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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In re: Arizona THERANOS, INC., Litigation	**No. 2:16-cv-2138-HRH** **(Consolidated with)** **No. 2:16-cv-2373-HRH** **No. 2:16-cv-2660-HRH** **No. 2:16-cv-2775-HRH** **-and-** **No. 2:16-cv-3599-HRH** **CONSOLIDATED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

I. INTRODUCTION

1. Blood tests and other clinical lab tests ("test results") are an everyday and invaluable part of the practice of modern medicine. Test results can offer crucial details about an individual's health and doctors rely on test results to detect everything from cholesterol and glucose levels to infections, blood cell counts and cancer.

2. Test results aid in the process of medical diagnosis and treatment decisions, and in some cases are a prerequisite for additional medical tests. Because test results are such a foundational part of medical treatment, test results that are unreliable or inaccurate can be catastrophic: serious conditions may go undetected, patients may not receive the treatments and medications that they need, and patients may be misdiagnosed and receive treatments or medications that they have no need for. It is absolutely critical that consumers be able to rely on test results.

3. This consumer class action is based on Defendants' promotion and sale of blood tests that were unreliable, Defendants' false and misleading promises that Theranos test results were reliable and accurate, and should be relied on by consumers and their medical providers in making health decisions, and on Defendants' long-standing concealment from customers of information demonstrating that such tests were not, in fact, reliable or accurate. Defendants have failed to deliver the products and services they promised, and that their customers reasonably expected, and have endangered their customers' health and well-being, the very thing they promised to promote and protect.

4. Theranos test results were marketed by Defendants as a "disruptive" technology in the blood testing and laboratory services business. What allegedly made

Theranos's technology a breakthrough was its proprietary "Edison" blood testing devices. In contrast to the large needle and numerous tubes required in a typical venipuncture blood draw, Theranos's Edison devices were handheld devices, supposedly able to take a few drops of blood from a patient's finger placed into a nanotainer capsule, and reliably conduct hundreds of blood tests, all outside a lab.

5. Theranos sold its new "tiny blood test" at Wellness Centers at Defendant Walgreens Boots Alliance, Inc.-owned Walgreens pharmacies in Arizona and California, at a Capital BlueCross Capital Blue retail store in Pennsylvania, and at Theranos-owned Wellness Centers in Arizona and California. Theranos and Walgreens assured customers that these tests were highly accurate and reliable, industry-leading in quality, and that they had been developed and validated under, and were compliant with, federal guidelines, and encouraged customers to use the Theranos test results to make health and treatment decisions.

6. Defendants' promises and representations were false. For starters, the Edison devices did not work and Theranos's tests conducted on Edison were not accurate or reliable. While Defendants have long known this, it was confirmed publicly on May 18, 2016, when Theranos conceded that it had informed regulators that it had voided "all" blood-testing results from its proprietary Edison devices.[1]

7. Theranos also tested thousands of customers' blood on devices other than the Edison machine without explaining this fact to consumers, and in fact misled

[1] John Carreyrou, *Theranos Voids Two Years of Edison Blood-Test Results*, Wall St. J. (May 18, 2016) (Ex. A).

consumers to think that its Edison technology was being used. As Defendants knew, these non-Edison tests, too, lacked the accuracy and reliability that Defendants had promised and that the customers had reasonably expected and paid for. What Defendants knew was confirmed by, *inter alia*, numerous citations issued by the federal government regarding the non-compliance of Theranos's testing labs, Theranos's voiding of tests run on non-Edison devices from 2014 and 2015,[2] and by the fact that the government banned Ms. Holmes from owning or operating a blood-testing business for at least two years and revoked Theranos's license to operate a lab.

8. Many thousands of people, including Plaintiffs, believed Defendants' false representations and promises regarding the accuracy and reliability of Theranos's test results. For years, Defendants hid the truth about Theranos's unreliable, flawed testing from the public.

9. None of the consumers who obtained test results from Theranos received what they paid for and what they reasonably expected—*i.e.*, test results they could rely on. All of them received tests that they decidedly could not reasonably rely on given the numerous problems alleged herein that have come to light. Worse yet, as a result of the unreliable and inaccurate Theranos test results, many consumers have been subjected to unnecessary or potentially harmful treatments, and/or have been denied the opportunity to seek treatment for a treatable condition.

[2] In the Scottsdale Facility, for example, regulators found that Theranos used mis-programmed machines to evaluate blood coagulation tests, failed to properly gauge water purity in machines it used, and failed to meet laboratory quality standards.

10. Plaintiffs, for themselves and all others similarly situated, (*i.e.*, the members of the Classes described and defined within this Complaint), bring this action for, *inter alia*, damages, restitution, other monetary relief, and an order enjoining Defendants from engaging in further deceptive representations, concealment and other unlawful acts, pursuant to the Arizona Consumer Fraud Statute, A.R.S. §§ 44-1521 *et seq.*; California Business and Professional Code §§17200, *et seq.*; California Business & Professional Code §§ 17500, *et seq.*; California Civil Code §§1750, *et seq.*; California Civil Code §§1709-1710; Civil RICO 18 U.S.C. §§ 1961-1968; and common law causes of action for fraud, civil conspiracy to commit fraud, negligent misrepresentation, unjust enrichment, and aiding and abetting.

II. JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2) because at least one member of the Class is a citizen of a state that is different from Defendants and because, upon information and belief, the aggregate amount in controversy exceeds $5,000,000 exclusive of costs and interest, and there are more than 100 members in the proposed Class and Subclasses.

12. This Court has personal jurisdiction over Defendants because Defendants have conducted and continue to conduct business in the State of Arizona, and because Defendants have committed acts and omissions complained of herein in the State of Arizona.

13. Venue as to Defendants is proper in this judicial district because a substantial part of the events and omissions giving rise to the claims alleged herein

occurred in this District. Venue is also proper because Defendants have conducted, and continue to conduct, business within this District.

III. PARTIES

14. Plaintiff A.R. is a resident and citizen of San Jose, California and is using his initials to protect his privacy in this litigation.

15. Plaintiff B.B. is a resident and citizen of Cuyahoga Falls, Ohio, and is using her initials to protect her privacy in this litigation. In 2014, B.B. resided in Arizona.

16. Plaintiff B.P. is a resident and citizen of Phoenix, Arizona and is using his initials to protect his privacy in this litigation.

17. Plaintiff D.L. is a resident and citizen of Maricopa, Arizona and is using her initials to protect her privacy in this litigation.

18. Plaintiff L.M. is a resident and citizen of Chandler, Arizona and is using her initials to protect her privacy in this litigation.

19. Plaintiff M.P. is a resident and citizen of Scottsdale, Arizona and is using his initials to protect his privacy in this litigation.

20. Plaintiff R.C. is a resident and citizen of Sun City West, Arizona and is using his initials to protect his privacy in this litigation.

21. Plaintiff R.G. is a resident and citizen of Gilbert, Arizona and is using his initials to protect his privacy in this litigation.

22. Plaintiff S.J. is a resident and citizen of Mesa, Arizona and is using her initials to protect her privacy in this litigation.

23. Plaintiff S.L. is a resident and citizen of Chandler, Arizona and is using his

initials to protect his privacy in this litigation.

24. Defendant Theranos, Inc. ("Theranos" or the "Company") is based in Palo Alto, California. Theranos operates, or during the relevant time period operated, two laboratories: one in Newark, California, and another in Scottsdale, Arizona. Through Wellness Centers located predominantly in Walgreens pharmacies in Arizona and California, and also in Theranos-owned Wellness Centers in Arizona and California, Theranos sold testing services to individuals. Since it began offering testing services in 2013, Theranos has conducted 6.1 million diagnostic tests.

25. Defendant Walgreens Boots Alliance, Inc. ("Walgreens"), of Deerfield, Illinois, is a global pharmacy-led health and well-being enterprise, which, among other segments, operates the Walgreens retail pharmacy chain in the United States.

26. Defendant Elizabeth Holmes, a citizen and resident of California, is the founder of Theranos and at all relevant times has been Theranos's Chief Executive Officer. On information and belief, Ms. Holmes has had a primary role in, and in significant part has directed, Theranos's misconduct as alleged herein. Further, Ms. Holmes personally made material misrepresentations and omissions as alleged herein. On information and belief, Ms. Holmes has personally received millions, if not billions, of dollars in compensation as a result of the business and revenue generated through the misconduct alleged herein.

27. The true names and capacities of Defendants sued herein as DOES 1 through 10, inclusive, are currently unknown to Plaintiffs, who therefore sue such Defendants by such fictitious names. Each of the Defendants designated herein as a DOE

is legally responsible in some manner for the unlawful acts referred to herein. Plaintiffs may seek leave of Court to amend this Complaint to reflect the true names and capacities of the Defendants designated herein as DOES when such identities become known.

28. Based upon information and belief, Plaintiffs allege that at all times mentioned herein, each and every Defendant was acting as an agent and/or employee of each of the other Defendants, and at all times mentioned was acting within the course and scope of said agency and/or employment with the full knowledge, permission, and consent of each of the other Defendants. In addition, each of the acts and/or omissions of each Defendant alleged herein were made known to, and ratified by, each of the other Defendants.

IV. FACTUAL BACKGROUND

A. Theranos

29. Theranos was founded in 2003 by Elizabeth Holmes, then a sophomore at Stanford studying chemical engineering, who dropped out a few months later to focus on the Company. Ms. Holmes, the Company's CEO, has maintained that she developed the idea for the Company as a result of her self-professed phobia of needles.[3] According to published reports, Theranos initially focused on development of a hand-held device that would use a tiny needle to obtain a small drop of blood for analysis. By 2008, the project had grown into what is now known as the Edison device.

[3] Marco della Cava, *Change Agents: Elizabeth Holmes Wants Your Blood*, USA Today (Jul. 26, 2014), http://www.usatoday.com/story/tech/2014/07/08/change-agents-elizabeth-holmes-theranos-blood-testing-revolution/12183437/ (last visited Nov. 8, 2016).

30. In contrast to the large needle and numerous tubes required in a typical venipuncture blood draw, Theranos's Edison device was designed to eliminate the need for laboratories altogether. The concept was that a nanotainer containing a few drops of blood from a finger stick would be placed into a cartridge which would, in turn, be placed into a proprietary Edison device (which Theranos executives have never allowed to be photographed), where a button pushed by a staff person would generate results that automatically would be transmitted to Theranos's databases. This concept would have enabled Theranos to conduct all testing outside of the laboratory in the Wellness Centers and thus – according to Defendants – revolutionize testing by significantly reducing the time and costs involved.

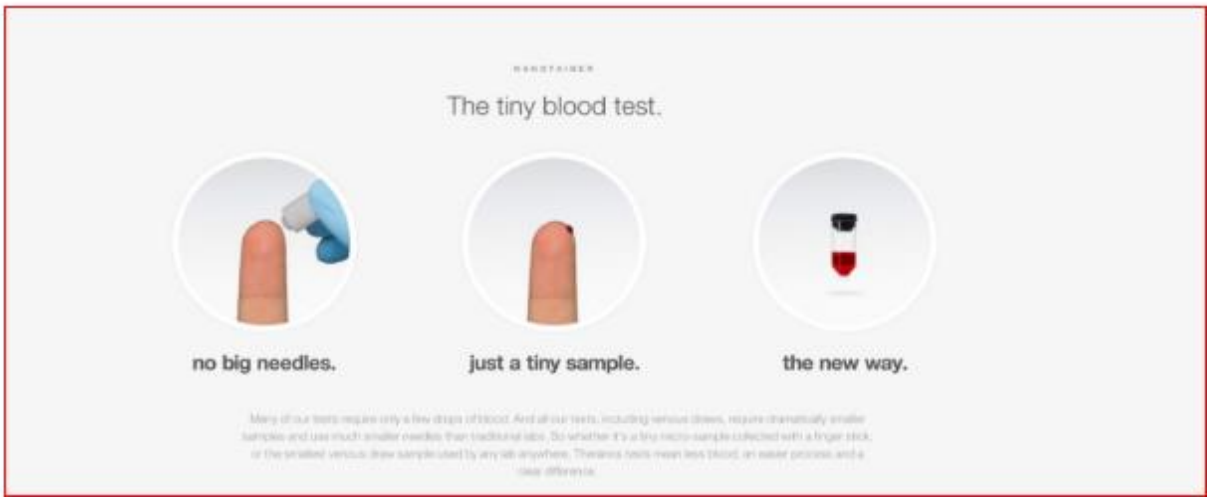
31. Neither Ms. Holmes nor the other Defendants ever explained to the public the science or technology underlying the Edison device, claiming a need to protect Theranos's intellectual property. Despite the industry practice for companies to publish their results and allow for peer review by experts in the field when launching a new medical product, Theranos has still never published its data or allowed for peer review.[4] One writer described Ms. Holmes's explanation of what Theranos does as "comically vague" after she explained "[a] chemistry is performed so that a chemical reaction occurs and generates a signal from the chemical interaction with the sample, which is translated

[4] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015) (Ex. B).

into a result, which is then reviewed by certified laboratory personnel."[5]

32. Despite limited scientific information, based on Defendants' representations people believed that Theranos's Edison technology was a true disruptive technology breakthrough. Holmes was hailed as the next Steve Jobs, and by 2014, Theranos was valued at $9 billion – approximately the same as each of its two largest and long established competitors in the medical testing industry.[6]

33. By way of example, Defendants advertised the Theranos "tiny blood test" technology as follows:

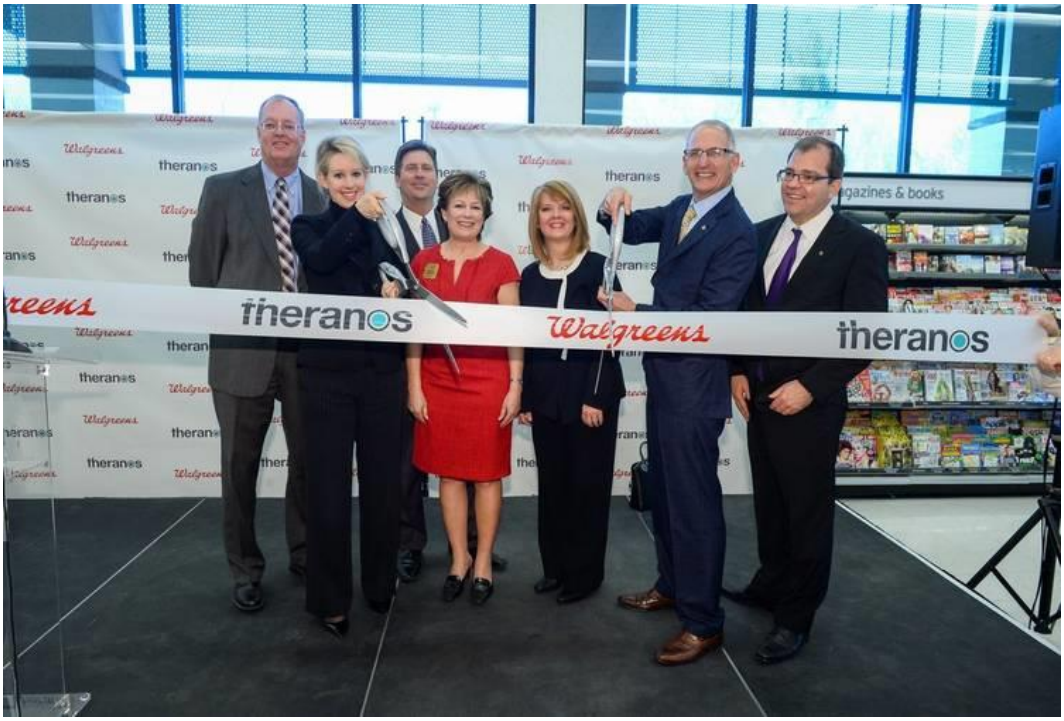


34. By 2011, Theranos was in talks with both Safeway and Walgreens to offer Theranos testing in their stores. In 2013, Theranos entered into a partnership agreement

[5] Ken Auletta, *Blood, Simpler*, The New Yorker (Dec. 15, 2014), http://www.newyorker.com/magazine/2014/12/15/blood-simpler (last visited Nov. 8, 2016).

[6] Steve Denning, *Is Theranos Too Good To Be True?*, Forbes (Feb. 13, 2016), http://www.forbes.com/sites/stevedenning/2016/02/13/is-theranos-too-good-to-be-true/#47de558857f8 (last visited Nov. 8, 2016).

with Walgreens, under which Walgreens invested $140 million in Theranos, and Theranos agreed to operate clinics, which it called "Wellness Centers," at Walgreens Pharmacies in Arizona and California. Following the launch of the partnership in 2013, Theranos and Walgreens planned to build Theranos Wellness Centers in more than 8,200 Walgreens stores nationwide.[7]



http://www.wsj.com/articles/walgreen-terminates-partnership-with-blood-testing-firm-theranos-1465777062

B. Walgreens Knowingly Ignored Repeated Red Flags About the Reliability of Theranos's Testing

35. Before entering into the partnership with Theranos, Walgreens's Chief Medical Officer neither reviewed Theranos's technology nor independently validated or

[7] Press Release, Theranos, Inc., *Theranos Selects Walgreens as a Long-Term Partner Through Which to Offer Its New Clinical Laboratory Service* (Sept. 9, 2013), https://news.theranos.com/2013/09/09/theranos-selects-walgreens-as-a-long-term-partner-through-which-to-offer-its-new-clinical-laboratory-service/ (last visited Nov. 8, 2016).

verified the accuracy, reliability, or results of the tests.[8] Nevertheless, and despite the fact that Walgreens executives had expressed doubts about the reliability of Theranos tests and the quality of its equipment and/or facilities, Walgreens said it was confident in the data before introducing the services.[9]

36. In fact, although a Johns Hopkins University scientist had requested, on Walgreens' behalf, that Theranos provide his researchers with an Edison device so that they could verify the technology for Walgreens, and Ms. Holmes initially agreed to provide one, the device was never provided.[10] Instead, Walgreens got a prototype which the Johns Hopkins team tried to evaluate, but the prototype was useless when evaluating the accuracy and reliability of the tests because it produced results such as "low" or "high" rather than numeric values that could be compared to other labs' tests. As a result, there was no way to compare results from the prototype Edison device to the results of other commercially-available tests.[11]

37. In the summer of 2011, just after Theranos and Walgreens signed their initial letter of agreement, Walgreens sent a delegation, including its finance chief, internal auditor, and lab experts from a consulting firm called Collaborate, LLC, to a meeting at Theranos headquarters in Palo Alto, the purpose of which was to gain a

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[8] *Pressure is Mounting on a Startup That Has Tried to Shake Up the Lab-Test Market,* Economist (Apr. 23, 2016), http://www.economist.com/news/business/21697273-pressure-mounting-startup-has-tried-shake-up-lab-test-market-blood-sports (last visited Nov. 22, 2016).

