)). Plaintiffs agree, stating that wire fraud occurs when a defendant makes a misrepresentation "with (1) knowledge that it is false or (2) with

'reckless indifference' to 'truth or falsity.'" Doc. 538 at 20 (citing *United States v. Munoz*, 233 F.3d 1117, 1136 (9th Cir. 2000)).

Plaintiffs also argue that actual knowledge of fraud can be shown by a defendant's willful blindness to the truth. Doc. 538 at 20. They cite *Glob-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011), which explains that defendants "who deliberately shield[] themselves from clear evidence of critical facts that are strongly suggested by the circumstances . . . are just as culpable as those who have actual knowledge." *Id.* at 766. Plaintiffs assert that a defendant is willfully blind if it subjectively believes that there is a high probability of fraud and takes deliberate actions to avoid learning that fact. *Id.* at 769; *see also Kuzma v. N. Arizona Healthcare Corp.*, 607 F. Supp. 3d 942, 951 (D. Ariz. 2022) (a jury may find "knowing" conduct where a defendant "was aware of a high probability" of illegal conduct and "deliberately avoided learning the truth"). Walgreens accepts Plaintiff's assertion: "Plaintiff's correctly observe that 'willful blindness' (also referred to as 'deliberate ignorance') can satisfy the actual knowledge requirement." Doc. 555 at 8.²

Thus, the Court concludes that Plaintiff's RICO predicate requires proof that Walgreens either actually knew it was making false statements (a level of knowledge that can also be shown by willful blindness) or acted with reckless indifference to the truth or falsity of its statements. The Court adopts these definitions:

- "Actual knowledge . . . describe[s] the state of mind when [the] defendant, in fact, knows of the existence of the [illegal conduct]." *United States v. Heredia*, 483 F.3d 913, 922 (9th Cir. 2007).
- A "willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts." *Glob.-Tech Appliances, Inc.*, 563 U.S. at 769.

A jury can "rationally find willful blindness even though it has rejected . . .

² Although willful blindness is also referred to as deliberate ignorance, this order will use the phrase willful blindness. *See, e.g., United States v. Yi*, 704 F.3d 800, 804 (9th Cir. 2013) (using terms interchangeably).

evidence of actual knowledge." *United States v. Yi*, 704 F.3d 800, 804 (9th Cir. 2013)

• "[A] reckless defendant is one who merely knows of a substantial and unjustified risk of such wrongdoing." *Glob.-Tech Appliances, Inc.*, 563 U.S. at 770.

B. RICO Associated-In-Fact Enterprise.

Plaintiffs' RICO claims include additional elements. A RICO plaintiff must show conduct of an "enterprise through a pattern of racketeering activity." *Odom v. Microsoft Corp.*, 486 F.3d 541, 547 (9th Cir. 2007). An "enterprise" may be an "association," 18 U.S.C. § 1961(4), and "[a]n associated-in-fact enterprise is a group of persons associated together for a common purpose of engaging in a course of conduct." *United States v. Christensen*, 828 F.3d 763, 780 (9th Cir. 2015) (cleaned up). Thus, to establish such an enterprise, a plaintiff must prove that the group acted with a "common purpose." *Id*.

Walgreens argues that a common purpose to commit fraud – as alleged in this case (*see* Doc. 159, ¶ 525) – can be shown only if the participants in the enterprise had actual knowledge of the fraud. Doc. 521 at 27 (citing *Stitt v. Citibank, N.A.*, No. 12-cv-03892, 2015 WL 75237, at *5 (N.D. Cal. Jan. 6, 2015) (RICO plaintiffs required to show that each of "the enterprise members actually knew of the alleged fraudulent common purpose, or that they 'formed' the enterprise to participate" in that purpose)). Plaintiffs do not disagree, but they again note that the actual knowledge requirement can be satisfied by proof of willful blindness. Doc. 538 at 28. Walgreens agrees. *See* Doc. 555 at 8. Thus, to prove the common purpose element of the associated-in-fact enterprise, Plaintiffs must prove that Walgreens either had actual knowledge of the fraud or remained willfully blind to it.

C. State Consumer Protection Statutes.

Plaintiffs assert that the intent necessary for their claims under the ACFA, UCL, and FAL can be satisfied by willful blindness. Doc. 538 at 21-22 (citing cases). Walgreens agrees. Doc. 555 at 8.

As Plaintiffs note, the ACFA broadly prohibits the misrepresentation or omission of any material fact in connection with the sale or advertisement of consumer goods and services. Ariz. Rev. Stat. § 44-1522(A). In a criminal case, the Arizona Supreme Court has held that even where a defendant charged with fraud "had no actual knowledge," he could still be found guilty if he was "aware of the high probability that the scheme was fraudulent and deliberately shut his eyes to avoid learning the truth." *State v. Haas*, 675 P.2d 673, 680 (Ariz. 1983). Proof of consumer fraud by willful blindness has been applied in at least one Arizona civil case. *See Estée Lauder Cosms. Ltd. v. Get Your Mac On, LLC*, No. 13-0634, 2015 WL 274133, at *3 (D. Ariz. Jan. 22, 2015) (civil counterfeiting claim under Ariz. Rev. Stat. § 44-1453(A)).