[9] *Id.*

[10] Christopher Weaver and John Carreyrou, *Craving Growth, Walgreens Dismissed Its Doubts About Theranos*, Wall St. J. (May 25, 2016) (Ex. C).

[11] *Id.*

firsthand view of the Theranos business and its capabilities.[12]

38. At that meeting, however, the consulting lab experts were chaperoned during the entire visit, including during visits to the restroom, and were not allowed access to Theranos's lab area or Edison technology. Despite the lack of access, Walgreens did discover problems with Theranos's information management systems meant to keep track of patients.[13]

39. According to published reports, throughout the process, Walgreens executives nevertheless looked the other way. They did not press for further verification, and instead went ahead with the Theranos business relationship, despite their concerns about the reliability of Theranos's facilities and tests. Walgreens apparently was afraid that Theranos would respond to its questions by choosing another retail chain to work with as a partner.[14]

40. Thereafter, later in 2011, Collaborate, LLC, issued a report concluding that Walgreens needed more information to assess the proposed partnership with Theranos.[15]

41. Similarly, in October 2012, Walgreens sent two executives and a retired Quest Diagnostics Corp. executive to Theranos to review quality-control data. According to reports, the retired Quest executive stated that they were not allowed inside Theranos's lab, and while they were led to believe the data they reviewed was from an Edison

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[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*

device, Theranos did not confirm that it was.[16] Walgreens continued to work on the partnership agreement despite the lack of access to the technology and despite its concerns about the reliability of Theranos's facilities and tests. According to published reports, Walgreens executives were privy to information that Safeway, Inc. had also agreed to host Theranos testing sites at some of its stores. According to reports, Safeway dissolved its partnership with Theranos before it began hosting Theranos testing sites in Safeway stores due, in part, to its due diligence that raised questions about the accuracy of Theranos's testing. For example, the unreliability of Theranos tests became apparent after Safeway employees in Pleasanton, California had their blood tested by both Theranos and another conventional lab, and the test results differed significantly.[17]

42. In response to pressure from Theranos, and despite its concerns, Walgreens ceded even more control over the Wellness Centers to Theranos in the final agreement reached between Walgreens and Theranos, and Walgreens gave up the right to review Theranos's clinical data or financial records.

43. Under the Theranos/Walgreens joint venture agreement, Theranos opened 40 Wellness Centers within Walgreens pharmacy stores in Arizona, and one in a pharmacy in California, to sell the majority of its tests.[18]

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[16] *Id.*

[17] John Carreyrou, *Safeway, Theranos Split After $350 Million Deal Fizzles*, Wall St. J. (Nov. 10, 2015) (Ex. D).

[18] James B. Stewart, *A Marriage Gone Bad: Walgreens Struggles to Shake Off Theranos*, N.Y. Times (Apr. 21, 2016), http://www.nytimes.com/2016/04/22/business/a-once-avid-ally-walgreens-is-struggling-to-shake-off-theranos.html (last visited Nov. 8, 2016).

C. Defendants Widely Marketed Theranos Testing as Accurate and Reliable

44. Despite the known lack of hard data about the technology and known (but concealed from the public) reliability problems and concerns about the Theranos tests, Defendants widely marketed the tests as being reliable and encouraged consumers to use the test results to make decisions about their health and treatment. Defendants' representations in this regard were pervasive such that Plaintiffs and the entire Class, as well as medical providers in all relevant geographic areas, were exposed to them. Defendants designed their representations and marketing in order to give the impression to consumers and medical providers that Theranos testing was reliable and accurate and should be used in making health decisions.

45. When the Theranos-Walgreens partnership was publicly announced, Defendants' press release stated that the deal would offer consumers access to "less invasive and more affordable clinician-directed lab-testing, from blood samples as small as a few drops, or 1/1000 the size of a typical blood draw." Defendants' press release touted Theranos's "CLIA-certified laboratory services," and promised that its "proprietary laboratory infrastructure minimizes human error through extensive automation to produce high quality results." It stated,"[t]his is the next step in Walgreens' efforts to transform community pharmacy, giving our patients and customers convenient access to the comprehensive care they need, right in their communities."[19]

[19] Press Release, Theranos, Inc., *Theranos Selects Walgreens as a Long-Term* Partner *Through Which to Offer Its New Clinical Laboratory Service*, (Sept. 9, 2013), https://news.theranos.com/2013/09/09/theranos-selects-walgreens-as-a-long-term-

Ms. Holmes told The New Yorker that Theranos "ha[s] data that show you can get a perfect correlation between a finger stick and a venipuncture for every test that we run."[20]

46. Defendants' advertisements for Theranos were rampant, including in Arizona. In addition to the advertisements and disclosures in the Walgreens stores and Theranos Wellness Centers, Defendants ran commercials on television, had billboards along the main interstate in Phoenix, and had advertisements in the Phoenix Sky Harbor International Airport.[21]

47. Defendants' sales materials highlighted the proprietary technology and described its offerings as a "tiny blood test," and a "new way" of testing. The materials repeatedly referenced a smaller sample size and depicted the nanotainer. Additionally, the materials assured that Theranos was "industry leading in quality and its tests were highly accurate and developed and validated under and to Federal guidelines."

48. Thousands of consumers, including Plaintiffs, believed Defendants' representations, and used Theranos to perform testing services, including many who went to Walgreens locations to obtain Theranos testing services.

49. Walgreens and Theranos jointly marketed Theranos's testing services to customers. Upon information and belief, marketing decisions about the representations

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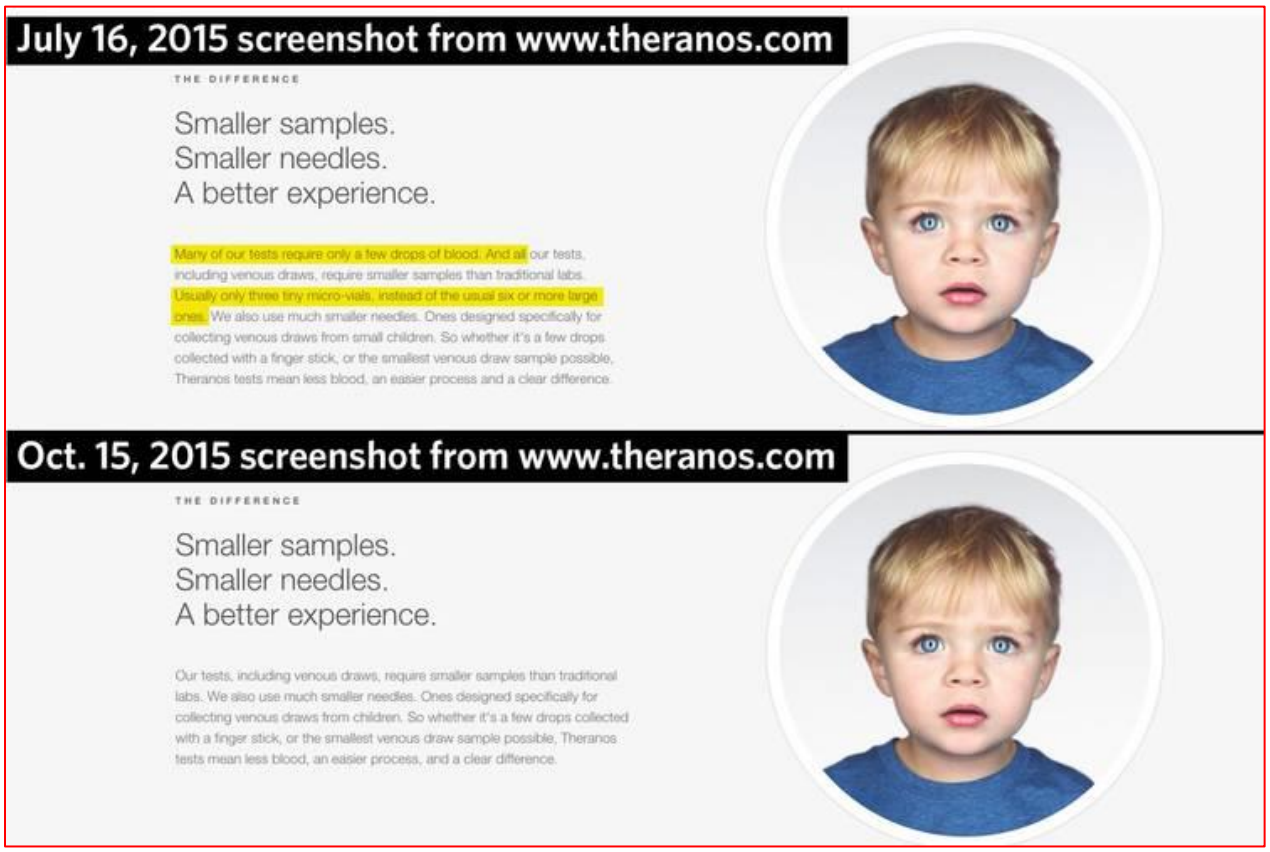
partner-through-which-to-offer-its-new-clinical-laboratory-service/ (last visited Nov. 16, 2016).

[20] Ken Auletta, *Blood, Simpler*, The New Yorker (Dec. 15, 2014), http://www.newyorker.com/magazine/2014/12/15/blood-simpler (last visited Nov. 8, 2016).

[21] Seung Lee, *Arizona: Where Theranos Still Has a Friend*, Newsweek (Jun. 14, 2016) http://www.newsweek.com/arizona-where-theranos-still-has-friend-469942 (last visited Nov. 8, 2016).

that Plaintiffs and Class members saw were made in California and Arizona, and Defendant Theranos maintained its website from California.

50. According to reports, prior to October 2015, promotional materials promised that "usually only three tiny micro vials" of blood would be collected "instead of the six or more large ones," because "many" of Theranos's tests required no more than "a few drops of blood." Theranos reportedly deleted the highlighted portions of the materials below in mid-2015 to supposedly improve its "marketing accuracy," after it moved away from Edison testing following a surprise inspection by the FDA:[22]



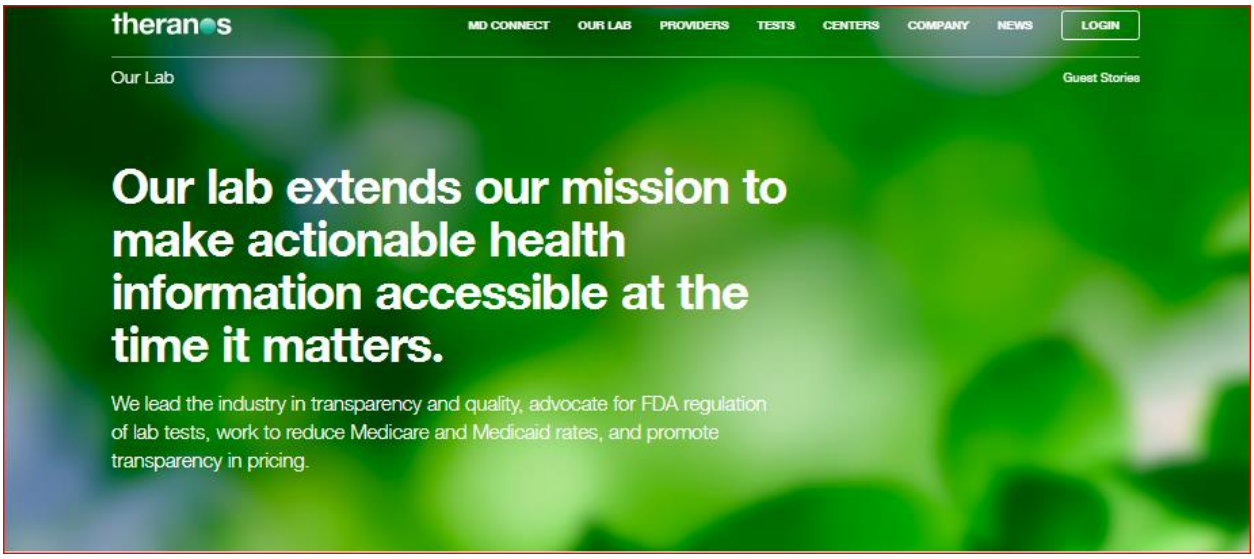
51. On another webpage advertisement to Walgreens customers, Defendants

[22] John Carreyrou, *Hot Startup Theranos Dials Back Lab Tests at FDA's Behest*, Wall St. J. (Oct. 16, 2015) (Ex. E).

stated that smaller samples directly benefited patients by dramatically reducing the time it takes to analyze samples because its technology enabled a "more timely diagnosis to support better, more informed treatment."[23]

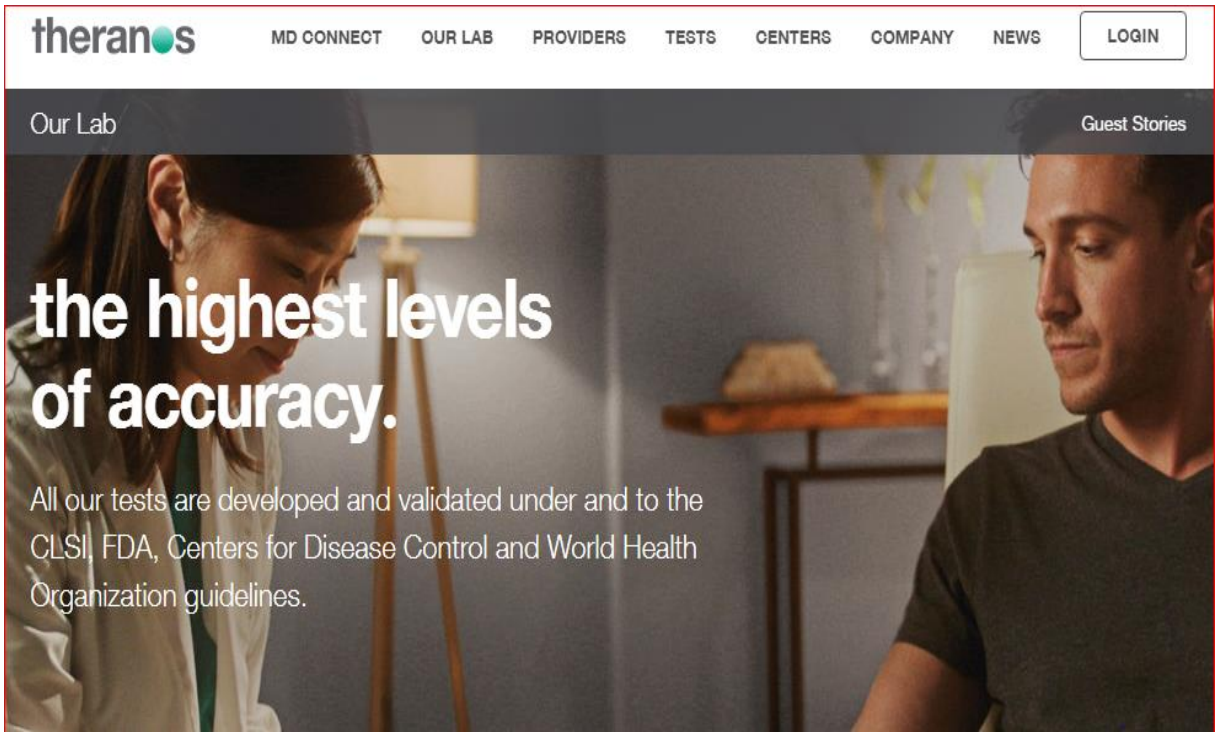
52. Defendants offered a variety of testing directly to consumers:

[23] Walgreens website, *Theranos, the Lab Test, Reinvented*, http://www.walgreens.com/pharmacy/lab-testing/home.jsp (last visited May 22, 2016); https://web.archive.org/web/20160407050109/http://www.walgreens.com/pharmacy/lab-testing/home.jsp (last visited Aug. 15, 2016).



53. As in the above example, Defendants represented that Theranos test results could be relied on by consumers and their doctors in making health decisions, that they provided "actionable health information at the time it matters" to consumers, and that they "lead the industry in transparency and quality."

54. Defendants advertised that the Theranos testing labs were accurate and "validated," and compliant with federal regulations or law. For example:



55. Defendants' advertising served another purpose as well: to lobby the State of Arizona to pass a law allowing consumers to purchase a blood test without a healthcare provider's order. Theranos's lobbying and advertising efforts were successful and the bill was signed in April 2015, despite opposition from the Arizona Medical Association. At the bill's signing, Ms. Holmes stated that "Theranos is about access – eliminating the need for painful needles and vials of blood, replacing that with tiny samples taken in convenient locations at convenient hours of operation, always for a fraction of the cost charged elsewhere – to build a health care system in which early detection and prevention become reality. That is why we worked to pass this law; it is why we believe Arizona's law can and should serve as a model for the nation for direct

access testing."[24] The law also allowed laboratories to provide blood test results directly to patients, bypassing involvement by doctors, who are trained to question unusual results.

56. Defendants established numerous Theranos Wellness Center facilities inside select Walgreens retail stores, including 40 such locations in Arizona and one such location in California. *See* Ex. F. At each of these Wellness Centers, and at the other facilities where Theranos tests were offered, consumers could choose from a wide selection of Theranos tests with or without the guidance of a health care provider. The Theranos "direct testing menu" identifies more than 200 different medical tests and combinations of tests (panels). *See* Ex. G. To obtain one or more of these testing services, the consumer only needed to complete a one-page "Theranos direct testing order form." *See* Ex. H. The testing services were marketed and sold directly to consumers, as explained in the pamphlet "a guide to direct testing." *See* Ex. I.

57. The Theranos testing order form and guide to direct testing pamphlet, which Plaintiffs and the Class were all exposed to, contained further representations and promises that Theranos tests were reliable and could and should be used in medical treatment decisions and other health decisions. For example, the testing order form encouraged consumers to consult with their doctors for "interpretation of the test results." The guide to direct testing touted that the Theranos tests would allow consumers to "own

[24] Press Release, Theranos, Inc., *Theranos Founder and CEO Elizabeth Holmes Speaks at Arizona Bill Signing*, (Apr. 6, 2015), https://news.theranos.com/2015/04/06/theranos-founder-and-ceo-elizabeth-holmes-speaks-at-arizona-bill-signing/ (last visited Nov. 22, 2016).

your own health like never before," allow consumers to "get vital information about their health when it matters most" and allow them to "become better informed earlier" and enable them to "work with their physician to be proactive and address potential problems sooner." The guide also stated that consumers could use Theranos test results to monitor their vital health issues such as "monitor[ing their] thyroid, blood glucose, sexual health, and more," and directed consumers to consult with their physicians using the test results once they received them.

58. Defendants knew and intended for consumers to rely on their representations, knew that, by the very nature of blood tests and also based on Defendants' representations, consumers who purchased and submitted to Theranos blood testing would reasonably expect the test results to be reliable, and knew that the Theranos partnership with Walgreens, a well-established pharmacy entity, and the presence of Wellness Centers in Walgreens stores, would further lead customers to believe that the Theranos tests were reliable and trustworthy.

D. Defendants' Statements About Theranos Tests Were Knowingly False

59. Defendants' pervasive promises to customers that the Theranos tests were accurate and reliable were knowingly false. In fact, Theranos's testing services—including both the tests conducted using the Edison device and the other tests performed with other devices—were decidedly inaccurate and/or unreliable. Defendants knew this to be the case, and yet concealed that material information from consumers for years.

60. Theranos' tests were not fit for their ordinary purposes and the purposes for which they were sold by Defendants.

61. *Any* consumer who had a Theranos test could not reasonably rely on the results of such tests in light of the litany of problems that have now come to light.

62. First of all, when the Theranos and Walgreens Wellness Centers opened, the Edison devices were not yet beyond the prototype stage.

63. As Theranos knew and Walgreens knew or reasonably should have known at the time, Theranos did not have the necessary FDA approval, known as a CLIA waiver, to use the Edison device for conducting on-site blood testing at the Wellness Centers, with the sole exception of a single test (Herpes Simplex HSV-1), for which the Company obtained approval in July 2015.[25] Theranos sought FDA approval for more than 120 of its tests, none of which have been approved at this time.[26]

64. Despite Defendants' representations to the public about the centrality of the nanotainer and Theranos's proprietary technology, by the end of 2014, Theranos was using its proprietary Edison devices and nanotainers for only 15 out of 205 tests.[27] By June 2015, Theranos had stopped using the Edison device altogether.[28] In a report

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[25] Press Release, Theranos, Inc., *Statement from Theranos* (Oct. 28, 2015), https://news.theranos.com/2015/10/28/statement-from-theranos-3/ (last visited Nov. 22, 2016); Lauren F. Friedman, *Controversial Multibillion-Dollar Health Startup Theranos Just Got a Huge Seal of Approval from the US Government* (Jul. 2, 2015), http://www.businessinsider.com/theranos-gets-fda-approval-2015-7 (last visited Nov. 8, 2016).

[26] Roger Parloff, *A Second FDA Approval Frees Theranos To Do a Blood Test Outside Lab*, Fortune (Jul. 16, 2015), http://fortune.com/2015/07/16/fda-clears-theranos-to-do-test-outside-lab/ (last visited Nov. 8, 2016).

[27] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015) (Ex. B).

[28] Beth Mole, *Theranos Throws in the Towel on Clinical Labs, Officially Pivots to Devices*, Ars Technica (Oct. 5, 2016), http://arstechnica.com/science/2016/10/theranos-

detailing objectionable conditions at Theranos dated September 16, 2015, the FDA informed Theranos that, among other things, the agency considered the nanotainer devices to be uncleared medical devices being shipped in interstate commerce between California, Arizona, and Pennsylvania.[29]

65. Thousands of consumers arrived at the Wellness Centers expecting a finger prick, but instead they received conventional venous blood draws. Defendants knew that customers were receiving venous blood draws and therefore knew, or should have known, that Theranos was not in fact using its finger prick Edison devices. At no point did Defendants disclose to consumers that the blood draw would be anything other than the minimal blood draw they were advertising.

66. Because Theranos did not have FDA approval to conduct tests on the Edison device outside of a laboratory setting (with the limited exception for HSV-1 noted above), when Defendants drew blood at the Wellness Centers, the samples obtained then had to be couriered to one of two centralized labs, either in Newark, California, or Scottsdale, Arizona. The proprietary Edison devices were only located in the Newark laboratory. Accordingly, all the finger stick blood samples were analyzed at the Newark facility, with the potential exception of samples that Theranos, remarkably, diluted in

throws-in-the-towel-on-clinical-labs-officially-pivots-to-devices/ (last visited Nov. 8, 2016).

[29] Department of Health and Human Services Form FDA-483 (inspection report) (Sept. 16, 2015), http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm469395.pdf (last visited Nov. 8, 2016).

order to run them on conventional machinery.[30]

67. The Scottsdale Lab only performed analyses on venipuncture tests. Over 90 percent of Theranos's testing was done at its Scottsdale lab. Theranos has also disclosed that it outsourced certain "highly complex" tests to third-party, university-affiliated labs, despite its statements that it was able to run all of the over 200 tests it offers on its Edison devices.

68. In the context of a regulated laboratory, Theranos did not need FDA approval to perform testing using the Edison devices (because they were not selling the Edison devices), so long as Theranos's lab operations were in compliance with federal guidelines and met proficiency testing and other safeguards; however, the blood labs Theranos used failed to comply with such testing and guidelines according to published reports.

69. Defendants' statements to customers—that testing was accomplished through proprietary analysis, which was accurate and compliant with federal regulations and guidelines—were false, both as to the Edison tests and the other Theranos tests. Simply put, consumers did not receive what they paid for and what they reasonably expected, when they obtained testing services from Defendants. None of them could reasonably rely on the accuracy of the test results they received, in light of the litany of problems that have come to light.

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[30] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015) (Ex. B).

E. FDA, CMS, and Other Regulators Crack Down on Theranos

70. In March 2014, a former Theranos employee alleged to New York State's public-health lab that the company may have manipulated the proficiency testing process, in part by intentionally excluding data that showed Theranos's technology to be unreliable.[31] The lab responded that the practices described would be a "violation of the state and federal requirements," and forwarded the allegations to the Centers for Medicare and Medicaid Services.[32]

71. In April 2015, Arizona Department of Health Services inspectors identified multiple deficiencies at Theranos's Scottsdale laboratory, including issues with Theranos's proficiency testing.[33]

72. In September 2015, a former Theranos lab employee filed a complaint with CMS alleging that Theranos instructed lab employees to keep testing patients with the Edison devices despite indications of "major stability, precision and accuracy" problems with those devices.[34]

73. As discussed above, in October 2015 the FDA released inspection reports of Theranos declaring the nanotainer to be an "uncleared medical device." The investigation also found deficiencies in Theranos's processes for handling customer

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[31] John Carreyrou, *Theranos Whistleblower Shook the Company—And His Family*, Wall St. J. (Nov. 16, 2016) (Ex. J).
[32] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015) (Ex. B).
[33] Ken Alltucker, *Arizona Inspectors Find Theranos Lab Issues*, AZ Central (Nov. 30, 2015), http://www.azcentral.com/story/money/business/consumers/2015/11/27/arizona-inspectors-find-theranos-lab-issues/76021416/ (last visited Nov. 16, 2016).
[34] John Carreyrou, *U.S. Probes Theranos Complaints*, Wall St. J. (Dec. 20, 2015) (Ex. J).

complaints, monitoring quality and vetting suppliers.[35]

74. In January 2016, the Centers for Medicare and Medicaid Services (CMS) cited the Newark lab for multiple serious deficiencies. Among other things, the report stated that in October 2014, 29 percent of quality control checks performed on the Edison devices produced results outside the acceptable range and that in February 2015, quality checks on an Edison test measuring a hormone affecting testosterone levels failed 87 percent of the time.

75. The letter from CMS, dated January 25, 2016, noted that, based on a December 2015 survey, Theranos was found to be out of compliance with five CLIA Condition-level requirements, at least one of which posed "immediate jeopardy to patient health and safety," meaning the condition had "already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."[36]

76. Inspection reports found that Edison devices in the lab often failed to meet the Company's own accuracy requirements, including a test to detect prostate cancer. In one report, inspectors found that 81 of 81 final patient results of a blood clotting test

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[35] *Id.*

[36] Carolyn Y. Johnson, *Deficiencies at Theranos "Pose Immediate Jeopardy to Patient Health,"* The Washington Post (Jan. 27, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/01/27/regulators-find-deficiencies-at-theranos-that-pose-immediate-jeopardy-to-patient-health/ (last visited Nov. 8, 2016).

reported to patients on the blood thinner Warfarin were not accurate.[37]

77. In addition, the FDA observed that there were no quality audits being performed at the Newark lab, in contravention of FDA regulations.[38]

78. At the very time that Defendants were widely touting Theranos's compliance with federal regulations, Theranos had been repeatedly sanctioned by federal authorities for non-compliance, yet Theranos failed to disclose that fact.

79. On March 18, 2016, Theranos received another letter from the Centers for Medicare and Medicaid Services (CMS) referenced "RE: PROPOSED SANCTIONS - CONDITIONS NOT MET IMMEDIATE JEOPARDY", which stated that the Company had not remedied the deficiencies identified by CMS in its January letter. Outlining Theranos's failures to meet quality-control standards, such as improper freezer temperatures, lack of proper documentation, improper equipment calibration, and unqualified personnel, CMS notified Theranos that it was out of compliance with accepted clinical laboratory standards, still had not established compliance with the CLIA requirements previously identified, and had not demonstrated that the laboratory had "abated immediate jeopardy." Notice of Sanctions pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) was provided.[39]

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[37] Andrew Pollack, *Report Shows Theranos Testing Plagued by Problems*, N.Y. Times (Mar. 31, 2015), http://www.nytimes.com/2016/04/01/business/report-shows-theranos-testing-plagued-by-problems.html?_r=0 (last visited Nov. 8, 2016).

[38] Department of Health and Human Services Form FDA-483 (inspection report) (Sept. 16, 2015), http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm469395.pdf (last visited Nov. 8, 2016).

[39] *See*, http://www.wsj.com/public/resources/documents/hhslettertheranos.pdf (last visited Aug. 15, 2016).

80. As these reports indicate, Theranos's conventional laboratory operations in both Scottsdale and Newark were found to be flawed by government regulators. According to published reports, at Theranos's Scottsdale lab, the Company performed lab tests with certain Siemens lab equipment programmed to the wrong settings, and failed to adequately gauge the purity of the water input into Siemens lab equipment, which could affect the outcome of the results of testing run on such devices.

81. A peer-reviewed study published March 28, 2016 by researchers at the Icahn School of Medicine at Mount Sinai showed that results for cholesterol tests done by Theranos differed enough from the two largest laboratory companies that it could negatively impact patient care.

82. Regardless, Defendants continued to falsely market Theranos testing services as accurate and reliable, and continued to encourage consumers to use Theranos test results to make decisions about their health and treatment.

83. In April 2016, Theranos revealed that it was under investigation by the U.S. Department of Justice as well as the Securities and Exchange Commission, and that the Department of Justice had requested documents. Walgreens and the New York State Department of Health also received subpoenas. Investigators are also examining whether Theranos misled government officials. [40]

84. On June 30, 2016, members of the House Energy and Commerce Committee requested briefing from Theranos regarding Theranos's failure to comply

[40] Christopher Weaver, John Carreyrou, and Michael Siconolfi, *Theranos Is Subject of Criminal Probe by U.S.*, Wall St. J. (Apr. 18, 2016) (Ex. L).

with federal regulatory standards governing clinical laboratory testing, and the resulting impact on patients nationwide. The Committee expressed concern over "Theranos's disregard for patient safety and its failure to immediately address concerns by federal regulators," and requested "information about how company policies permitted systematic violations of federal law."[41]

85. On July 7, 2016, the Centers for Medicare and Medicaid Services issued a 33-page Notice to Theranos executives stating that it was revoking the CLIA certificate of Theranos's Newark laboratory and banning the owners and operator(s) of Theranos, including Elizabeth Holmes, from owning or running a lab for at least two years. Citing deficiencies in Theranos's training of lab personnel, quality assurance, and procedures for assessing the "patient impact" of its proficiency testing, among other shortcomings, CMS also threatened to impose a monetary penalty of $10,000 per day for each day of non-compliance.[42]

86. As a result of revelations regarding problems with Theranos's technology and laboratory standards, Theranos test results have lost all credibility within the medical community. Geoffrey Baird, a pathology professor at the University of Washington, reportedly said about Theranos: "I'm incredibly confused by what these people [at

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[41] Committee on Energy & Commerce Democrats Press Release, *Democratic Committee Leaders Request Information from FDA and CMS on Theranos' Inaccurate Blood* Tests, (Jul. 26, 2016), http://democrats-energycommerce.house.gov/newsroom/press-releases/democratic-committee-leaders-request-information-from-fda-and-cms-on (last visited Nov. 22, 2016).

[42] http://online.wsj.com/public/resources/documents/r_Theranos_Inc_CMS_07-07-2016_Letter.pdf (last visited Nov. 22, 2016).

Theranos] are doing. No lab is run like this."[43] Tim Hamill, medical director of UC San Francisco's clinical labs at China Basin and Parnassus reportedly stated: "The fact that there are so many [deficiencies identified by CMS] gives me the impression that these guys don't know what they're doing."[44] Other doctors reportedly have "stopped steering patients to Theranos because of results they didn't trust."[45] In the words of one Forbes reporter, "If there is working technology at Theranos . . . you wouldn't be able to tell."[46]

87. Partner Fund Management, which invested $96.1 million in Theranos in early 2014, filed a shareholder suit on October 10, 2016. The lawsuit alleges that Ms. Holmes, Chief Operating Officer Sunny Balwani, and Theranos engaged in securities fraud, negligent misrepresentation and violations of the Delaware deceptive trade practices act, among other things. [47]

88. In addition, Theranos whistleblower Tyler Schultz recently stepped forward

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[43] Matthew Herper, *Something May Be Working At Theranos, But You Don't Know What It Is*, Forbes (Jun. 17, 2016), http://www.forbes.com/sites/matthewherper/2016/06/17/something-may-be-working-at-theranos-but-you-dont-know-what-it-is/#42ced77176a8.

[44] Nick Stockton, *Theranos's Lab Problems Go Way Deeper Than Its Secret Tech*, Wired (Apr. 27, 2016), https://www.wired.com/2016/04/theranos-lab-problems-go-way-deeper-secret-tech/ (last visited Nov. 16, 2016).

[45] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015) (Ex. B).

[46] Matthew Herper, *Something May Be Working At Theranos, But You Don't Know What It Is*, Forbes (Jun. 17, 2016), http://www.forbes.com/sites/matthewherper/2016/06/17/something-may-be-working-at-theranos-but-you-dont-know-what-it-is/#42ced77176a8.

[47] Reed Abelson and Katie Benner, *Theranos Sued by Investor Who Accuses It of Securities Fraud*, N.Y. Times (Oct. 10, 2016), http://www.nytimes.com/2016/10/11/business/theranos-sued-by-investor-who-accuses-it-of-securities-fraud.html (last visited Nov. 8, 2016).

to provide a detailed account of his experience as a Theranos employee. Mr. Schultz was the first to report Theranos's fraudulent conduct to state regulators.[48]

89. Mr. Schultz was employed by Theranos as an assay validation team member and was responsible for verifying and documenting the accuracy of tests run on Edison devices before they were deployed in the lab for use with patients.

90. Mr. Schultz stated that he found the results varied widely when tests were rerun with the same blood samples. In order to reduce this variability, he states that Theranos routinely discarded outlying values from validation reports it compiled.

91. For example, one validation report about an Edison test to detect a sexually-transmitted infectious disease said the test was sensitive enough to detect the disease 95% of the time. But when Mr. Shultz looked at the two sets of experiments from which the report was compiled, they showed sensitivities of 65% and 80%. Thus, if 100 people infected with the disease were tested only with the Edison device, as many as 35 of them would likely incorrectly get a result concluding they were disease-free.

92. Mr. Schultz then moved to Theranos's production team, where he was responsible for quantifying how much patient tests should be allowed to vary during daily quality-control checks. Labs are permitted to set those parameters subject to them being within the bounds of accepted industry guidelines.

93. Mr. Schultz observed that the Edison devices often failed Theranos's quality-control standards. Mr. Schultz further stated that Sunny Balwani, the No. 2

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[48] John Carreyrou, *Theranos Whistleblower Shook the Company–and His Family*, Wall St. J. (Nov. 16, 2016) (Ex. J).

executive at Theranos under Ms. Holmes, pressured lab employees to ignore the failures and run blood tests on the devices anyway, contrary to accepted lab practices.

94. Mr. Schultz also states that he informed Ms. Holmes of his concerns in early 2014.

95. Unsatisfied with the actions that Mr. Balwani and Ms. Holmes had taken, Mr. Schultz states that he anonymously emailed his complaint to New York officials who administered a proficiency-testing program in which Theranos was enrolled.

96. In April 2014, Mr. Schultz again informed Ms. Holmes of the quality-control failures. A few days later, Mr. Balwani responded to Mr. Schultz with the following email:

> We saw your email to Elizabeth. Before I get into specifics, let me share with you that had this email come from anyone else in the company, I would have already held them accountable for the arrogant and patronizing tone and reckless comments.

97. Mr. Schultz resigned from his position with Theranos shortly thereafter.

98. On November 8, 2016, Walgreens filed a lawsuit against Theranos in the District of Delaware, alleging that Theranos breached its contractual obligations by, *inter alia*, providing testing services to Walgreens customers that Theranos knew lacked accuracy or reliability, and by misrepresenting that its testing was reliable and accurate and concealing that the opposite was true.[49]

[49] Case No. 1:16-cv-01040-SLR (D. Del.), Dkt. 8.

F. Defendants Continued to Fail to Protect Customers

99. Defendants failed to disclose to consumers and to the public the known accuracy and reliability problems and concerns about Theranos tests, and in fact made false affirmative promises that stated and suggested that the tests were reliable. These omissions and statements persisted from before the tests were first offered to the public all the way through the present.