Under the UCL and FAL, a plaintiff must show the failure to disclose facts a defendant knew or believed to be true. *Dreamstime.com*, *LLC v. Google LLC*, No. 20-16472, 2022 WL 17427039, at *2 (9th Cir. Dec. 6, 2022) (Under the UCL, "[p]arties have no legal duty to disclose facts that they do not know or believe to be true.") (citing *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1145 n.5 (9th Cir. 2012)). Although the case law is dated, the parties agree that the California consumer protection statutes require either actual knowledge or willful blindness. *See Levy v. Irvine*, 66 P. 953, 956 (Cal. 1901) (defendant could not "willfully shut his eyes to the means of information which he knows is at hand, and if he does so his willing ignorance is to be regarded as equivalent to actual knowledge"); *Buena Vista Oil Co. v. Park Bank of Los Angeles*, 180 P. 12, 14 (Cal. Ct. App. 1919) (same).

E. Battery and Medical Battery.

"An actor is subject to liability to another for battery if the actor intentionally engages in an act that results in harmful or offensive contact with the person of another." *Duncan v. Scottsdale Med. Imaging, Ltd.*, 70 P.3d 435, 438 (2003) (citation omitted). A health care provider may commit battery if a patient does not consent to an invasive medical procedure. *Id.* Consent is ineffective if the patient "is induced to consent by a

substantial mistake concerning the nature of the invasion of his interests . . . and the mistake is known to the other or is induced by the other's misrepresentation." *Id.* at 440 (quoting Restatement (Second) of Torts § 892B (1965)).

The Arizona Supreme Court has held "that if a patient's consent is obtained by a health care provider's fraud or misrepresentation, a cause of action for battery is appropriate." *Duncan*, 70 P.3d at 440. To establish Walgreens's liability for battery, therefore, Plaintiffs must show that their consent to the blood test was obtained by Walgreens's fraud or misrepresentation. Actual intent to defraud will suffice for such a claim, as will willful blindness. As noted above, defendants "who deliberately shield[] themselves from clear evidence of critical facts that are strongly suggested by the circumstances . . . are just as culpable as those who have actual knowledge." *Glob-Tech Appliances*, 563 U.S. at 766; *see also Haas*, 675 P.2d at 680; *Estée Lauder*, 2015 WL 274133 at *3.3

F. Intent Summary.

To avoid summary judgment on their allegation of a RICO common purpose, their claims under the AFCA, UCL, and FAL, and their battery claims, Plaintiffs must present sufficient evidence for a reasonable jury to find that Walgreens either knew of Theranos's fraud or willfully blinded itself to the fraud. While the intent element of the RICO predicate act (wire fraud) can be satisfied by the lower standard of reckless indifference, that standard will be irrelevant if Plaintiffs cannot show the higher intent required for the common purpose element of an associated-in-fact RICO enterprise – summary judgment will be granted on the RICO claim. The Court therefore will not address the reckless indifference standard further in this order.

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³ Further, Arizona courts hold that a defendant need not be certain that an adverse result will occur before it can be liable for the misrepresentation needed for battery. "Substantial certainty" – which could exist when a defendant willfully blinds itself to a high probability that adverse results will occur – can suffice. *See A.G. v. Paradise Valley Unified Sch. Dist. No. 69*, 815 F.3d 1195, 1210 (9th Cir. 2016).

III. Plaintiffs' Evidence.

Because Plaintiffs can defeat summary judgment by producing sufficient evidence for a reasonable jury to find that Walgreens willfully blinded itself to Theranos's fraud – a somewhat lower threshold than actual knowledge of the fraud – the Court will focus on willful blindness. If Plaintiffs cannot produce sufficient evidence of willful blindness, they certainly cannot produce sufficient evidence of actual knowledge and summary judgment is warranted on all counts. If they can produce sufficient evidence of willful blindness, they defeat summary judgment on all claims regardless of whether they can make the higher showing of actual knowledge, although a separate analysis will be required for punitive damages.

Willful blindness contains two prongs: (1) "a subjective belief that there is a high probability a fact exists" – in this case, a high probability that the Theranos product was not legitimate and had not been shown to provide accurate results; and (2) "deliberate actions taken to avoid learning the truth" – in this case, conscious actions by Walgreens to avoid learning the truth about the Theranos product. *Yi*, 704 F.3d at 804 (citing *Glob.-Tech Appliances, Inc.*, 563 U.S. at 769-70).