100. In fact, even after the damning CMS report became public in January 2016, Defendants still did not take immediate steps to protect the consumers who obtained testing services from Theranos. Walgreens, for its part, failed to take immediate action even at this stage and instead gave Theranos 30 days to resolve the critical issues CMS identified at the Newark lab, and closed only a single Wellness Center. Not only did Walgreens permit the remaining 40 Wellness Centers to remain open, it made no effort to notify prospective patients about potential concerns about the reliability of Theranos's testing. Nor did Walgreens notify patients who had previously received Theranos's tests at the Wellness Centers that their test results may not have been accurate or reliable.

101. Because it had no choice due to regulatory action, Theranos has now completely voided tens of thousands of its tests results. In many cases, it took months to inform customers and their doctors that the test results should not be relied on. The Wall Street Journal reported on Theranos sending so-called "corrected results" to some patients. Disturbingly, in some instances, the "corrected results" were even more

inaccurate than the initial inaccurate and unreliable results Theranos provided.[50]

102. Even beyond the tens of thousands of completely voided Theranos tests, no consumer who had a Theranos test (regardless of whether Theranos has technically "voided" their test results) could reasonably rely on the results they received given the numerous compliance issues and the extensive list of other accuracy and reliability problems that have come to light.

103. It was not until June 14, 2016, almost six months after CMS's report first became public, and well after Defendants were aware of reliability problems across the Theranos testing spectrum, that Walgreens announced it was ending its relationship with Theranos.[51] Days later, Theranos sent letters to providers encouraging them to direct patients to one of four Theranos-operated Wellness Centers in Arizona. The letters assured providers that Theranos was "*open for business*, confident in our technologies, and steadfast in our commitment to make lab tests fast, convenient, and affordable for everyone." (emphasis in original). The letters did not disclose CMS's sanctions, that Theranos no longer used the Edison device and finger prick tests, the other problems identified with both the Newark and Scottsdale testing facilities, that it had voided all Edison tests performed in 2014 and 2015 as well as other tests, or that its tests were inaccurate and unreliable. To the contrary, Theranos continued to suggest that its test were accurate and reliable. Nor was the material information that Defendants concealed

[50] Christopher Weaver, *Agony, Alarm and Anger for People Hurt by Theranos's Botched Blood Tests*, Wall St. J. (Oct. 20, 2016) (Ex. M).
[51] Michael Siconolfi, Christopher Weaver, John Carreyrou, *Walgreen Terminates Partnership With Blood-Testing Firm Theranos*, Wall St. J. (Jun. 13, 2016) (Ex. N).

available from Theranoss website that the letter asked providers to direct their patients to.

104. Theranos has apparently not learned its lesson, despite endangering the health of thousands of patients. The Centers for Medicare and Medicaid Services banned Ms. Holmes from owning or operating a blood-testing business for at least two years and revoked Theranos's license to operate a lab in California.[52] Yet Theranos and Ms. Holmes, apparently undeterred, are now developing a "miniLab" to run diagnostic tests on small amounts of blood. One doctor, after watching Ms. Holmes's presentation at the annual meeting of the American Association for Clinical Chemistry, noted that it was not clear how the Edison and miniLab differed, and that Ms. Holmes had not actually shown that the device could perform a large number of tests on a single drop of blood.[53] Theranos's deception and secrecy continues; the miniLab has not been evaluated by a third party and lacks FDA approval.

G. Defendants' Misconduct Has Significantly Harmed Consumers

105. As a direct result of Defendants' misconduct alleged herein, Plaintiffs and the other consumers who comprise the proposed Class and Subclasses in this case have been harmed in numerous respects, including but not limited to: (a) paying—out-of-pocket, through health insurance, or through another collateral source—for Theranos tests that they cannot reasonably rely upon and/or have been voided; (b) paying for

[52] John Carreyrou, Michael Siconolfi, and Christopher Weaver, *Theranos Dealt Sharp Blow as Elizabeth Holmes is Banned From Operating Labs*, Wall St. J. (Jul. 8, 2016) (Ex. O).

[53] Abigail Tracy, *The Medical Community Isn't Letting Theranos Off the Hook*, Vanity Fair (Aug. 4, 2016), http://www.vanityfair.com/news/2016/08/theranos-interview-what-went-wrong (last visited Nov. 3, 2016).

subsequent, replacement testing services from other companies; (c) paying additional money to doctors or other health professionals as a result of the inaccurate and unreliable Theranos tests; (d) being subject to unnecessary or potentially harmful treatments, and/or being denied the opportunity to seek treatment for a treatable condition; and (e) severe emotional stress and anxiety associated with receiving the inaccurate and unreliable Theranos test results.

106. Defendants have all benefited financially and otherwise from their misconduct alleged herein, including but not limited to from revenue that all of the Defendants have received for Plaintiffs' and the Class members' tests, and additional business that Walgreens has generated as a result of having Theranos testing facilities in its retail stores.

H. Factual Allegations Regarding Plaintiffs

Plaintiff A.R.

107. On or around June 19, 2015, Plaintiff A.R. purchased Theranos blood tests at a Walgreens Pharmacy in Palo Alto, California. The tests that he purchased included tests regarding protein, blood sugar, cholesterol, and vitamin levels. A.R. purchased Theranos tests to get accurate results about his health. He trusted Theranos and Walgreens to provide reliable test results.

108. A.R. had received orders from his medical care provider to have blood testing performed. A.R. was referred to Theranos by his medical care provider. In choosing to have his blood tested by Theranos, he relied on the representations in Defendants' materials regarding the accuracy and reliability of the test results. He also

expected tests conducted at Walgreens to be trustworthy and reliable.

109. A.R. paid approximately $41.79 out of pocket for the Theranos tests.

110. When he purchased Theranos tests, one or more vials of blood were drawn from a vein in A.R.'s arm.

111. Having been led to believe the Theranos results were accurate, A.R. relied on them, using the results to make decisions concerning his health.

112. His Theranos tests indicated that his Vitamin D levels were low, his blood sugar was high, and his LDL (cholesterol) level was high, and medication was prescribed for him as a result.

113. The Theranos tests that A.R. purchased were not reliable.

114. After learning that his Theranos tests were not reliable, he revisited his doctor.

115. Plaintiff A.R. would not have purchased any Theranos tests if he had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

116. In addition to the other harm described herein, Plaintiff A.R. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he purchased.

Plaintiff B.B.

117. On or around October 3, 2014, Plaintiff B.B. purchased eight Theranos blood tests at a Walgreens Pharmacy in Gilbert, Arizona. The tests that she purchased included tests regarding her thyroid. B.B. purchased Theranos tests to get accurate

results about her health. She trusted Theranos and Walgreens to provide reliable test results.

118. B.B. had received orders from her medical care provider to have blood testing performed. B.B. was informed by her medical care provider that Theranos was the least invasive alternative for blood testing, and also that Theranos tests were cheaper and that the Walgreens locations provided extended hours for her to get tested. In choosing to have her blood tested by Theranos, she relied on representations in Defendants' materials (including on the Theranos and Walgreens websites, and in press releases) regarding the accuracy and reliability of the test results. She also expected tests conducted at Walgreens to be trustworthy and reliable.

119. B.B. paid approximately $81.04 out of pocket for the Theranos tests.

120. When she purchased Theranos tests, one or more vials of blood were drawn from a vein in B.B.'s arm. This was different from the less invasive test that she had expected based on the representations from Defendants that she saw.

121. Having been led to believe the results were accurate, B.B. relied on them, using the results to make decisions concerning her health.

122. The Theranos tests that B.B. purchased were not reliable.

123. After learning that her Theranos tests were not reliable, she had her blood retested multiple times by another company.

124. Plaintiff B.B. would not have purchased any Theranos test if she had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

Plaintiff B.P.

125. Beginning approximately in early 2014, Plaintiff B.P. purchased Theranos blood tests several times at a Walgreens Pharmacy in Ahwatukee Village, Phoenix, Arizona. The tests that he purchased included tests regarding diabetes and cholesterol. B.P. purchased Theranos tests to get accurate results about his health. He trusted Theranos and Walgreens to provide reliable test results.

126. B.P. had received orders from his medical care provider to have blood testing performed. B.P. was informed by his physician that Theranos was the cheapest and least invasive alternative for the tests. In choosing to have his blood tested by Theranos, he relied on representations in Defendants' materials (including in the Walgreens store) regarding the accuracy and reliability of the test results. He also expected tests conducted at Walgreens to be trustworthy and reliable.

127. B.P. paid hundreds of dollars out of pocket for the Theranos tests.

128. The first several times that B.P. underwent blood testing by Theranos, nanotainer technology was used to draw relatively small blood samples. Starting in or around mid-2015, Theranos began collecting both nanotainer vials and one or more larger vials of blood from a vein in B.P.'s arm. By around early 2016, Theranos collected one or more larger vials of blood from a vein in B.P.'s arm during each of his quarterly visits.

129. Having been led to believe the results were accurate, B.P. relied on them, using the results to make decisions concerning his health.

130. Based on his Theranos test results, his doctor diagnosed him with diabetes and high cholesterol, and prescribed certain medications.

131. The Theranos tests that B.P. purchased were not reliable.

132. After learning that his Theranos tests were not reliable, he had his blood tested by another company. The results reflected that he is healthier than the Theranos tests had indicated.

133. Plaintiff B.P. would not have purchased any Theranos test if he had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

134. In addition to the other harm described herein, Plaintiff B.P. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he purchased.

Plaintiff D.L.

135. On or around June 1, 2015, and December 14, 2015, Plaintiff D.L. purchased Theranos blood tests at a Walgreens Pharmacy in Chandler, Arizona. D.L. purchased Theranos tests to get accurate results about her health. She trusted Theranos and Walgreens to provide reliable test results.

136. D.L. had received orders from her medical care provider to have blood testing performed. D.L. was informed by her physician that Theranos was the quickest and cheapest alternative for the tests. In choosing to have her blood tested by Theranos, she relied on representations in Defendants' materials (including in the Walgreens store) regarding the accuracy and reliability of the test results. She also expected tests conducted at Walgreens to be trustworthy and reliable.

137. D.L. paid for the Theranos tests out of pocket and/or through her health

insurer.

138. Each time she purchased a Theranos test, one or more vials of blood were drawn from a vein in D.L.'s arm.

139. Having been led to believe the results were accurate, D.L. relied on them, using the results to make decisions concerning her health.

140. Based on the results of her Theranos tests, D.L. tested positive for Sjogrens syndrome, which required her to seek treatment from her doctor, to be tested for food allergies, and to spend considerable time learning about Sjogrens syndrome and the impact her diagnosis would have on her lifestyle.

141. The Theranos tests that D.L. purchased were not reliable.

142. After learning that her Theranos tests were not reliable, she had her blood tested by another company and consulted with her doctor, who after reviewing the new test results has now confirmed that she does not have Sjogrens syndrome.

143. Plaintiff D.L. would not have purchased any Theranos test if she had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

144. In addition to the other harm described herein, Plaintiff D.L. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests she purchased.

Plaintiff L.M.

145. On or around October 5, 2015, Plaintiff L.M. purchased Theranos blood tests at a Walgreens Pharmacy in Chandler, Arizona. The tests that she purchased

included tests regarding her thyroid. L.M. purchased Theranos tests to get accurate results about her health. She trusted Theranos and Walgreens to provide reliable test results.

146. L.M. had received orders from her medical care provider to have blood testing performed. L.M. was informed by her physician that Theranos was the cheapest alternative for the tests. In choosing to have her blood tested by Theranos, she relied on representations in Defendants' materials regarding the accuracy and reliability of the test results. She also expected tests conducted at Walgreens to be trustworthy and reliable.

147. L.M. paid approximately $59.34 out of pocket for the Theranos tests.

148. When she purchased Theranos tests, one or more vials of blood were drawn from a vein in L.M.'s arm. This was different from the less invasive test that she had expected based on the representations from Defendants that she saw.

149. Having been led to believe the results were accurate, L.M. relied on them, using the results to make decisions concerning her health.

150. Based on the results of her Theranos tests, L.M. was diagnosed by her physician as having Hashimoto's Disease, which was devastating to her and required lifestyle changes, medical appointments, and taking unnecessary medication.

151. The Theranos tests that L.M. purchased were not reliable.

152. In approximately March 2016, at her physician's direction, L.M. had her blood re-tested by a different testing company, repeating the same tests that Theranos had conducted. These results were dramatically different than the Theranos test results, and as per her physician invalidated the diagnosis of Hashimoto's Disease, meaning L.M. had

been needlessly pursuing a course of treatment for a condition she did not have.

153. Plaintiff L.M. would not have purchased any Theranos test if she had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

154. In addition to the other harm described herein, Plaintiff L.M. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests she purchased.

Plaintiff M.P.

155. On or around November 2015, Plaintiff M.P. purchased Theranos blood tests at a Walgreens Pharmacy in Tempe, Arizona. The tests that he purchased included STI panels. M.P. purchased Theranos tests to get accurate results about his health. He trusted Theranos and Walgreens to provide reliable test results.

156. In choosing to have his blood tested by Theranos, he relied on representations in Defendants' materials (including at the Walgreens store and the information he viewed on the Theranos website) regarding the accuracy and reliability of the test results. He also expected tests conducted at Walgreens to be trustworthy and reliable.

157. M.P. paid for the Theranos tests out-of-pocket.

158. The tests that M.P. purchased were not reliable.

159. M.P. paid out-of-pocket to be retested with STI panels after learning that the Theranos tests were unreliable.

160. Plaintiff M.P. would not have purchased any Theranos test if he had known

that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

161. In addition to the other harm described herein, Plaintiff M.P. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he purchased.

Plaintiff R.C.

162. On or around February 2015, Plaintiff R.C. purchased Theranos blood tests at a Walgreens Pharmacy in Sun City West, Arizona. The tests that he purchased included tests regarding his heart health. R.C. purchased Theranos tests to get accurate results about his health. He trusted Theranos and Walgreens to provide reliable test results.

163. R.C. had received orders from his medical care provider to have blood testing performed to monitor his heart health. In choosing to have his blood tested by Theranos, he relied on representations in Defendants' materials (including at the Walgreens store) regarding the accuracy and reliability of the test results. He also expected tests conducted at Walgreens to be trustworthy and reliable.

164. R.C. paid for the Theranos tests through Medicare.

165. When R.C. purchased Theranos tests, Theranos used nanotainer technology to draw relatively small blood samples. Unlike what had been advertised, however, the process was painful and was not quick as advertised. The phlebotomist struggled to secure enough blood from R.C.'s finger and had to repeat the painful process several times before collecting enough to test.

166. Having been led to believe the results were accurate, R.C. relied on them, using the results to make decisions concerning his health.

167. The Theranos tests that R.C. purchased were not reliable.

168. The results from his Theranos tests indicated that R.C. was in good health. Based on these results, his doctor recommended that R.C. maintain his current medication regime and to return in one year for repeat testing, and R.C. believed his current lifestyle and medication regimen was working for him and that he had been successful in getting his heart health under control.

169. Less than one month later, R.C. suffered a heart attack. R.C. was admitted to the hospital, had two stents placed, and had numerous follow up medical appointments. R.C. and his cardiologist were particularly concerned that R.C. had suffered a heart attack given that his blood panels came back clear (from his Theranos tests) less than a month prior. Additional blood work performed during his hospitalization strongly suggested that the near-contemporaneous Theranos blood tests were inaccurate.

170. Subsequently, as alleged above, Theranos voided the results of all of the "tiny" blood tests, which would have included R.C.'s tests.

171. Since his 2015 heart attack, R.C. has been receiving medical care using traditional blood testing procedures from companies other than Theranos.

172. Plaintiff R.C. would not have purchased any Theranos test if he had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

173. In addition to the other harm described herein, Plaintiff R.C. suffered

emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he purchased.

Plaintiff R.G.

174. On or around September 10, 2015, Plaintiff R.G. purchased Theranos blood tests at a Walgreens Pharmacy in Gilbert, Arizona. The tests that he purchased included tests regarding his sexual health. R.G. purchased Theranos tests to get accurate results about his health. He trusted Theranos and Walgreens to provide reliable test results.

175. R.G. had seen and heard advertisements for Theranos that caused him to believe it was testing of the future. In choosing to have his blood tested by Theranos, he relied on representations in Defendants' materials (including a billboard) regarding the accuracy and reliability of the test results. He also expected tests conducted at Walgreens to be trustworthy and reliable.

176. R.G. paid approximately $121.63 out of pocket for the Theranos tests.

177. When he purchased Theranos tests, one or more vials of blood were drawn from a vein in R.G.'s arm.

178. Having been led to believe the results were accurate, R.G. relied on them, using the results to make decisions concerning his health.

179. The results from his Theranos tests indicated that he had tested positive for HIV (specifically, the HIV 1+2 Antigen/Antibody Combo was "reactive").

180. After receiving the test results from Theranos, R.G., he was extremely concerned and visited his physician, began doing research about HIV/AIDS, and had his blood re-tested by two different companies. These test results came back negative.

181. The Theranos tests that R.G. purchased were not reliable.

182. Plaintiff R.G. would not have purchased any Theranos test if he had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

183. In addition to the other harm described herein, Plaintiff R.G. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he purchased.

Plaintiff S.J.

184. In or around July, 2015, Plaintiff S.J. purchased her first Theranos blood test and urinalysis at a Theranos Wellness Center co-located at a Walgreens retail store in Mesa, Arizona. The tests that she purchased were for a routine health check including diabetes and triglyceride levels. S.J. was referred to Theranos by her physician, based on plaintiff's financial needs and Theranos's reputation for affordable testing. S.J. trusted Theranos and Walgreens to provide reliable test results.

185. S.J.'s results from her first Theranos test indicated that she had diabetes, and S.J.'s physician immediately ordered her to be placed on diabetic medications.

186. S.J. firmly believed she did not have diabetes and obtained a re-test. For the re-test, she went back to the same Theranos Wellness Center co-located at a Walgreens retail store in Mesa, Arizona.

187. S.J. paid for all Theranos testing through Medicare.

188. Having been led to believe the lab results were accurate following two, similarly reported Theranos tests, S.J. and her physician relied on the results to make

decisions concerning her health, including a course of medications which ultimately made S.J. very ill. S.J. became so ill that she was treated at urgent care where she made the decision to cease all medications prescribed for diabetes.

189. Following her reaction to the diabetes medication, along with her original belief that she did not have diabetes, S.J. began seeing another physician who ordered repeat lab testing to be done at a non-Theranos facility. As S.J. originally believed, the results confirmed that S.J. in fact, did not have diabetes, and had been improperly diagnosed and treated.

190. The Theranos tests that S.J. purchased were not reliable.

191. Plaintiff S.J. would not have purchased any Theranos test if she had known that Theranos's tests were inaccurate or unreliable.

192. In addition to the other harm described herein, Plaintiff S.J. suffered emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests she purchased.

Plaintiff S.L.

193. On or about February 19, 2015, and October 5, 2015, Plaintiff S.L. purchased Theranos blood tests at a Walgreens Pharmacy in Chandler, Arizona. The tests that he purchased included tests regarding diabetes and his liver. S.L. purchased Theranos tests to get accurate results about his health. He trusted Theranos and Walgreens to provide reliable test results.

194. Prior to each visit, S.L. had seen and heard advertisements for Theranos that caused him to believe that Theranos test results would be as reliable as other labs'

results, and that Theranos was the cheapest and least invasive alternative option for blood testing. In choosing to have his blood tested by Theranos, he relied on representations in Defendants' materials (including on Theranos's website and in advertisements) regarding the accuracy and reliability of the test results. He also expected tests conducted at Walgreens to be trustworthy and reliable.

195. S.L. paid approximately $100 out of pocket for the Theranos tests.

196. When he purchased Theranos tests, one or more vials of blood were drawn from a vein in S.L.'s arm. This was different from the less invasive test that he had expected based on the representations from Defendants that he saw.

197. Having been led to believe the results were accurate, S.L. relied on them, using the results to make decisions concerning his health.

198. The results from his Theranos test indicated certain levels that were elevated from the prior year and that he was diabetic. His doctor ordered an ultrasound of the liver, and he took medication for diabetics.

199. The Theranos tests that S.L. purchased were not reliable.

200. At his doctor's direction, S.L. had his blood re-tested by another company and his results were in the normal range, including showing he was pre-diabetic, significantly different from his Theranos tests.

201. Plaintiff S.L. would not have purchased any Theranos test if he had known that the Theranos testing facilities were not as described, and that Theranos's tests were inaccurate or unreliable.

202. In addition to the other harm described herein, Plaintiff S.L. suffered

emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he purchased.

V. CLASS ACTION ALLEGATIONS

203. Plaintiffs bring this action on behalf of themselves and proposed Class and Subclasses pursuant to Federal Rules of Civil Procedure Rule 23, defined as follows:

> **Class**: All purchasers of Theranos testing services, including consumers who paid out-of-pocket, through health insurance, or through any other collateral source (collectively, "Purchasers").
>
> **Arizona Subclass**: All Purchasers of Theranos testing services in Arizona.
>
> **California Subclass:** All Purchasers of Theranos testing services in California.

204. This action is brought as a class action and may properly be so maintained pursuant to the provisions of Rule 23 of the Federal Rules of Civil Procedure. Plaintiffs reserve the right to amend or modify the Class and Subclass descriptions with greater specificity or further division into subclasses or limitation to particular issues, based on the results of discovery. Excluded from the Class and Subclasses are Defendants, their affiliates, employees, officers and directors, persons or entities, and the Judge(s) assigned to this case.

205. **Numerosity** – The members of the Class and Subclasses are so numerous that their individual joinder is impracticable. On information and belief, there are at least thousands of members in each of the Class and Subclass. The membership of the Class and Subclasses are determinable by objective criteria using Defendants' own records.

206. **Common Question of Fact and Law** – There are questions of law and fact common to the Class and Subclasses. These questions predominate over any questions

affecting only individual class members. These common legal and factual issues include, but are not limited to:

A. Whether Defendants marketed Theranos's testing services as being reliable;

B. Whether Defendants' representations regarding the reliability of Theranos's testing services were material;

C. Whether Theranos and Walgreens had contractual obligations with Plaintiffs and the Class regarding Theranos's testing services;

D. Whether Defendants were obligated to provide testing services and test results that were reliable;

E. Whether Theranos's testing services were reliable;

F. Whether Defendants had a duty to disclose to Plaintiff and the Class material information regarding the reliability of Theranos's testing services;

G. Whether Defendants concealed material information about the reliability of Theranos test results and/or about the compliance of Theranos's testing facilities and/or equipment;

H. Whether Defendants agreed to a partnership through which they would enter the market for direct-to-consumer testing by advertising, promoting, and selling products and services that consumers would use to make decisions about their health;

I. Whether Defendants together constitute an association-in-fact enterprise within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c);

J. Whether Defendants' conduct violates the laws as set forth in the causes of action;

K. Whether Plaintiffs and the Class have been harmed as a result of Defendants' conduct alleged herein;

L. Whether Defendants have been unjustly enriched as a result of their conduct alleged herein;

207. **Typicality** – The claims of the representative Plaintiffs are typical of the claims of the Class and Subclasses. Plaintiffs and the Class and Subclasses were subject to the same common pattern of conduct by Defendants, and the Plaintiffs, like the other members of the Class and Subclasses, have sustained damages arising from Defendants' violations of the law, as alleged herein.

208. **Adequacy** – The representative Plaintiffs will fairly and adequately represent and protect the interests of the Class and Subclass members and have retained counsel who are experienced and competent trial lawyers in complex litigation and class action litigation. There are no material conflicts between the claims of the representative Plaintiffs and the members of the Class and Subclasses that would make class certification inappropriate. Counsel for the classes will vigorously assert the claims of all Class and Subclass members.

209. **Predominance and Superiority** – This suit may be maintained as a class action under Federal Rule of Civil Procedure 23(b)(3) because questions of law and fact common to the Class and Subclasses predominate over the questions affecting only individual members, and a class action is superior to other available means for the fair

and efficient adjudication of this dispute. The damages suffered by individual Class and Subclass members are small compared to the burden and expense of individual prosecution of the complex and extensive litigation needed to address Defendants' conduct. Further, it would be virtually impossible for the class members to individually redress effectively the wrongs done to them. Even if class members themselves could afford such individual litigation, the court system could not. In addition, individualized litigation increases the delay and expense to all parties and to the court system resulting from complex legal and factual issues of the case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. By contrast, the class action device presents far fewer management difficulties; allows the hearing of claims which might otherwise go unaddressed because of the relative expense of bringing individual lawsuits; and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court. Plaintiffs anticipate no unusual difficulties in managing this class action.

210. Plaintiffs contemplate the eventual issuance of notice to the proposed Class and Subclass members setting forth the subject and nature of the instant action. Upon information and belief, Defendants' own business records and electronic media can be utilized for the contemplated notice. To the extent that any further notice may be required, Plaintiffs would contemplate the use of additional media and/or mailings.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*)
(Against All Defendants)
(On Behalf of Arizona Subclass Only)

211. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

212. Plaintiffs bring this claim on behalf of themselves and the Arizona Subclass.

213. Defendants are "persons" within the meaning of A.R.S. § 44-1521(6).

214. Theranos lab panels and blood tests sold in Arizona are "merchandise" within the meaning of A.R.S. § 44-1521(5).

215. Defendants have engaged in deception, unfair acts or practices, fraud, false pretenses, false promises, misrepresentation, concealment, suppression and omission of material facts, as prohibited by A.R.S. § 44-1522(A).

216. Defendants marketed and sold unreliable Theranos tests that they knew to be unreliable and/or which they failed to take sufficient steps to ensure the reliability of, and encouraged consumers to rely on such tests to make decisions about their health and treatment.

217. Defendants knew that Plaintiffs and the Class would reasonably expect their Theranos tests to be reliable, given, *inter alia*, the nature and importance of blood testing, Defendants' representations, and the involvement of Walgreens.

218. Defendants made material misrepresentations, false promises, and

omissions, including but not limited to:

A. False and misleading statements that Theranos tests were reliable;

B. False and misleading statements that Theranos's testing facilities and equipment were sufficient and complied with applicable laws and regulations;

C. False and misleading statements that Theranos's testing services were industry leading in quality;

D. False and misleading statements that Theranos's testing services were less invasive than traditional tests and/or were quicker than traditional tests;

E. False and misleading statements that Theranos's laboratory infrastructure minimized human error to produce high quality results;

F. Failure to disclose and active concealment of known material information about the unreliability of Theranos's testing services;

G. Failure to disclose and active concealment of known material information about the non-compliance of Theranos's testing facilities and/or equipment;

H. Failure to disclose and active concealment of the fact that Walgreens had agreed not to require or obtain objective proof that Theranos's testing services were reliable;

I. Failure to disclose and active concealment of the fact that Walgreens had agreed to conduct no oversight of Theranos's laboratory testing practices;

J. Failure to disclose and active concealment of the fact that Theranos employees were not adequately trained to perform their job functions without

endangering patients, as described in letters from CMS;

K. Failure to disclose and active concealment of the fact that Theranos manipulated its internal proficiency testing process; and

L. Failure to disclose and active concealment of the fact that Theranos's internal validation tests showed that Theranos's technology was unreliable.

219. Defendants knew, or with reasonable care should have known, that their promises and representations were false and material, and that the facts they failed to disclose and concealed were material.

220. Defendants had exclusive and superior knowledge regarding the material information that they concealed.

221. Defendants' misrepresentations and omissions were pervasive.

222. Defendants intended for Plaintiffs and Arizona Subclass members to rely on their misrepresentations, false promises, and omissions concerning Theranos testing.

223. Plaintiffs and the Arizona Subclass members have reasonably relied on the false promises, material misrepresentations and omissions made by Defendants, including but not limited to by paying (out-of-pocket and/or through health insurance or another collateral source) for Theranos testing services, permitting Defendants to take blood samples from them, and relying on Theranos test results to make decisions about their health.

224. Defendants' conduct was wanton and reckless, and Defendants demonstrated reckless indifference to the rights, health, and safety of Plaintiffs and

members of the Arizona Subclass.

225. As a result of the A.R.S. § 44-1522(A) violations described above, Plaintiffs and each and every Arizona Subclass member have suffered actual damages.

226. On behalf of themselves and Arizona Subclass members, Plaintiffs seek relief as prayed for below.

SECOND CAUSE OF ACTION
(Fraud)
(Against All Defendants)

227. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

228. Plaintiffs bring this claim on behalf of themselves and the Class.

229. Defendants marketed and sold unreliable Theranos tests that they knew to be unreliable and/or which they failed to take sufficient steps to ensure the reliability of, and encouraged consumers to rely on such tests to make decisions about their health and treatment.

230. Defendants knew that Plaintiffs and the Class would reasonably expect their Theranos tests to be reliable, given, *inter alia*, the nature and importance of blood testing, Defendants' representations, and the involvement of Walgreens.

231. Defendants, who had or should have had superior knowledge regarding Theranos testing, were in a unique position to prevent harm to their customers. Instead, Defendants made false representations to Plaintiffs and the Class about Theranos tests and the accuracy and reliability of same, and concealed material information from them regarding the true nature of Theranos tests and Theranos's facilities and equipment.

232. At all relevant times, Defendants had a duty to disclose all facts material to Plaintiffs' and the Class members' submission to Theranos testing, purchase of Theranos testing, and reliance upon Theranos test results. Defendants have intentionally misrepresented, concealed, and otherwise not disclosed material facts as alleged herein.

233. Defendants had exclusive and superior knowledge regarding the material information that they concealed.

234. Defendants' misrepresentations and omissions were known by Defendants to be false, misleading, and material. Walgreens also deliberately ignored and deliberately remained ignorant of material facts about Theranos testing.

235. Defendants' misrepresentations and omissions were pervasive.

236. Defendants intended for Plaintiffs and Class members to rely on their misrepresentations and omissions concerning Theranos testing.

237. Plaintiffs and the Class members have reasonably relied on the misrepresentations and omissions made by Defendants, including but not limited to by paying (out-of-pocket and/or through health insurance or another collateral source) for Theranos testing services, permitting Defendants to take blood samples from them, and relying on Theranos test results to make decisions about their health.

238. Plaintiffs and the Class were actually misled and deceived. As a direct result of Defendants' conduct, they were induced to undergo blood draws they would not have undergone, to pay for Theranos products and/or services that they would not have purchased (out-of-pocket and/or through health insurance or another collateral source), and to rely on Theranos test results they would not have relied upon had they known the

truth, to make decisions concerning their health.

239. As a foreseeable and natural consequence of Defendants' conduct, Plaintiffs and the Class have suffered actual damages.

240. Defendants' misconduct alleged herein was intentional, deliberate, and willful.

241. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

THIRD CAUSE OF ACTION
(Negligence)
(Against All Defendants)

242. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

243. Plaintiffs bring this claim on behalf of themselves and the Class.

244. Defendants, who had or should have had superior knowledge regarding Theranos testing, were in a unique position to prevent harm to their customers. Instead, Defendants made false representations to Plaintiffs and the Class about Theranos tests and the accuracy and reliability of same, and concealed material information from them regarding the true nature of Theranos tests and Theranos's facilities and equipment.

245. At all relevant times, Defendants had a duty to disclose all facts material to Plaintiffs' and the Class members' submission to Theranos testing, purchase of Theranos testing, and reliance upon Theranos test results.

246. At all relevant times, Defendants had a duty to provide Plaintiffs and the Class with testing that was safe, reliable, and compliant with applicable laws and

regulations.

247. Defendants breached these duties by, *inter alia*, making material misrepresentations and omissions as alleged herein, and by promoting and selling tests that were unreliable, not safe for consumers to rely on, conducted in a manner that did not satisfy applicable laws, regulations, and/or standards for quality control, conducted in laboratories that did not meet applicable laws, regulations, and/or standards for safety and training, and conducted on inadequately maintained and calibrated equipment.

248. At all relevant times, Walgreens had a duty to Plaintiffs and the Class to take reasonable steps to ensure that Theranos's testing was reliable and safe.

249. Walgreens breached this duty and acted unreasonably by deliberately ignoring and deliberately remaining ignorant of material facts about Theranos testing, and by promoting Theranos tests to its patrons as reliable, less invasive, quicker than traditional testing methods, safe, and highly accurate, despite having doubts and concerns about the reliability of the tests, without requiring objective evidence from Theranos that the tests were reliable, and while maintaining no oversight of Theranos's testing services.

250. Walgreens knew and expected that consumers would look to it for information concerning "care they need." With full knowledge that consumers would rely on its endorsement of Theranos, Walgreens failed to take reasonable steps to prevent consumers from submitting to, paying for, and relying upon unreliable and unsafe Theranos testing services.

251. By promoting the Theranos tests without adequately investigating the truth of promotional statements, and by permitting such tests to be conducted in Walgreens

clinics, despite having concerns and doubts about the reliability of Theranos tests, and after it had knowledge that the tests were in fact unreliable, Walgreens acted unreasonably under the circumstances.

252. Plaintiffs and the Class were damaged as a direct and proximate result of Defendants' negligent conduct, including by submitting to blood draws they would not have undergone, paying for Theranos products and/or services that they would not have purchased (out-of-pocket and/or through health insurance or another collateral source), and relying on Theranos test results, they would not have relied upon had they known the truth, to make decisions concerning their health.

253. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

FOURTH CAUSE OF ACTION
(Negligent Misrepresentation)
(Against All Defendants)

254. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

255. Plaintiffs bring this claim on behalf of themselves and the Class.

256. Defendants specifically and expressly misrepresented material facts to Plaintiffs and the Class, as alleged herein.

257. Defendants knew, or in the exercise of reasonable diligence should have known, that their express representations regarding Theranos testing's accuracy, reliability, safety, speed, means of testing, and compliance with applicable laws and regulations, were false and misleading. Defendants made such statements without

reasonable grounds for believing them to be true.

258. Defendants' misrepresentations and omissions were pervasive.

259. Defendants knew, or in the exercise of reasonable diligence should have known, that the ordinary consumer would rely on and be misled by Defendants' misrepresentations.

260. Plaintiffs and the Class justifiably relied on Defendants' misrepresentations.

261. As a result of Defendants' conduct, Plaintiffs and the Class have suffered actual damages.

262. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

FIFTH CAUSE OF ACTION
(Breach of Contract)
(Against Theranos and Walgreens)

263. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

264. Plaintiffs bring this claim on behalf of themselves and the Class.

265. To Plaintiffs and the Class, Defendants offered to provide accurate, reliable, test results using proprietary Theranos technology, in exchange for submission to blood draws and payment of financial compensation, paid out-of-pocket by the consumer and/or paid through the consumer's health insurance or other collateral sources. Defendants assured customers that Theranos had the expertise and capability to provide accurate and reliable test results, and that Theranos's results were reliable, accurate, and of the highest

quality.

266. Defendants' promises and obligations were set forth in, among other places, the Theranos direct testing order form (*See* Ex. H), the Theranos guide to direct testing (*See* Ex. I), and in marketing materials and other statements by Defendants regarding Theranos's testing services that were pervasive. Defendants had express and/or implied contracts with Plaintiffs and the Class members.

267. Plaintiffs and the Class relied on Defendants' promises and covenants regarding Theranos blood testing in agreeing to have their blood tested by Theranos.

268. Plaintiffs and the Class members all accepted Defendants' offers, creating uniform or substantially similar implied and/or express contracts to perform testing and to provide reliable test results.

269. Plaintiffs and the Class performed all of their obligations under the contracts. They each submitted to blood draws performed by Defendants. They each paid money for Theranos test results offered by Defendants, either out of pocket or through their health insurance or other collateral sources.

270. Defendants breached their contracts with Plaintiffs and the Class by, *inter alia*: (1) failing to deliver testing services and test results that were reliable or of the accuracy or quality promised, leaving Plaintiffs and the Class with test results they could not reasonably rely upon; (2) conducting testing using traditional blood testing methodologies and equipment instead of the promised minimally invasive state-of-the art proprietary technology; (3) not ensuring that Theranos's equipment met its own and/or reasonable quality standards; (4) not ensuring that their services were tendered with

reasonable care and workmanlike effort, including by failing to comply with applicable laws, regulations, and standards for laboratory testing services; and (5) failing to timely notify customers of the test results' unreliability and known inaccuracies.

271. Each Class member did not receive the benefit of their bargain—including reliable test results from a company with the expertise and capability to provide accurate and reliable test results.

272. As a result of Defendants' breaches described above, Plaintiffs and the Class have suffered damages.

273. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

SIXTH CAUSE OF ACTION
(Unjust Enrichment)
(Against All Defendants)

274. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

275. Plaintiffs bring this claim on behalf of themselves and the Class, and as appropriate bring this claim in the alternative to their legal claims.