Summary judgment is warranted if the evidence, viewed in the light most favorable to the nonmoving party, shows "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment may be granted if Plaintiffs fail to present sufficient evidence to establish an element essential to their case and on which they will bear the burden of proof at trial – in this case, Walgreens's willful blindness. *Celotex*, 477 U.S. at 322. To avoid summary judgment, Plaintiffs must produce enough evidence for a reasonable jury to return a verdict in their favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "Credibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions, not those of a judge." *Id.* at 255. Plaintiffs' evidence must "be believed, and all justifiable inferences are to be drawn in [their] favor." *Id.*

A. Kevin Hunter.

As noted above, Walgreens retained Kevin Hunter, the CEO and Managing Partner of Colaborate, a laboratory management consulting firm, to investigate the Theranos method. Doc. 521 at 8. Hunter and Colaborate expressed enthusiasm for the technology Theranos appeared to have developed, but recommended that "Walgreens proceed with an in-depth diligence around the science and scalability of Theranos Systems hardware and test menu platform with realistic expectations." Doc. 520-8 at 16. When deposed in this case, Hunter explained the point of this recommendation: "to make sure that there was a product behind the promise, if you will, and that the bold claims could be backed up." Doc. 541-67 at 6.4 "[M]any times" Hunter voiced the opinion that Walgreens "needed to know more" about the Theranos product. *Id.* Hunter "openly expressed" the need to "wrestle some of this to the ground and get proof." *Id.* By "proof," Hunter meant "[a]n instrument that work[ed], that could do a parallel test, and, you know, something that could be replicated in a scientific environment, something that had peer-reviewed studies. I mean, that's the way laboratories work." *Id.* "[T]here wasn't any of that that we'd seen at that time." *Id.*

When asked if he ever got the proof he was seeking, Hunter said:

No. I eventually had an instrument on my desk that didn't work and expired reagents. And even when we went out to do the site visit, we tried to do parallel studies at Stanford, right around the corner, and they wouldn't allow us to do it. We never got it.

Id.

The site visit Hunter referred to occurred in August 2010. Hunter and several others from Walgreens traveled to the Theranos facility in California. Hunter testified about what happened:

⁴ The Court cites to exhibits in Doc. 541 throughout this order. The reader should note that a few of these exhibits (which are identified by exhibit number in Doc. 541) were corrected in Doc. 556 (where they are also identified by exhibit number).

[W]hat I had planned when we went out to Palo Alto for a site visit, I think in August [2010] or whenever that was, we had Stanford on standby. There was four of us, I guess, that were going to get our test performed at Theranos, go right around the corner to Stanford, have the exact same test performed, and the cholesterol here should be the same as a cholesterol here or an A1C should be the same here as it is there, those types of things. And we wanted to do that so we could – so we had something as proof that the test worked. And, you know, we weren't able – they didn't allow us to do that.

Id. at 7.

In addition to a parallel blood test to confirm the Theranos instruments worked, Hunter asked that Walgreens be allowed to inspect the Theranos lab. His purpose was to verify the legitimacy of the Theranos product. *Id.* at 14. Although the lab inspection was on the meeting agenda for the Palo Alto visit and the Walgreens team was in the building where the laboratory was located, Theranos refused to allow an inspection. Hunter testified: "I was there to see the lab. I was there to see the instruments. I was there to help them do diligence, and it didn't happen." *Id.* at 7; *see also id.* at 13. Elizabeth Holmes and Sunny Balwani refused the lab inspection and every other effort he made to conduct due diligence. *Id.* at 7.

Not only was the comparison testing not allowed, but Theranos did not even return test results for blood actually drawn from the Walgreens meeting participants:

- A. They actually did draw some of our samples, and Dr. Jay went crazy saying he wanted to review the lab results. You know, they played the game that there wasn't a doctor that had ordered the test so they couldn't give us results back. Dr. Jay said, well, I'm a doctor. I ordered the tests. Give us the results back. And we never got the results before we left.
- Q. Did you ever get the results?
- A. Never did. Neither did anybody at the party, the launch party, where they took people's blood. They took Kermit Crawford's blood, the CEO of Walgreens, and said they'd get him his lab results, and they never did.

 $Id.^5$

Hunter was not the only person with concerns about the lack of proof that the Theranos product worked. "[W]ith the exception of Dr. Rosan, people were beginning to have concerns. You know, we were all moving to the show-me state where we wanted to see it, not just be told that it did these great things." *Id.* at 11. When Hunter eventually received an actual Theranos device – the Edison – he was not allowed to open it to see how it worked. *Id.* at 12. He was told by Walgreens that the contract with Theranos prohibited Walgreens from looking inside the Edison. *Id.* Hunter testified:

- A: I really wanted to open it up and see what was going on inside of there because it wasn't working. We couldn't get it to work. . . . I mean, I was doing everything I could to try to figure out what was going on in that box.
- Q. And did you ever figure out what was going on in that box?
- A. I did not.

Id.

Walgreens's continuing lack of proof that the Edison actually worked eventually led Hunter to conclude that Theranos could not be believed. He expressed that view to Walgreens:

A. It was just, every week there was another story. Okay. Well, we've sent an update through the cellular powers. The software will be fixed this week. You know, we're sending you new reagents that are not expired. You know, and it was just a story. Every week was another story.

And so finally by December, it was just like, you know, look, I'm going to quit asking because I don't believe – I don't believe what I'm being told.