276. Defendants marketed and sold unreliable Theranos tests that they knew to be unreliable and/or which they failed to take sufficient steps to ensure the reliability of, and encouraged consumers to rely on such tests to make decisions about their health and treatment.

277. Defendants knew that Plaintiffs and the Class would reasonably expect their Theranos tests to be reliable, given, *inter alia*, the nature and importance of blood

testing, Defendants' representations, and the involvement of Walgreens.

278. Defendants made material misrepresentations and omissions, as alleged herein, that were known, or through reasonable care should have been known, by Defendants to be false and material, and were intended by Defendants to mislead Plaintiffs and the Class.

279. Defendants' misrepresentations and omissions were pervasive.

280. Plaintiffs and the Class were actually misled and deceived. They were induced by Defendants to, among other things, purchase and submit to testing which they would not otherwise have purchased or submitted to, and which is not reasonably reliable or of value in light of the numerous problems that have come to light.

281. Plaintiffs lost money as a result of Defendants' conduct.

282. Defendants were enriched by their conduct, including but not limited through revenues received from Plaintiffs' and the Class members' tests.

283. It would be inequitable and unjust for Defendants to retain the money that they have received by their conduct.

284. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

SEVENTH CAUSE OF ACTION
(Aiding and Abetting Fraud)
(Against Walgreens)

285. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

286. Plaintiffs bring this claim on behalf of themselves and the Class.

287. Theranos committed fraud resulting in injury to Plaintiffs and the Class, as alleged herein. Walgreens' conduct alleged herein enabled, substantially assisted, encouraged, and was a substantial factor in, the commission of such fraud.

288. Walgreens knew, or knowingly and deliberately failed to discover, that Theranos's testing was not reliable, and that Theranos laboratories were not compliant with applicable laws and regulatory standards, and presented an immediate danger to patient safety. Walgreens had actual knowledge of measures that it could have taken to prevent Walgreens clinics and marketing from being used to perpetrate fraud, to provide consumers with accurate information, and to reduce the reach of Theranos's fraudulent conduct, but nevertheless knowingly and deliberately decided not to adopt such measures, and instead chose to maintain policies that enabled and assisted the fraud.

289. Before and during the commission of the fraud, Walgreens intended to aid and abet, and did substantially assist, Theranos in fraud perpetrated on Plaintiffs and the Class members by, *inter alia*, marketing, promoting, and otherwise treating Theranos's testing as reliable and compliant with applicable laws and standards, although Walgreens knew, or knowingly and deliberately failed to discover, that this information was false, by concealing material information about the reliability and safety of Theranos tests, by allowing Theranos tests to be sold and conducted in its pharmacies, and by making available Walgreens employees to facilitate the sale and conducting of Theranos testing services.

290. Walgreens' conduct alleged herein was knowing and intentional, and was carried out by Walgreens in order to benefit Walgreens, including in the form of ill-

gotten revenues. Upon information and belief, Walgreens received revenue from assisting in the perpetration of fraud by Theranos, including through sales of Theranos tests, and through increased sales of other Walgreens products to new and existing customers. Upon information and belief, Walgreens also benefited financially and reputationally as a result of being the first national retail store to provide direct-to-consumer testing services.

291. Plaintiffs and the Class incurred actual damage as a result of Walgreens' conduct in aiding and abetting fraud.

292. Walgreens' misconduct alleged herein was intentional, deliberate, and willful.

293. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

EIGHTH CAUSE OF ACTION
(Civil Conspiracy to Commit Fraud)
(Against All Defendants)

294. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

295. Plaintiffs bring this claim on behalf of themselves and the Class.

296. Defendants agreed to a partnership through which they would enter the market for direct-to-consumer testing by advertising, promoting, and selling products and services that consumers would use to make decisions about their health, while knowing that the products and services provided were not as advertised and were unreliable, and that their promotions and other statements in marketing such products and services were

false and/or unproven.

297. The object of Defendants' conspiracy was to sell testing services to consumers, thereby becoming the primary participants in the new, profitable, national market for direct-to-consumer testing services, while concealing that Theranos's testing services were unreliable, unsafe, and should not be used by consumers to make decisions about their health.

298. In furtherance of the conspiracy, Walgreens, Theranos, and Elizabeth Holmes agreed to, and did, commit fraud, and other violations of law as described herein.

299. In furtherance of the conspiracy, Theranos and Holmes committed the acts alleged herein, including providing the unreliable test results to consumers and encouraging consumers to rely on those results, fraudulently concealing material facts, and falsely representing Theranos's testing services as reliable, revolutionary, minimally invasive, fast, compliant with applicable laws and regulatory standards, and accurate.

300. In furtherance of the conspiracy, Walgreens committed the acts alleged herein. Among other things, Walgreens deliberately ignored problems about the reliability of Theranos testing, and deliberately and knowingly concealed from Plaintiffs and the Class that it had identified numerous red flags about Theranos and Theranos testing, and that it had conducted a grossly inadequate investigation of Theranos. Walgreens further executed an agreement with Theranos to market and provide Theranos products and services to Walgreens customers, and endorsed and promoted misrepresentations about Theranos testing services with knowledge of their falsity and/or ignorance of their truth. Walgreens further deliberately prevented its staff from

conducting any oversight or review of Theranos's conduct, including but not limited to toward Walgreens customers, despite having concerns and doubts about the reliability of Theranos tests, in an effort to conceal the truth from Defendants' customers, and the public, for as long as possible. Walgreens further agreed to provide space for Theranos inside its stores to drive retail consumers toward its services, and agreed to make available Walgreens employees who would facilitate the sale and performance of Theranos testing services.

301. Elizabeth Holmes agreed to falsely promote Theranos testing as reliable and compliant with applicable laws and regulations

302. As a result of the Defendants' conspiracy, Plaintiffs and the Class have suffered actual damages.

303. Defendants' misconduct alleged herein was intentional, deliberate, and willful.

304. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

NINTH CAUSE OF ACTION
(Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c))
(Against All Defendants)

305. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

306. Plaintiffs bring this claim on behalf of themselves and the Class.

307. 18 U.S.C. § 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or

foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity."

308. Theranos, Walgreens, and Elizabeth Holmes are "persons" within the meaning of 18 U.S.C. § 1961(3).

309. Theranos, Walgreens, and Elizabeth Holmes together constitute an association-in-fact enterprise within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c), and will be referred to herein as the Clinic RICO Enterprise.

310. The Clinic RICO Enterprise engaged in and affected interstate commerce within the meaning of 18 U.S.C. § 1962(c), including but not limited to commerce on the internet, and between residents of California, Arizona, and Pennsylvania.

311. The Clinic RICO Enterprise had an ongoing organization with an ascertainable structure, and functioned as a continuing unit with separate roles and responsibilities. For example, Theranos advertised Theranos testing services as revolutionary and reliable, when in fact its laboratories were staffed by inadequately trained personnel, used improperly calibrated equipment, and its test results were unreliable. Walgreens promoted and agreed to assist in promoting Theranos testing services to consumers, agreed to refrain from conducting any oversight or rigorous investigation regarding Theranos or its facilities and equipment, agreed to provide space for Theranos inside its stores to drive retail consumers toward its services, and agreed to make available Walgreens employees who would facilitate the sale and performance of Theranos testing services. Elizabeth Holmes agreed to falsely promote Theranos testing as reliable and compliant with applicable laws and regulations.

312. At all relevant times, Defendants operated, controlled, or managed the Clinic RICO Enterprise, and profited from the Clinic RICO Enterprise. Defendants were responsible for the content of all marketing, advertisements, and other public-facing representations regarding Theranos, and for the material omissions alleged herein.

313. The Clinic RICO Enterprise has had a common purpose: to sell Theranos testing services at Walgreens and Theranos clinics that could not have been sold had the true facts material to the transactions been disclosed.

314. Defendants conducted and participated in the conduct of the affairs of the Clinic RICO Enterprise through a pattern of racketeering activity, beginning at the latest in 2013, and continuing until 2016, and consisting of numerous and repeated violations of the federal mail and wire fraud statutes, which prohibit the use of any interstate or foreign mail or wire facility for the purpose of executing a scheme to defraud, in violation of 18 U.S.C. §§ 1341 and 1343.

315. Defendants devised and furthered the scheme to defraud by use of the mail, telephone, and internet, and caused to be transmitted, by means of mail and wire communications traveling in interstate commerce, writing(s), and/or signal(s), including the Theranos and Walgreens websites, online, mailed, televised, or other advertising, press releases, Theranos test results and other materials, and invoices for, and processing of, payments.

316. The conduct alleged herein was part of a scheme that Defendants formulated to defraud Plaintiffs and the Class, to receive financial and other benefits, and to become the primary participants in the new, profitable, national market for direct-to-

consumer testing services. Defendants perpetrated this scheme with the specific intent to deceive and defraud Plaintiffs and the Class, and Defendants did deceive and defraud Plaintiffs and the Class.

317. These acts of racketeering spanned at least three years and are not isolated or long-ago completed events. Through the conduct of the Clinic RICO Enterprise, Defendants have fraudulently sold millions of unreliable and dangerous Theranos tests to consumers.

318. As a foreseeable and natural consequence of Defendants' scheme, Defendants injured Plaintiffs and the Class in the form of their submission to and payment, out-of-pocket and/or through their health insurance or other collateral sources, for testing services that were unreliable, did not hold the promised value and were dangerous when used for their advertised purposes, and by steps taken and not taken by Plaintiffs and the Class in reliance upon the test results.

319. Defendants' acts also present a threat of continued racketeering activity, including but not limited to insofar as the Clinic RICO Enterprise has not issued formal invalidation notices for all Theranos test results.

320. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

TENTH CAUSE OF ACTION
Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(d)
(Against All Defendants)

321. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

322. Plaintiffs bring this claim on behalf of themselves and the Class.

323. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

324. For years, Defendants aggressively sought to induce and increase sales of Theranos testing services in an effort to bolster their revenues, augment profits, and increase their market share of the new, profitable, national market for direct-to-consumer testing services. Finding it impossible to achieve their ambitious goals lawfully, Defendants resorted to cheating through their fraudulent scheme and conspiracy.

325. Theranos, Elizabeth Holmes, and Walgreens objectively manifested an agreement to participate in the scheme to defraud consumers through the Clinic RICO Enterprise. Theranos, Holmes, and Walgreens objectively manifested an agreement on the common purpose of the Clinic RICO Enterprise, deliberately and knowingly selling unreliable and dangerous lab tests to consumers while making false representations and material omissions regarding their accuracy, reliability, and compliance with applicable laws and standards.

326. Further, Defendants objectively manifested an agreement to perpetrate this scheme through predicate acts amounting to a pattern of racketeering activity. Walgreens, Holmes, and Theranos agreed that some members of the Clinic RICO Enterprise would commit the predicate acts for the benefit of the Enterprise. Defendants further agreed to commit predicate crimes and to aid and abet the commission of predicate crimes by other members of the Clinic RICO Enterprise.

327. As a foreseeable and natural consequence of Defendants' conspiracy,

Defendants injured Plaintiffs and the Class in the form of their submission to and payment, out-of-pocket and/or through their health insurance or other collateral sources, for testing services that were unreliable and did not hold the promised value and were dangerous when used for their advertised purposes, and by steps taken and not taken by Plaintiffs and the Class in reliance upon the test results.

328. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

ELEVENTH CAUSE OF ACTION
(Violation of California Business & Professions Code Sections 17200, *et seq.*)
(Against All Defendants)

329. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

330. Plaintiffs bring this claim on behalf of themselves and the Class.

331. California's Unfair Competition Law ("UCL") defines unfair business competition to include any "unfair," "unlawful," or "fraudulent" business act or practice.

332. Defendants' unlawful, unfair, and fraudulent business acts and practices are described throughout this Complaint and include, but are not limited to: (a) marketing and selling unreliable Theranos tests that they knew to be unreliable and/or which they failed to take sufficient steps to ensure the reliability of, and encouraging consumers to rely on such tests to make decisions about their health and treatment; and (b) material misrepresentations and omissions as alleged herein.

333. Defendants' conduct alleged herein constitutes unlawful, unfair, and fraudulent business practices.

334. Defendants have violated the "fraudulent" prong of the UCL through their misrepresentations and omissions alleged herein. Defendants' misrepresentations and omissions were pervasive. Defendants' misrepresentations and omissions are likely to deceive and have a tendency to deceive reasonable consumers, and have deceived Plaintiffs and the Class. The facts misrepresented and/or concealed by Defendants would be material to a reasonable consumer.

335. Defendants had exclusive and superior knowledge regarding the material information that they concealed.

336. Plaintiff and the Class reasonably relied upon Defendants' misrepresentations and omissions to their detriment.

337. Defendants have violated the "unfair" prong of the UCL through their misconduct alleged herein, under both the Cel-Tech "tethering" test[54] and "balancing" test.

338. Defendants' conduct alleged herein violates California public policy, including but not limited to as such policy is reflected in California's Consumer Legal Remedies Act (Cal. Civ. Code § 1750, *et seq.*), Cal. Civ. Code § 1710, Cal. Comm. Code §§ 2314-2315, and in California common law.

339. Defendants' conduct alleged herein is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers. Defendants have engaged in a years-long, pervasive scheme of: (a) promoting and selling unreliable Theranos tests and

[54] *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163 (1999).

encouraging consumers to rely on those tests in making decisions about their health; (b) misrepresenting the reliability and other details about Theranos testing services; and (c) concealing from consumers material information about the reliability of Theranos tests and the compliance of Theranos with applicable laws and standards. This conduct is immoral, unethical, and unscrupulous. Moreover, Defendants' conduct is oppressive and substantially injurious to consumers. Among other things, as a direct result of Defendants' conduct alleged herein, Plaintiff and the Class have paid money and submitted to Theranos testing that was not only unreliable, but put their health at risk.

340. Defendants' conduct is also unlawful in that it violates Civil RICO (18 U.S.C. §§ 1961-1968); California's False Advertising Law, (Cal. Bus. & Prof. Code § 17500, *et seq.*), California's Consumer Legal Remedies Act, (Cal. Civ. Code § 1750, *et seq.*), statutory deceit, (Cal. Civ. Code § 1710), the Arizona Racketeering Act, (A.R.S. §§ 13-2301-04), and common law fraud, civil conspiracy to commit fraud, negligence, and negligent misrepresentation, which not only result in liability as to the individual causes of action, they also provide a basis for a finding of liability under California Business and Professions Code §§ 17200, *et seq.*

341. Furthermore, Defendants' conduct violates declared legislative policies as set forth by the federal government in 40 C.F.R. § 600.307(a)(ii)(A); 40 C.F.R. § 600.302-08(b)(4) and 16 C.F.R. § 259.2(a).

342. As a result of Defendants' violations of California's Unfair Competition Law, Plaintiffs and the Class have suffered actual damages, including the loss of money and/or property to Defendants in exchange for testing they would not, with knowledge of

the truth, have allowed to be performed, and which is unreliable, not worth the promised value, and dangerous.

343. Absent injunctive relief, Defendants' violations will continue to harm consumers.

344. Pursuant to California Business and Professions Code §§ 17200 and 17203, on behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

TWELFTH CAUSE OF ACTION
(Violation of California Business & Professions Code Sections 17500, *et seq.*)
(Against All Defendants)

345. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

346. Plaintiffs bring this claim on behalf of themselves and the Class.

347. California Bus. & Prof. Code § 17500 states: "It is unlawful for any … corporation … with intent directly or indirectly to dispose of real or personal property … to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated … from this state before the public in any state, in any newspaper or other publication, or any advertising device, … or in any other manner or means whatever, including over the Internet, any statement … which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

348. Defendants have committed acts of untrue and misleading advertising, by disseminating materially misleading and deceptive information, and omitting material information, as alleged herein, for purposes of inducing consumers to purchase and

submit to Theranos testing services.

349. Defendants' misrepresentations and omissions were pervasive.

350. Defendant's misrepresentations deceived, and have a tendency to deceive the general public regarding the reliability and value of Theranos tests. The misrepresentations and omissions by Defendants alleged herein were material in that a reasonable person would attach importance to them and would be induced to act on the information in making decisions.

351. Defendants had exclusive and superior knowledge regarding the material information that they concealed.

352. Plaintiffs and the Class reasonably relied on Defendants' misrepresentations and omissions to their detriment.

353. As a result of Defendants' violations, Plaintiffs and the Class have suffered actual damages, including the loss of money and/or property to Defendants in exchange for testing they would not, with knowledge of the truth, have allowed to be performed, and which is unreliable and dangerous.

354. Absent injunctive relief, Defendants' violations will continue to harm consumers.

355. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

THIRTEENTH CAUSE OF ACTION
(Violation of California Civil Code Section 1750 *et seq.*)
(Against All Defendants)

356. Plaintiffs incorporate the substantive allegations contained in all prior and

succeeding paragraphs as if fully set forth herein.

357. Plaintiffs bring this claim on behalf of themselves and the Class.

358. Defendants are "persons" under Cal. Civ. Code § 1761(c).

359. Plaintiffs and the members of the Class are "consumers" under Cal. Civ. Code § 1761(d).

360. Plaintiffs and each Class member's purchase of Theranos tests constitute "transactions" under Cal. Civ. Code § 1761(e).

361. Theranos tests are "goods" and/or "services" under Cal. Civ. Code § 1761 (a-b).

362. Plaintiff and Class members purchased Theranos tests for personal, family, and household purposes within the meaning of California Civil Code § 1761(d).

363. As alleged herein, Defendants have engaged in unfair or deceptive acts or practices that violated California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, *et seq.* by, among other things, representing that Theranos testing services have characteristics, uses, benefits, and qualities which they do not have; representing that Theranos testing services are of a particular standard, quality, and grade when they are not; and advertising Theranos testing services with the intent not to sell them as advertised. Cal Civ. Code § 1770 (5), (7), and (9).

364. Defendants actively failed to disclose and concealed material facts about Theranos tests, and otherwise engaged in activities with a tendency or capacity to deceive, as described herein.

365. Defendants' misrepresentations and omissions were pervasive.

366. Defendants' CLRA violations materially affected the decisions of Plaintiffs and Class members. Plaintiffs and the Class members reasonably relied upon Defendants' material misrepresentations and omissions, and would not have purchased Theranos tests or submitted their blood for testing to Defendants had they known the truth.