⁵ "Dr. Jay," later referred to as "Dr. Rosan," was Dr. Jay Rosan, Walgreens's Senior Vice President of Health Innovation. Hunter testified that he was a continual advocate for moving forward with the Theranos partnership. Doc. 556-4 at 5-6, 11, 13, 15, 17.

Q. And who did you share your lack of belief in what you were being told about the Theranos instrument with?

A. Everybody.

Id.

When asked what he told "everybody" at Walgreens, Hunter gave this answer:

That I didn't believe the technology and that we shouldn't spend one more dime, one more hour on a conference call. We – until they are willing to give us an instrument that works and do parallel studies and those types of things, that we should no longer spend any time on this, because as far as I was concerned, it wasn't a viable business.

Id. at 13.

Hunter wrote a memo to Walgreens after the Palo Alto visit. He noted that issues with Theranos "could be indicators of a systemic, structural deficiency in their ability to utilize appropriate project management principles[.]" Doc. 520-14 at 2. He noted a "lack of cooperation in methods to correct deficiencies" and a "[p]lausible overselling or overstating in terms of where they are at scientifically with the cartridges/devices[.]" Doc. 520-14. at 2-3. Hunter – a lab expert Walgreens brought in to evaluate the Theranos product – never was convinced that it was legitimate and in fact, as quoted above, concluded that Theranos could not be believed. Doc. 541-67 at 17. "I started becoming more direct and probably less politically correct and started becoming more of a pain in some people's side." *Id*.

In late 2011, Walgreens phased Hunter out of his involvement with the Theranos laboratory and the legitimacy of its product. A reasonable jury could conclude that this change in assignment was due to Hunter's continuing demand for actual proof that the Theranos product worked:

I wasn't the fair-haired boy anymore. I was the one who was asking the tough questions and, you know, backing Elizabeth into tough corners. You know, Dr. Jay was – Dr. Jay was having to play a lot more interference than he probably wanted to. And, you know, it was – you know, Dr. Jay flat came

right out and said, it's easier for us to get this thing done if you move to the side a little bit. And so, you know, that was the beginning of the end, right?

Id.

Walgreens executive "Renaat [Van Den Hooff] came to me and said, Kevin, you know, in order for you to be at peace to keep helping us, you need to assume that we're going to get the documentation or the evidence that this is legitimate[.]" *Id.* at 18. Based on Hunter's testimony, the facts below, and other evidence in the case, a reasonable jury could find that Walgreens never got the evidence.

B. CLIA Certification.

Walgreens's briefing emphasizes that the Theranos laboratory received CLIA certification. Walgreens quotes Hunter's description of the lab certification process: the "laboratory must demonstrate its compliance with federal standards in areas of administration, proficiency test participation, patient test management, quality control, personnel, quality assurance, inspections, and computer systems." Doc. 521 at 11.

Plaintiffs counter with evidence that the CLIA certification did not verify the efficacy of the Theranos product, a fact known to Walgreens. They also assert that a reasonable jury could find that Walgreens knew Theranos obtained the CLIA certification fraudulently.

Hunter testified that Theranos could not have obtained a CLIA certification for its new product because that product did not work. Theranos therefore must have obtained the certification by using another company's product. He warned Walgreens:

[O]ne of my concerns was there's no way they got a CLIA license on the Edison device, and I knew that they had gotten a CLIA license. And so my comment to Walgreens at the time was, they're using off-the-shelf instrumentation because nobody can come in and give you a CLIA license on a predicate device that's not – that's not FDA cleared.

Doc. 541-67 at 19. The parties disagree on whether Hunter was in a position to know about the CLIA certification, with Plaintiff's claiming that the CLIA application was submitted

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while Hunter was on the project and would have revealed that Theranos equipment was not being used for the certification. Doc. 538 at 11-13; Doc. 555 at 16-17.

But Plaintiffs do not rely on Hunter's testimony alone. They also cite the proficiency test that was part of the CLIA certification. An email from Elizabeth Holmes indicates that the proficiency test results were to be printed for Walgreens, suggesting Walgreens actually saw it.⁶ Doc. 541-51 at 2. The proficiency test report contains more than 90 references to "Siemens," a brand of lab testing equipment not made by Theranos. *Id.* at 3-17. From this document, Plaintiffs argue, Walgreens knew that Theranos had obtained the CLIA certification by using Siemens equipment, not its own blood testing equipment. If true, this had at least two implications. First, Walgreens knew that the Theranos technology had not been validated under the CLIA. Second, Walgreens knew Theranos was misleading others into thinking its technology had been certified when in fact its laboratory was using equipment from other companies.⁷