367. As a result of the CLRA violations described herein, Plaintiffs and the Class have suffered actual damages.

368. On behalf of the Class, Plaintiffs seeks injunctive relief to enjoin the CLRA violations alleged herein. Plaintiffs also seek attorneys' fees and costs.

369. In accordance with California Civil Code § 1782(a), Defendants Theranos and Walgreens have been sent notice of their CLRA violations by certified mail, return receipt requested. Theranos and Walgreens have failed to provide appropriate relief for their CLRA violations within 30 days of these notification letters. This Consolidated Complaint differs from the original complaints filed in the underlying cases, so Interim Co-Lead Plaintiffs' Counsel is sending renewed notice to Defendants Theranos and Walgreens, and to Defendant Holmes, concurrent with the filing of this Consolidated Complaint. *See* Ex. P. If Defendants fail to provide appropriate relief within 30 days of such notice, Plaintiffs intend to amend the Consolidated Complaint as of right under Fed. R. Civ. P. 15(a)(1) to request actual and punitive damages for the CLRA violations alleged herein.

370. Venue is proper under California Civil Code § 1780(d) because Defendants do business in this county and a substantial portion of the transactions at issue occurred in

this county. Plaintiffs' declaration establishing that this Court has proper venue for this action is attached hereto. *See* Ex. Q.

FOURTEENTH CAUSE OF ACTION
(California Civil Code §§ 1709- 1710 - Deceit)
(Against All Defendants)

371. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.

372. Plaintiffs bring this claim on behalf of themselves and the Class.

373. California Civil Code § 1709 provides that "[o]ne who willfully deceives another with intent to induce him to alter his position to his injury or risk, is liable for any damage which he thereby suffers."

374. California Civil Code § 1710 defines "deceit" as (1) The suggestion, as a fact, of that which is not true, by one who does not believe it to be true; (2) The assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true; (3) The suppression of a fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact; or, (4) A promise, made without any intention of performing it.

375. Defendants' material misrepresentations and omissions alleged herein constitute deceit under California Civil Code § 1710. Defendants' misrepresentations and omissions were pervasive. Plaintiffs and the Class have reasonably relied on the material misrepresentations and omissions made by Defendants. As a result, Plaintiffs and the Class have suffered actual damages.

376. Defendants' misconduct alleged herein was intentional, deliberate, and willful, and was perpetrated by Defendants with the intent to, *inter alia*, cause Plaintiffs and the Class to rely on Theranos's unreliable test results in making decisions about their health and treatment.

377. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for below.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class and Subclasses, demand judgment against and general and special relief from Defendants as follows:

1. An order certifying that the action may be maintained as a class action under Federal Rule of Civil Procedure 23 as defined herein and appointing Plaintiffs and Interim Co-Lead Counsel to represent the defined Class and Subclasses;

2. An order permanently enjoining Defendants' misconduct alleged herein;

3. An order awarding Plaintiffs and the Class damages and restitution;

4. An order requiring Defendants to disgorge all profits and compensation improperly obtained by Defendants as a result of such acts and practices declared by this Court to be an unlawful;

5. An order requiring Defendants to pay punitive, exemplary, and treble damages;

6. An order requiring Defendants to pay attorneys' fees, costs, and expenses;

7. An order requiring Defendants to pay pre-judgment and post-judgment

interest; and

8. Such other and further relief as the Court deems appropriate.

VIII. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all claims so triable.

DATED this 22nd day of November, 2016.

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Additional Plaintiffs' Counsel

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2016, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to all CM/ECF registrants.

By: s/ T. David Copley
T. David Copley

EXHIBIT A

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/theranos-voids-two-years-of-edison-blood-test-results-1463616976

TECH

Theranos Voids Two Years of Edison Blood-Test Results

Company led by Elizabeth Holmes withdraws all Edison results from 2014 and 2015, issues tens of thousands of corrected blood-test reports

Theranos founder and CEO Elizabeth Holmes speaking in San Francisco last year. *PHOTO: JEFF CHIU/ASSOCIATED PRESS*

By JOHN CARREYROU
May 18, 2016 8:16 p.m. ET

Theranos Inc. has told federal health regulators that the company voided two years of results from its Edison blood-testing devices, according to a person familiar with the matter.

The Edison machines were touted as revolutionary and were the main basis for the $9 billion valuation attained by the Palo Alto, Calif., company in a funding round in 2014. But Theranos has now told regulators that it threw out all Edison test results from 2014 and 2015.

The company has told the Centers for Medicare and Medicaid Services that it has issued tens of thousands of corrected blood-test reports to doctors and patients, voiding some results and revising others, according to the person familiar with the matter.

That means some patients received erroneous results that might have thrown off health decisions made with their doctors.

> The corrected reports include the voided Edison results and many tests run on traditional laboratory machines, the person said.

Several physician practices in the Phoenix area confirmed receiving corrected test reports from Theranos in recent weeks.

The move is part of Theranos's attempt to persuade the agency not to impose stiff sanctions it threatened in the aftermath of its inspection of the company's Newark, Calif., laboratory. The voided and revised test results are one of the most dramatic steps yet taken by Theranos.

Company records reviewed during the inspection showed that the California lab ran about 890,000 tests a year. The inspection found that Edison machines in the lab often failed to meet the company's own accuracy requirements.

Theranos has told regulators that it used the Edison for 12 types of tests out of more than 200 offered to consumers and stopped using the devices altogether in late June 2015, the person familiar with the matter said.

"There have been massive recalls of single tests in the past, but I'm not aware of one where a company recalled the entirety of the results from its testing platform," said Geoffrey Baird, associate professor in the department of laboratory medicine at the University of Washington in Seattle. "I believe that's unprecedented."

In response to questions from The Wall Street Journal about the blood-test corrections, Theranos spokeswoman Brooke Buchanan said: "Excellence in quality and patient safety is our top priority and we've taken comprehensive corrective measures to address the issues CMS raised in their observations. As these matters are currently under review, we have no further comment at this time."

CMS declined to comment.

RELATED

- Theranos Executive Sunny Balwani to Depart Amid Regulatory Probes (May 12)
- Regulators Propose Banning Theranos Founder Elizabeth Holmes for at Least Two Years (April 13)
- Theranos Devices Often Failed Accuracy Requirements (March 31)
- Walgreens Threatens to End Theranos Agreement (Feb. 10)
- Deficiencies Found at Theranos Lab (Jan. 24)
- At Theranos, Many Strategies and Snags (Dec. 27)
- Hot Startup Theranos Has Struggled With Its Blood-Test Technology (Oct. 16)

In March, CMS proposed banning Theranos founder Elizabeth Holmes from the blood-testing business for at least two years after concluding that the company failed to fix what regulators have called major problems at the California lab. The agency is the federal overseer of clinical labs.

CMS also has threatened to revoke the California lab's federal license and impose fines against Theranos.

The company has said it has taken broad corrective actions in response to the government's concerns. Among other steps, Theranos has filed a detailed correction plan with regulators, hired a new director for the California lab and suspended most testing there.

Last week, Theranos announced the departure of Sunny Balwani, its No. 2 executive, who also was under the threat of a two-year ban from the blood-testing industry.

CMS is expected to announce a final decision on the sanctions soon. If the agency decides to go through with any sanctions, Theranos could appeal to an administrative law judge and then a departmental appeals board.

Drugstore operator Walgreens Boots Alliance Inc. was among those informed by Theranos about the corrected test results issued to doctors and patients, according to people familiar with the matter.

Walgreens has been Theranos's main conduit to consumers since the companies announced a partnership in 2013. In January, though, Walgreens notified Theranos that it intends to terminate the partnership unless Theranos quickly puts itself back in compliance with federal regulations.

Theranos has declined to quantify to Walgreens the scale of its test corrections, adding more friction to the relationship, said the people with knowledge of their discussions. Walgreens spokesman Michael Polzin said the company declined to comment.

One family practitioner in a suburb of Phoenix said a Theranos representative dropped off a stack of 20 corrected test reports a few weeks ago. Many of the voided results were for calcium, estrogen and testosterone tests.

The doctor said one corrected report is for a patient she sent to the emergency room after receiving abnormally elevated test results from Theranos in late 2014.

The corrected report from Theranos now shows normal values for those tests, according to the doctor.

Broadway East Internists in Mesa, Ariz., has received corrected reports for blood-coagulation tests that Theranos performed in its Arizona laboratory.

The company's Arizona lab wasn't part of last fall's inspection, isn't facing a sanctions threat and continues to run a variety of tests on samples drawn from patients at 40 Theranos wellness centers at Walgreens drugstores.

A person familiar with the matter said the Arizona lab performed the blood-coagulation tests with a traditional machine from Siemens AG that was programmed to the wrong settings by Theranos.

The Arizona lab also failed several tests to gauge the purity of the water it uses in its Siemens machines, which could affect the accuracy of some blood tests run on the devices, the person said.

The person added that Siemens has grown wary about its relationship with Theranos.

In an emailed statement, Siemens said it is "confident that, when maintained and used properly, our equipment and tests will perform to specifications and deliver fast, accurate and reliable results to our customers."

Last week, Siemens delivered lab equipment to a Theranos facility in the Harrisburg, Pa., area, according to the person familiar with the matter. The person said Theranos is preparing to open there what would be the company's third lab.

—Christopher Weaver and Michael Siconolfi contributed to this article.

Write to John Carreyrou at john.carreyrou@wsj.com

EXHIBIT B

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901

BUSINESS | TECH

Hot Startup Theranos Has Struggled With Its Blood-Test Technology

Silicon Valley lab, led by Elizabeth Holmes, is valued at $9 billion but isn't using its technology for all the tests it offers

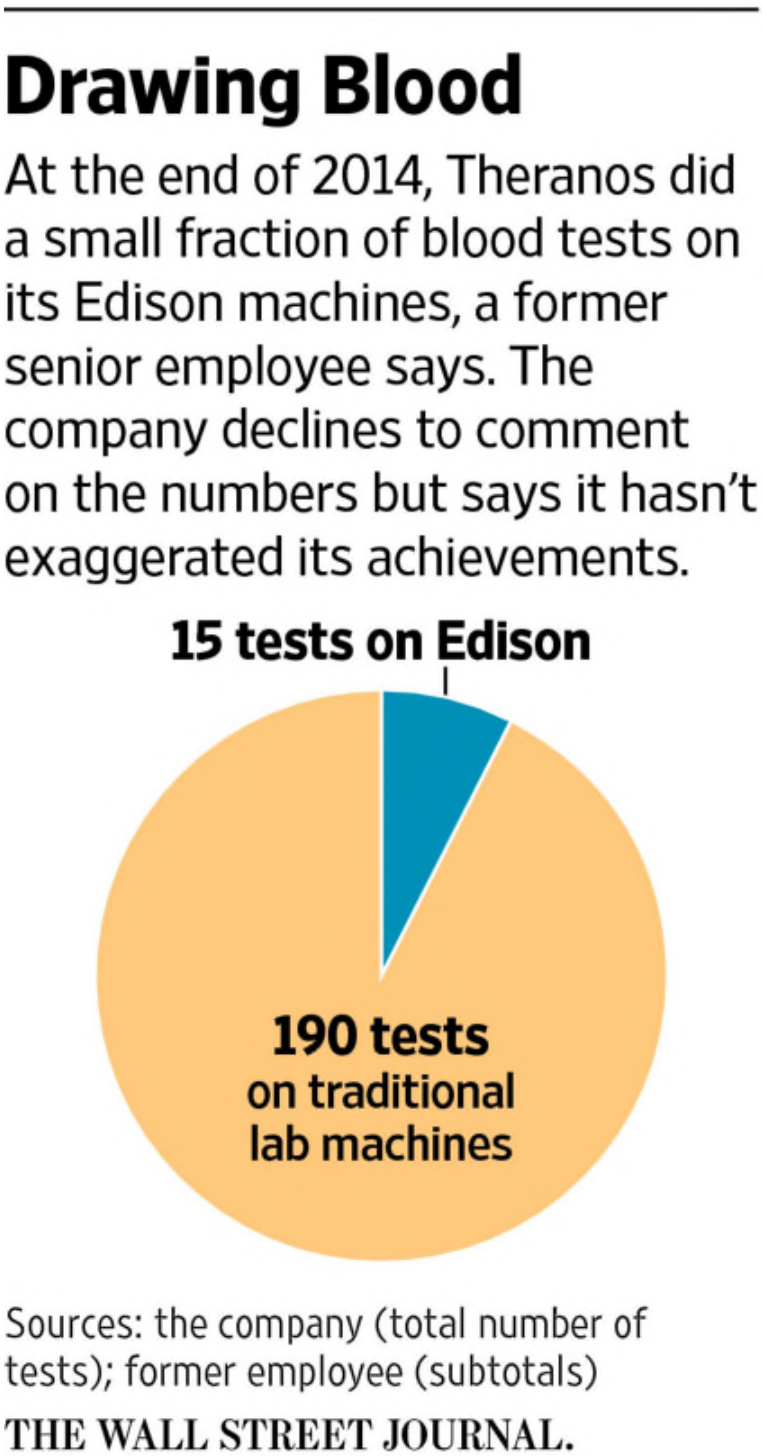
Elizabeth Holmes, Theranos's founder, chairman and chief executive, at the blood-testing company's headquarters in Palo Alto, Calif. Her ownership stake in Theranos is valued at more than $4.5 billion. *PHOTO: MARTIN E. KLIMEK*

By JOHN CARREYROU
Updated Oct. 16, 2015 3:20 p.m. ET

On Theranos Inc.'s website, company founder Elizabeth Holmes holds up a tiny vial to show how the startup's "breakthrough advancements have made it possible to quickly process the full range of laboratory tests from a few drops of blood."

The company offers more than 240 tests, ranging from cholesterol to cancer. It claims its technology can work with just a finger prick. Investors have poured more than $400 million into Theranos, valuing it at $9 billion and her majority stake at more than half that. The 31-year-old Ms. Holmes's bold talk and black turtlenecks draw comparisons to Apple Inc. cofounder Steve Jobs.

But Theranos has struggled behind the scenes to turn the excitement over its technology into reality. At the end of 2014, the lab instrument developed as the linchpin of its strategy handled just a small fraction of the tests then sold to consumers, according to four former employees.



One former senior employee says Theranos was routinely using the device, named Edison after the prolific inventor, for only 15 tests in December 2014. Some employees were leery about the machine's accuracy, according to the former employees and emails reviewed by The Wall Street Journal.

In a complaint to regulators, one Theranos employee accused the company of failing to report test results that raised questions about the precision of the Edison system. Such a failure could be a violation of federal rules for laboratories, the former employee said.

Theranos also hasn't disclosed publicly that it does the vast majority of its tests with traditional machines bought from companies like Siemens AG.

The Palo Alto, Calif., company says it abides by all applicable federal lab regulations and hasn't exaggerated its achievements. It disputes that its device could do just 15 tests, declining to say how many tests it now handles or to respond to some questions about its lab procedures, citing "trade secrets."

But Theranos's outside lawyer, David Boies, acknowledges that the company isn't yet using the device for all the tests Theranos offers. The transition to doing every test with the device is "a journey," he says.

DEVELOPING

- Theranos Dials Back Lab Tests at FDA's Behest

Asked about the claim on the company's website, Mr. Boies replied that using the device for the "full range" of blood tests is a goal Theranos will eventually achieve.

Theranos points out that it has publicly disclosed doing "certain esoteric and less commonly ordered tests" with traditional machines on blood drawn with smaller needles from veins.

During the Journal's reporting, Theranos deleted a sentence on its website that said: "Many of our tests require only a few drops of blood." It also dropped a reference to collecting "usually only three tiny micro-vials" per sample, "instead of the usual six or more large ones." Heather King, the company's general counsel, says the changes were made for "marketing accuracy."

Ms. King and Mr. Boies say Theranos's lab work is accurate. Theranos has performed tests on millions of patients referred by thousands of doctors and has received highly positive feedback, they say.

Ms. Holmes, Theranos's chairman and chief executive, declined interview requests from the Journal for more than five months. Last week, the company said she would be available to comment, but her schedule didn't allow it before publication of this article.

User-friendliness

Some doctors appreciate the company's user-friendliness. Results sometimes arrive within 15 minutes, says Scott Wood, a primary-care doctor in Menlo Park, Calif. "That's exciting and could be very useful in emergency situations," he says. When patients ask about trying Theranos, he replies: "Sure, go ahead."

Other doctors said they stopped steering patients to Theranos because of results they didn't trust. "I don't want my patients going there until more information and a better protocol are in place," says Gary Betz, an internist in Phoenix.

Ms. Holmes launched Theranos in 2003 when she was 19 and dropped out of Stanford University in her sophomore year.

Theranos is built around Ms. Holmes's self-professed phobia of needles. She has said in numerous public appearances that drawing a tiny amount of blood at a time from each patient's finger and avoiding the large syringes used by traditional labs will make patients less reluctant to get blood tests. That will lead to earlier diagnoses and save lives, according to Ms. Holmes.

Her first idea was a small arm patch to screen blood for infectious diseases and deliver antibiotics, according to Phyllis Gardner, a Stanford medical-school professor with whom Ms. Holmes consulted at the time. The patch never made it to market.

"She was a young kid with only rudimentary engineering training and no medical training," says Dr. Gardner, whose husband was a member of a Theranos advisory board and still owns shares in the company.

In 2005, Ms. Holmes hired Ian Gibbons, a British biochemist who had researched systems to handle and process tiny quantities of fluids. His collaboration with other Theranos scientists produced 23 patents, according to records filed with the U.S. Patent and Trademark Office. Ms. Holmes is listed as a co-inventor on 19 of the patents.

The patents show how Ms. Holmes's original idea morphed into the company's business model. But progress was slow. Dr. Gibbons "told me nothing was working," says his widow, Rochelle.

In May 2013, Dr. Gibbons committed suicide. Theranos's Ms. King says the scientist "was frequently absent from work in the last years of his life, due to health and other problems." Theranos disputes the claim that its technology was failing.

After Dr. Gibbons's widow spoke to a Journal reporter, a lawyer representing Theranos sent her a letter threatening to sue her if she continued to make "false statements" about Ms. Holmes and disclose confidential information. Ms. Gibbons owns Theranos shares that she inherited from her husband.

Two giant rivals

Theranos began offering tests to the public in late 2013. It opened 42 blood-drawing "wellness centers" in the Phoenix area, two in California and one in Pennsylvania. Most are in Walgreens Boots Alliance Inc. drugstores.