Paul Rust, a former Quest Diagnostics executive, was retained by Walgreens to review the Theranos proficiency test and correlation studies. Doc. 520, ¶ 37. He visited Theranos in 2012 with Dr. Rosan. Rust told Rosan that he (Rust) should personally inspect the Theranos lab, explaining that "I can't really do a good job for Walgreens unless I can get into the laboratory and see how they do this[.]" Doc. 541-68 at 8. Rust explained that proficiency testing rules "get broken all the time" and it was therefore important to visit the laboratory and talk to those who participated in the testing. *Id.* "[Y]ou really have to be suspicious about this when you see proficiency testing," he told Rosan. *Id.* In response, Rosan told Rust that he could not go into the Theranos laboratory because Elizabeth Homes had locked it. *Id.* Rust said "[w]ell, Dr. Rosan, I've never done anything like this before,

⁶ During oral arguments, counsel for Plaintiffs cited page 134 of the Rosan deposition (Exhibit 268) as further evidence that Walgreens actually saw the proficiency test, but the excerpts of the Rosan deposition submitted by Plaintiffs do not include page 134. *See* Doc. 556-3 at 8-9; *see also* Doc. 541 at 8-9.

⁷ If it is admitted at trial, the opinions of Dr. Baird, one Plaintiff's experts, will support this reading of the evidence. *See* Doc. 539-2 at 143-47.

not being able to talk to the people that do the work, and I'm a little concerned about it." *Id.* Rosan responded: "No, you don't have to be. They're doing fine work[.]" *Id.* Plaintiffs note that Rosan made this assertion without ever inspecting the Theranos lab. Doc. 538 at 15.

Rust's October 2012 report on the Theranos lab's proficiency testing – which Walgreens emphasizes in its arguments – contained this disclaimer:

This report is limited to a review of Proficiency Testing Reports and several Correlation Studies. It does not include an on-site inspection of the laboratory, any review of Standard Operating Procedures (SOPs) used for Proficiency Testing or any interviews with the technologists or their supervisors who perform the tests. . . . Since Consultant is not aware of the unique nature of their technology, it was not possible to determine what, if any, impact the unique technology has on quality or the potential for errors.

Doc. 520-30 at 2.

Rust's report concluded with this limitation: "Consultant cannot comment on how well the employees embrace quality nor can Consultant give an unqualified opinion on the many areas of quality which can only be reviewed in the lab itself." *Id.* at 10. Plaintiffs argue that Rust's experience, like the experiences of Hunter and others, clearly showed Walgreens that Theranos was avoiding scrutiny of its laboratory and its product – on "many areas of quality." *Id.*

Plaintiffs contend that Walgreens simply accepted this lack of transparency, asserting that Walgreens never inspected the Theranos lab. *See* Doc. 541-66 at 3 (Van Den Hooff deposition: "But it's irrelevant because, you know, there's one authority that needs to inspect a lab, has the authority and the knowledge and to do a lab inspection, and that is in this case CMS who provides the CLIA certification. And Walgreens or Walgreens's employees are not equipped to do that."). This was true even though Walgreens later had concerns about Theranos maintaining its CLIA certification. *See* Doc. 541-16 at 2 (Dec. 5, 2013 internal Walgreens email: "Overall concern on the lack of operational strictness with updating/following/maintaining SOPs – very unusual for a CLIA lab").

The evidence could also support a jury finding that Walgreens did not ask for proficiency test results after 2012. *See* Doc. 539-2 at 82 (Dr. Rosan deposition: "I didn't think there were any additional ones. They already had their inspection done."). Nor did it receive other customary diligence documents. *See* Doc. 541-54 at 15 (June 3, 2010 PowerPoint presentation: "Attempts to structure an equity position have been difficult. Theranos has . . . "not been willing to provide necessary information to assess their intrinsic value."); Doc. 541-47 at 2 (Apr. 25, 2010 consultant email: "[T]he whole approach piece has me very uncomfortable. [It's] entirely backwards and we'll have to do what we can to fix it[.] The biggest challenge in these things – is the partner falls for the other partner too soon in the process. If that happens diligence becomes a box-checking exercise rather than one really focused on exploring whether the combination makes sense.").

C. Johns Hopkins Letter.

Walgreens's motion asserts that physicians from Johns Hopkins University verified the accuracy of the testing done by the Theranos product. It cites a two-page letter, dated April 27, 2010, regarding a meeting between five people from Johns Hopkins, Elizabeth Holmes and Sunny Balwani from Theranos, and Dr. Rosan from Walgreens. Doc. 520-5. The letter states that the Johns Hopkins team received a presentation from Theranos and reviewed proprietary Theranos data. Based on this meeting, the Johns Hopkins team concluded that the Theranos technology was "novel and sound" and "would be useful in the retail clinical setting," and identified "[n]o major weaknesses[.]" *Id.* at 4. The letter also stated, however, that it "in no way signif[ies] an endorsement by Johns Hopkins Medicine to any product or service." *Id.*

Plaintiffs point to a 2015 email from a Johns Hopkins vice president who was at the 2010 meeting. 541-53 at 2. In commenting on the meeting and resulting letter, he stated that "[t]he main thing to consider is this was essentially a review of their data." *Id.* "[W]e had proposed to do some independent research or validation studies. We were never given the opportunity to conduct these studies or evaluate the actual technology." *Id.*

Id.

Hunter, who worked with Walgreens during the same year that the Johns Hopkins meeting occurred, testified that the Hopkins letter "had been touted as proof that the technology was legitimate." Doc. 541-67 at 16. When he finally saw the letter, he was not persuaded:

[Theranos claimed] that the instrument[s] were in use and endorsed by Johns Hopkins. And that wasn't the case. And so they kept saying, yeah, we even have a letter to prove it.

And so for months, I was like, I need to see this letter from Johns Hopkins. And I was promised and promised and promised I'd get to see it. And they said, oh, yeah, they've done all kinds of trials and tests and it's being used every day and all this kind of stuff.

And I finally went to Renaat [a Walgreens executive] and said, I've got to see the Johns Hopkins report. And he reluctantly gave it to me.

And I walked back in a few minutes later and I said, Read the last sentence. Read the last sentence. There's nothing here. This is a meeting that Dr. Jay and Elizabeth and Sunny had with a doctor, not Johns Hopkins, a doctor that happened to work at Johns Hopkins, that gave them a letter that said, oh, by the way, this information is just being provided as an overview.

And so the way that this was – this document was being treated was that this was proof that the Theranos technology was legitimate, and the reality is, it was a meeting in April that Dr. Rosan and Elizabeth had set up with this one doctor, a couple doctors, from Johns Hopkins. That's it. And it was probably a couple-hour meeting. It was not anywhere near what this document was said to include.

D. Pharmaceutical Company Endorsements.

Walgreens also notes that Theranos claimed its product had been validated by several national pharmaceutical companies and gave Walgreens reports from some of those companies. Doc. 520-3. The reports were fabrications, but Walgreens argues it was

unaware of this fact.

Plaintiffs note that Innosight, a company retained by Walgreens to evaluate the potential Theranos deal, recommended that Walgreens speak with the pharmaceutical companies about their validations of the Theranos technology. *See* Doc. 541-48 at 21 (PowerPoint presentation by Innosight suggesting "discussions with the pharmaceutical companies Theranos partnered with for the clinical trial work (e.g., Pfizer, GSK, Schering-Plough)"); Doc. 541-49 at 5 (recommending "[d]ue diligence interviews with existing pharmaceutical partners [to] provide insight around clinical trials"). Walgreens never spoke to the companies. Dr. Rosan testified that he never spoke to them and does not know if anyone else from Walgreens did. Doc. 556-3 at 6. And Plaintiffs note that the purported reports did not mention comprehensive validation studies, but at most included trials with eight blood samples and even included typos. *See* Doc. 539-1 ¶ 2.

E. Evidence that Theranos Product Was Not Ready for Launch.

Plaintiffs present evidence that Walgreens knew the Theranos product presented problems when used. *See* Doc. 541-63 at 2 (June 19, 2014 email from Walgreens to Theranos sharing feedback from a Walgreens technician that "[g]reen CTNs have been working well but, purple CTNs have been failing fairly regularly."); Doc. 541-64 at 2 (May 15, 2014 internal Walgreens email: "there are air bubbles, wicking issues, or activated CTN does not go into a nanotainer 2 consecutive times and you don't believe it is human error, notify Theranos and they will advise you [on] next steps."); Doc. 541-34 at 2 (Nov. 15, 2013 internal Walgreens email: "CTN issue – the first draw done on 11/13 at 5453 was a faulty ctn We sent this to Theranos."); Doc. 541-23 at 3 (Mar. 5, 2013 internal Walgreens email: "[Y]ou and I both know that Theranos has an inability to hit timelines. I believe that they knew all along that we would need to centrifuge specimens and were hoping that they would have things ready in time for the March launch[.] And it is only 3 DAYS before we begin training and they just []now share with us the fact that we are adding a centrifuge to the SOPS. Yikes.").

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The evidence also shows that Theranos likely could not then expand operations as needed for the Walgreens stores. Doc. 541-16 at 2 (Dec. 5, 2013 internal Walgreens email: "40-50% of draws are vein draws" when the expected number was only 3%); Doc. 541-31 at 2-3 (Jan. 2, 2013 internal Walgreens email: "To date, Theranos has not indicated readiness yet for going past the two [stores] in Phoenix. No indication from Theranos about new store openings[.] Theranos may not be ready [because of] potential resource constraints and [d]elays in science (higher vein draws than expected)").

F. Evidence of Walgreens's Motive.

Plaintiffs allege that Walgreens moved forward with the pilot stores even though it knew from the experiences of Hunter, Rust, and others that Theranos could not be believed and had never demonstrated the effectiveness of its blood testing technology or even allowed an inspection of its lab. Plaintiffs' ascribe this to Walgreens's profit and growth motives. *See* Doc. 520-2 (Mar. 29, 2010 internal Walgreens email: "[T]he key is who gets FDA approval first . . . and they appear in the lead[.] We will be the gateway into primary care and the gateway out. Then we really will be the most important player in US healthcare."); Doc. 556-4 at 5 (Hunter deposition: "Dr. Rosan was very, very high on Theranos and wanted to go to market tomorrow[.] He was trying to make a name for himself. He was the one who brought this opportunity to Walgreens. He saw this as, you know, an opportunity, right? And so he naturally was pushing all of us."). Plaintiffs particularly note a February 2013 statement by Walgreens executive Wade Miquelon that "[w]e need a profit rocket now. I see know [sic] other initiative in our arsenal with this much upside." Doc. 541-28 at 2.

G. Plaintiffs' Evidence Clears the Threshold Needed for a Jury Trial.

Walgreens makes vigorous arguments in response. It asserts, first and foremost, that it was a victim of the Theranos fraud like many others. It contends that it brought in a variety of experts to evaluate Theranos and its product, relied on federal certifications of the Theranos lab, examined data that validated the legitimacy of the Theranos product, and

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was not willfully blind to any risk of fraud. Walgreens argues that Hunter's testimony cannot reasonably be believed by a jury because it is not corroborated by other evidence and in fact is contradicted by the testimony of numerous other witnesses.

These are potent arguments. They may well persuade a jury to rule in favor of Walgreens at trial. But the Court cannot weigh the evidence or make credibility determinations. It must accept Plaintiffs' evidence as true and draw all reasonable inferences in Plaintiffs' favor. *Anderson*, 477 U.S. at 255. The standard has been explained well – and in terms particularly apt for this case – by Professor Gensler:

Courts must take care . . . not to make weight or credibility determinations under the guise of determining what a rational jury could find. If the nonmoving party has evidence that could, if believed by the jury, support a finding for him, the fact that there is strong contradictory evidence does not permit the court to reject the nonmoving party's version. For example, a court may not reject a nonmoving party's proof on the basis that it is "uncorroborated" or contradicted by the testimony of all of the other witnesses. If the nonmoving party's evidence would be sufficient if believed, the fact that multiple other witnesses contradict the nonmoving party's story does not lead to the conclusion that no rational jury could ever find for the nonmoving party. The jury may conclude that the other witnesses are lying or mistaken. . . . In the end, a lack of corroboration, the presence of strong contradictory evidence, or the self-serving and untrustworthy nature of the nonmoving party's story may strongly influence the jury's determination about what to believe. But the task of weighing potentially sufficient evidence and assessing credibility must be left to the jury.

S. Gensler and L. Mulligan, 2 Federal Rules of Civil Procedure, Rules and Commentary Rule 56 (2022).

Plaintiffs' evidence, if believed, could support a reasonable jury's finding that Walgreens knew there was a high probability the Theranos blood testing method lacked reliable results, was not market-ready, and had received only minimal regulatory scrutiny – the first step of the willful blindness test. *Yi*, 704 F.3d at 804. And it was not merely a matter of negligent or reckless failure to verify information. Hunter testified that he grew to disbelieve what Theranos was saying and, as a consultant brought in to validate the

Theranos lab work, conveyed this disbelief to Walgreens. Rust explained that it was highly unusual not to do closer inspections of the laboratory – he'd never seen it before – and he could not vouch for the Theranos method in the absence of such inspections. Innosight urged Walgreens to take the simple step of talking to the pharmaceutical companies that supposedly had validated the Theranos product, but Walgreens declined. Johns Hopkins did nothing more than review Theranos's own data in one meeting, a fact known to Walgreens when Theranos was touting the Hopkins letter as proof that its product worked. Considering this evidence, a reasonable jury could find that Walgreens deliberately avoided learning the truth – the second step for willful blindness. *Id.* The Court accordingly must deny Walgreens's motion for summary judgment on Plaintiffs' remaining claims.

III. Punitive Damages.

Walgreens argues that "Plaintiffs seek punitive damages under their battery and Arizona statutory fraud claims, requiring them to 'prove that defendant's evil hand was guided by an evil mind," and relies on Arizona punitive damages case law for its arguments. Doc. 521 at 29 (citations omitted). Plaintiffs do not disagree with this characterization of their punitive damages claim, and they too cite Arizona cases. Doc. 538 at 29-30 (citations omitted).

Punitive damages are awarded "in excess of full compensation to the victim in order to punish the wrongdoer and deter others from emulating his conduct." *Linthicum v. Nationwide Life Ins. Co.*, 723 P.2d 675, 679 (1986). It is not enough to prove the defendant committed a tort or statutory violation. "[S]omething more is required[.]" *Id.* A plaintiff must prove "that the defendant engaged in aggravated and outrageous conduct with an 'evil mind." *Hyatt Regency Phoenix Hotel Co. v. Winston & Strawn*, 907 P.2d 506, 518 (Ariz. Ct. App. 1995); *Gurule v. Ill. Mut. Life & Cas. Co.*, 734 P.2d 85, 86 (1987); *Rawlings v. Apodaca*, 726 P.2d 565, 578 (1986). "When defendant's motives are shown to be so improper, or its conduct so oppressive, outrageous or intolerable that such an 'evil mind'

may be inferred, punitive damages may be awarded." *Id.* (citing Restatement (Second) of Torts § 908(2)). Such damages are appropriate "only if the defendant's conduct or motive 'involves some element of outrage similar to that usually found in a crime." *Gurule*, 734 P.2d at 86.

Plaintiffs must also prove Walgreens's evil mind by clear and convincing evidence, *Linthicum*, 723 P.2d at 681, a burden of proof the Court must apply when ruling on Walgreens's motion. As the Supreme Court has explained, "the judge must view the evidence presented through the prism of the substantive evidentiary burden." *Anderson*, 477 U.S. at 254. Thus, no triable issue of fact exists on punitive damages unless Plaintiffs present sufficient evidence for a jury to find by clear and convincing evidence that Walgreens acted with an evil mind. *Id.* at 254-55.

Although the Court finds that Plaintiffs' evidence could support a jury finding of willful blindness, it would not support a finding of actual fraudulent knowledge and intent. Plaintiffs present no evidence that Walgreens actually knew of and embraced the Theranos fraud. And even if Plaintiffs had made this higher showing, it would not be enough for punitive damages. The Arizona Supreme Court has made clear that "punitive damages are not recoverable in every fraud case, even though fraud is an intentional tort." *Rawlings*, 726 P.2d at 578 n. 8; *see Dawson v. Withycombe*, 163 P.3d 1034, 1062 & n. 27 (Ariz. Ct. App. 2007).

Plaintiffs' evidence simply does not show "aggravated and outrageous" conduct on the part of Walgreens sufficient to warrant punishment by punitive damages, much less show it by clear and convincing evidence. *Linthicum*, 723 P.2d at 680. Plaintiffs argue that their evidence shows Walgreens knew "its conduct was likely to cause unjustified, significant damage to" Plaintiffs. *Rawlings*, 726 P.2d at 578. But even with this formulation of the intent requirement, Arizona law requires something more than even fraudulent intent, and Plaintiffs have not presented evidence of that something more. The Court therefore must grant summary judgment on Plaintiffs' punitive damages claim.

IV. Exhibits Lodged Under Seal.

Plaintiffs have lodged Exhibits 203-266, 269-275, and 281-291 under seal, stating that they did so because the documents were designated as confidential by Walgreens or other parties. Doc. 541. Plaintiffs state that they believe the documents should be filed publicly. *Id.* at 2. Walgreens does not oppose the public filing of Exhibits 204-215, 217, 219-237, 239, 240, 249-252, 255-258, 261-264, 269-274, and 282-289. Doc. 550 at 3.

Walgreens and Plaintiffs stipulate to seal Exhibits 216, 218, and 238. Doc. 550 at 5. They also stipulate to partially seal Exhibit 203. *Id.* at 4-5. The parties' stipulation demonstrates that Exhibits 216, 218, and 238 contain confidential medical records, and that the limited portions of Exhibit 203 to be sealed contains sensitive competitive information, each of which satisfies the compelling reasons standard for sealing attachments to dispositive motions. *See Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179-80 (9th Cir. 2006). The rest of Exhibit 203's relevant information will be publicly available on the docket in a redacted exhibit.

Walgreens states that Defendant Theranos designated Exhibits 241-248, 253, 254, 259, 260, 265, 266, and 290 as confidential. Doc. 550 at 4 n1. Theranos is now defunct and cannot make the showing required for sealing. These documents will be unsealed.

Walgreens also states that Defendant Holmes designated Exhibit 275 as confidential. *Id.* To ensure that it is acting on all relevant information, the Court will grant Defendant Holmes five business days from the date of this order to show compelling reasons for sealing Exhibit 275.

Walgreens states that Exhibit 281 was designated as confidential by an unidentified third party. *Id.* Because no party has shown that sealing this exhibit is warranted for compelling reasons, the exhibit will not be sealed.⁸

Finally, because Walgreens fails to address Exhibit 291, it will be unsealed.

⁸ Some exhibits have been lodged in connection with *Daubert* motions that the Court has not addressed. Sealing of these exhibits will be addressed when the Court rules on the *Daubert* motions.

IT IS ORDERED:

- 1. The Walgreens motion for summary judgment (Doc. 521) is **denied** with respect to Plaintiffs' remaining counts in this case, and **granted** with respect to Plaintiffs' claims for punitive damages.
- 2. All exhibits in Doc. 541, except Exhibits 203, 216, 218, 238, and 275, will be unsealed by the Clerk and shall remain Doc. 541. Exhibits. 203, 216, 218, and 238 shall be sealed, and the parties shall file a redacted version of Exhibit 203 in the public record.
- 3. Defendant Holmes shall have five business days from the date of this order to show compelling reasons for sealing Exhibit 275.
- 4. The jury trial in this case is set for September 5-8, 11-15, 18-22 and 25, 2023. The Court will schedule a conference call with the parties in the near future to set a final pretrial conference date and a hearing, if needed, on the *Daubert* motions, and to address staying the case with respect to Defendants Holmes and Balwani.

Dated this 4th day of May, 2023.

David G. Camplell

David G. Campbell Senior United States District Judge