Ms. Holmes successfully lobbied for an Arizona law that allows people to get tests without a doctor's order. Theranos's promise of fast results and prices that are "a fraction" of other labs pits it against Quest Diagnostics Inc. and Laboratory Corp. of America Holdings, which dominate the $75 billion-a-year blood-testing industry in the U.S.

While the biggest venture-capital firms specializing in health care aren't listed as Theranos investors, Oracle Corp. cofounder Larry Ellison and venture-capital firm Draper Fisher Jurvetson, have bought stakes in Theranos, according to data from Dow Jones VentureSource.

Theranos has raised several rounds of financing, most recently in June 2014. Like most closely held companies, Theranos has divulged little about its operations or financial results.

Clinical labs usually buy their testing instruments from diagnostic equipment makers. Before those makers can sell to labs, they must undergo vetting by the Food and Drug Administration.

Because Theranos doesn't sell its Edison machines to other labs, it didn't need the FDA's approval to start selling its tests. Still, the company has sought clearance for more than 120 of its tests in an effort to be rigorous and transparent.

A 'nanotainer' developed by Theranos to help it run tests from just a few drops of blood pricked from a person's finger. The tiny tube is about half an inch long. *PHOTO: MARTIN E. KLIMEK*

In July, Theranos announced the first FDA clearance of one of those tests, which detects herpes. The FDA and Theranos decline to comment on the status of the other submissions.

Whether labs buy their testing instruments or develop them internally, all are required to prove to the federal Centers for Medicare and Medicaid Services that they can produce accurate results. The process is known as proficiency testing and is administered by accredited organizations that send samples to labs several times a year.

Labs must test those samples and report back the results, which aren't disclosed to the public. If a lab's results are close to the average of those in a peer group, the lab receives a passing grade.

In early 2014, Theranos split some of the proficiency-testing samples it got into two pieces, according to internal emails reviewed by the Journal. One was tested with Edison machines and the other with instruments from other companies.

The two types of equipment gave different results when testing for vitamin D, two thyroid hormones and prostate cancer. The gap suggested to some employees that the Edison results were off, according to the internal emails and people familiar with the findings.

Senior lab employees showed both sets of results to Sunny Balwani, Theranos's president and chief operating officer. In an email, one employee said he had read "through the regulations more finely" and asked which results should be reported back to the test administrators and government.

Mr. Balwani replied the next day, copying in Ms. Holmes. "I am extremely irritated and frustrated by folks with no legal background taking legal positions and interpretations on these matters," he wrote. "This must stop."

He added that the "samples should have never run on Edisons to begin with."

Former employees say Mr. Balwani ordered lab personnel to stop using Edison machines on any of the proficiency-testing samples and report only the results from instruments bought from other companies.

The former employees say they did what they were told but were concerned that the instructions violated federal rules, which state that a lab must handle "proficiency testing samples...in the same manner as it tests patient specimens" and by "using the laboratory's routine methods."

THE WALL STREET JOURNAL

In its everyday business at the time, Theranos routinely used Edison machines to test patients' blood samples for vitamin D, the two thyroid hormones and prostate cancer, the former employees say.

In March 2014, a Theranos employee using the alias Colin Ramirez alleged to New York state's public-health lab that the company might have manipulated the proficiency-testing process.

Stephanie Shulman, director of the public-health lab's clinical-lab evaluation program, responded that the practices described by the anonymous employee would be a "violation of the state and federal requirements," according to a copy of her email.

What the employee described sounded like "a form of PT cheating," Ms. Shulman added, using an abbreviation for proficiency testing. She referred the Theranos employee to the public-health lab's investigations unit.

The New York State Department of Health confirms that it got a formal complaint in April 2014 "in regard to testing practices at Theranos" and forwarded it to the Centers for Medicare and Medicaid Services.

Asked about the complaint, Theranos confirms that the Edison system produced results for several tests last year that differed from results obtained from traditional equipment.

Leftover samples

But that comparison was based on "left-over proficiency testing samples" used "to conduct additional experiments and verify best practices," says Ms. King, Theranos's general counsel. The company has never failed proficiency testing, she adds.

She says Mr. Balwani's instructions were consistent with the company's "alternative assessment procedures," which it adopted because it believes its unique technology has no peer group and can be thrown off by the preservatives used in proficiency-testing samples.

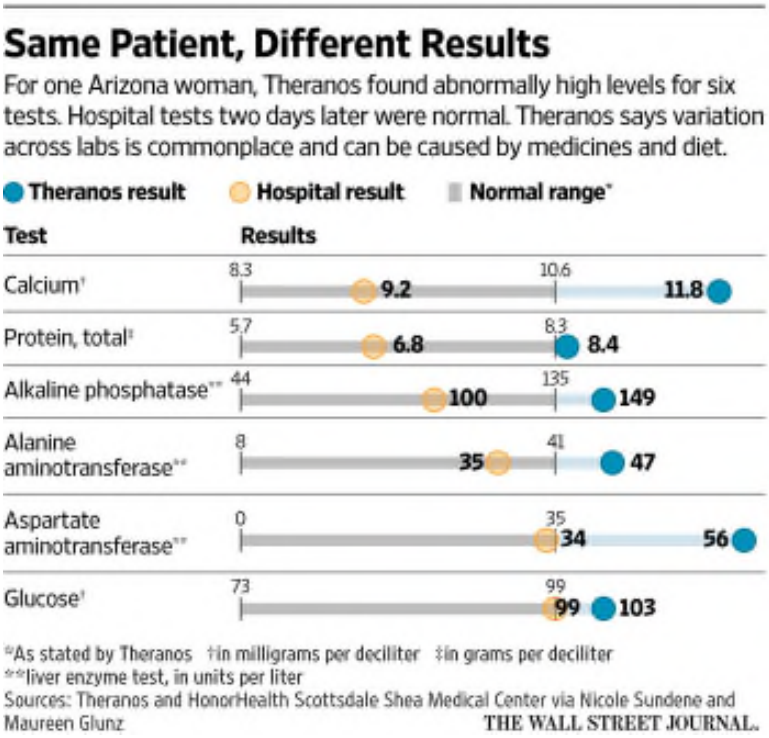
Theranos has been "upfront and transparent with regulators" about the procedures, Ms. King adds.

As of the end of 2014, Theranos did less than 10% of its tests on Edison machines, including tests for prostate cancer and pregnancy, one former senior employee says.

In addition to the 15 tests run on the Edison system, Theranos did about 60 more on traditional machines using a special dilution method, the former senior employee says. The company often collected such a small amount of blood that it had to increase those samples' volume to specifications required by those traditional machines, former employees say.

A third set of about 130 tests was run on traditional machines using larger samples drawn from patients' arms with a needle.

For tests done with dilution, the process caused the concentration of substances in the blood being measured to fall below the machines' approved range, three former employees say. Lab experts say the practice could increase the chance of erroneous results.



Most labs dilute samples only in narrow circumstances, such as when trying to find out by how much a patient has overdosed on a drug, say lab experts.

"Anytime you dilute a sample, you're adulterating the sample and changing it in some fashion, and that introduces more potential for error," says Timothy R. Hamill, vice chairman of the University of California, San Francisco's department of laboratory medicine. Using dilution frequently is "poor laboratory practice."

Theranos says dilution is common in labs but declines to say if it dilutes samples. Theranos's "methods for preparing samples for analysis are trade secrets and cannot be revealed," Ms. King says.

Those methods "have been disclosed" to regulators and don't "adversely impact the quality of its tests or the accuracy of its test results," she adds.

Former employees say diluting blood drawn from fingers contributed to accuracy problems early last year with a test to measure potassium. Lab experts say finger-pricked blood samples can be less pure than those drawn from a vein because finger-pricked blood often mixes with fluids from tissue and cells that can interfere with tests.

Some of the potassium results at Theranos were so high that patients would have to be dead for the results to be correct, according to one former employee.

Ms. King denies any problems with the potassium test and says Theranos has no indication that "inaccurate results were returned to patients."

Theranos challenged interpretations of its test results by health-care providers and patients whose medical records were reviewed by the Journal.

After those people spoke to the Journal, Theranos visited some of them and asked them to sign prepared statements that said the Journal mischaracterized their comments. Two did and one refused.

Carmen Washington, a nurse who worked at a clinic owned by Walgreens in Phoenix, says she began to question Theranos's accuracy after seeing abnormal results in potassium and thyroid tests.

She says she raised her concerns with the drugstore operator and Theranos's lab director, asking for data to show that the company's finger-prick testing procedures produced results as accurate as blood drawn from a vein.

"They were never able to produce them," she says. Ms. King says the company did show detailed testing-accuracy data to the nurse.

Theranos began offering testing to the public in late 2013. It opened 42 blood-drawing sites that it calls 'wellness centers' in the Phoenix area, two in California and one in Pennsylvania. Most are in Walgreens stores, including this one in Scottsdale, Ariz. *PHOTO: MICHAEL CHOW/THE ARIZONA REPUBLIC*

A Walgreens spokesman says the nurse kept writing lab orders for Theranos tests until she stopped working at the clinic in February. Walgreens says its partnership with Theranos has gone smoothly overall.

About a dozen doctors and nurses complained about test results by phone or email to the company from late 2013 to late 2014, a person familiar with the matter says. The Arizona attorney general's office, state health department and Better Business Bureau say they have received no complaints about Theranos.

A second opinion

Dr. Betz, the Phoenix doctor, says one of his female patients went to Theranos in August 2014 for a routine potassium test to monitor potential side effects from her blood-pressure medication. He says Theranos reported that her potassium level was close to the threshold considered critical.

Another lab reran the test three days later. The results came back normal.

Ms. King says Dr. Betz's nurses kept sending patients to Theranos until early this year.

Real-estate agent Maureen Glunz went to Theranos a few days before last Thanksgiving after complaining of ringing in her ear. Her blood was drawn from a vein in her arm. The results showed abnormally elevated levels of glucose, calcium, total protein and three liver enzymes.

Her primary-care doctor, Nicole Sundene, who is a naturopath, worried that Ms. Glunz might be at risk of a stroke and asked her to go to an emergency room. The hospital's tests two days later showed nothing abnormal.

Dr. Hamill of UC San Francisco says some of Ms. Glunz's results should "have fairly steady values...over relatively long time periods."

Ms. King says "some degree of variability in lab results across different laboratories is commonplace," adding that Ms. Glunz's medication and diet could have caused "fluctuations" in her results. None of the results were "close to the critical range," Ms. King adds.

It is misleading to draw conclusions from "a handful of patient anecdotes," she says.

Ms. Glunz says she likes Theranos's low prices and would go there again if she could be sure its tests are accurate. "But trial and error on people, that's not OK," she says.

Write to John Carreyrou at john.carreyrou@wsj.com

EXHIBIT C

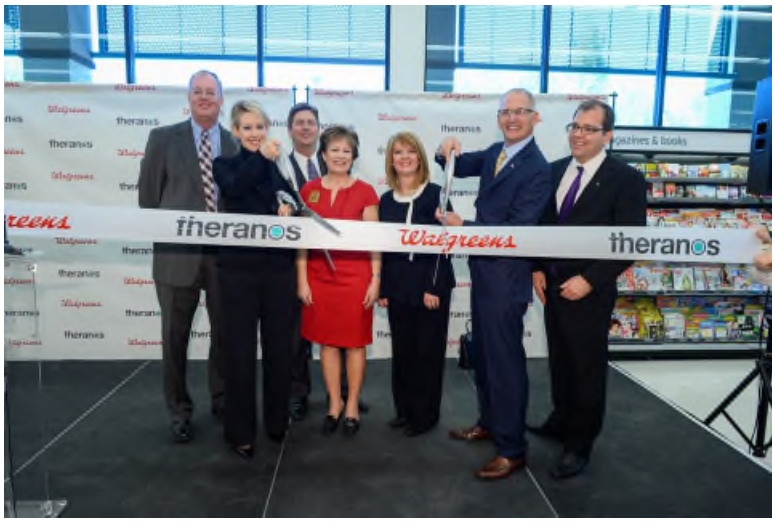
THE WALL STREET JOURNAL.

http://www.wsj.com/articles/craving-growth-walgreens-dismissed-its-doubts-about-theranos-1464207285

TECH

Craving Growth, Walgreens Dismissed Its Doubts About Theranos

Drugstore chain made blood-testing deal without fully validating the startup's technology, worrying that Elizabeth Holmes might balk; 'a very strange situation'



Theranos founder Elizabeth Holmes, left, at a ribbon-cutting ceremony in 2013 for the blood-testing company's partnership with Walgreens. At right are Gregory Wasson, then the drugstore operator's chief executive, and finance chief Wade Miquelon. *PHOTO: WALGREENS*

By CHRISTOPHER WEAVER and JOHN CARREYROU

May 25, 2016 4:14 p.m. ET

Walgreens was considering a partnership with Theranos Inc. when founder Elizabeth Holmes arrived at Johns Hopkins University in the spring of 2011. She brought with her a machine she said could test tiny samples of blood for dozens of conditions and thick binders of data to show its accuracy.

A Hopkins scientist told her that his researchers needed to put the device in their Baltimore laboratory to verify the technology on Walgreens' behalf, and Ms. Holmes agreed to provide one, say people familiar with the meeting.

It never happened. Walgreens wound up making a deal that included plans to put Theranos blood-testing centers in thousands of its drugstores across the U.S. despite never fully validating the startup's technology or thoroughly evaluating its capabilities, according to people familiar with the matter. This article is based on interviews with nearly 20 current or former Walgreens officials and advisers, former Theranos employees and government records.

The relationship is now in tatters, making Walgreens an extreme case study of what can go wrong when an established company that craves growth decides to gamble on an exciting and unproven startup.

Accuracy problems with Theranos's proprietary Edison testing devices, first reported by The Wall Street Journal last October, have become an embarrassment and potential legal liability for Walgreens Boots Alliance Inc., of Deerfield, Ill., which had been Theranos's main conduit to patients and a vital stamp of credibility. Regulators said in January some of Theranos's testing posed "immediate jeopardy" to patients' health.

Walgreens officials considered walking away from the partnership but then hesitated because of worries that Theranos might sue for breach of contract and claim billions of dollars in damages. Walgreens doesn't expect to recoup its investment of at least $50 million in Theranos.

Before announcing the deal in September 2013, some Walgreens executives and outside advisers had doubts about Theranos. Many of the questions were typical of a prospective investor trying to vet new technology created by a promising entrepreneur with a scant record.

When Walgreens pushed for answers, though, it received few that were useful from Theranos, which closely guarded its technology and operations.

Some people involved in the process say the startup's posture went beyond the endemic secrecy of Silicon Valley and believe they were sometimes misled.

Again and again, Walgreens moved forward anyway, partly because executives worried Theranos would choose a different drugstore chain as partner if they pressed Ms. Holmes too hard.

Elizabeth Holmes at the WSJDLive conference in October. Walgreens executives worried she would choose a different drugstore partner if they pushed too hard. *PHOTO: NIKKI RITCHER FOR THE WALL STREET JOURNAL*

In October 2012, Walgreens sent two executives and Paul Rust, a retired executive from clinical-lab company Quest Diagnostics Corp., on a trip that included a review of quality-control data at Theranos.

"It was a very strange situation," he recalls of the one-day visit. "The results were actually really good, but I was never allowed to go into the lab. I have no idea that the results I saw were run on the Edison devices or not."

Mr. Rust says he was "led to believe that they were being run on the Edison."

Later, he asked Walgreens executives if they had been granted access to Theranos's lab. "Much to my surprise, the Walgreens people themselves had not been in the lab," says Mr. Rust.

Former Walgreens officials involved in the negotiations say Theranos told them it could perform many tests using smaller amounts of blood because it had invented a proprietary device. That appealed to Walgreens because the company believed it could use Theranos's device to do many blood tests right in drugstores.

RELATED

- Theranos Voids Two Years of Edison Blood-Test Results (May 18)
- Regulators Propose Banning Theranos Founder Elizabeth Holmes for at Least Two Years (April 13)
- Theranos Devices Often Failed Accuracy Requirements (March 31)
- Walgreens Threatens to End Theranos Agreement (Feb. 10)
- Deficiencies Found at Theranos Lab (Jan. 24)
- At Theranos, Many Strategies and Snags (Dec. 27)
- Hot Startup Theranos Has Struggled With Its Blood-Test Technology (Oct. 16)
- The Startup Stock Tracker
- The Billion Dollar Startup Club

In reality, Theranos used Edison machines for just a fraction of its tests and ran the rest on conventional lab equipment, according to former Theranos employees. The company recently told the federal Centers for Medicare and Medicaid Services that it performed just 12 types of tests on the Edison, a person familiar with the matter says.

By last August, Theranos was doing all its tests on conventional devices, according to notes from a Food and Drug Administration investigator obtained by the Journal in a public-records request.

In response to questions from the Journal, Theranos spokeswoman Brooke Buchanan said: “We value our partnership with Walgreens and look forward to continuing to work together.” Walgreens spokesman Michael Polzin said the company declined to comment for this article.

According to Theranos’s website, it operates 45 wellness centers in Arizona and California, including 40 in Walgreens stores. The website says Theranos is planning to open more locations.

In January, Walgreens closed one location in California and notified Theranos it intends to terminate the partnership unless Theranos quickly puts itself back in compliance with federal regulations.

A federal inspection of Theranos’s lab in Newark, Calif., last fall found that the Edison devices often failed to meet the company’s own accuracy requirements. The company, based in Palo Alto, Calif., also faces criminal and civil investigations into whether it misled investors and regulators about its technology.

On Wednesday, a Theranos patient filed a federal lawsuit in California alleging that the company defrauded him by falsely saying it could accurately test small blood samples. The suit seeks class-action status.

Ms. Buchanan of Theranos said the lawsuit "is without merit. The company will vigorously defend itself against these claims."

Theranos has said it is working closely with regulators and cooperating fully with the criminal and civil investigations.

In a bid to avoid stiff government sanctions, Theranos recently told regulators it has issued tens of thousands of corrected blood-test reports to doctors and patients. As part of the sweeping corrective action, Theranos told regulators it voided all patient tests done on Edison devices in 2014 and 2015.

If federal officials decide to sanction Theranos, senior Walgreens officials believe that would likely give Walgreens a strong defense in any of breach-of-contract litigation.

Top officials at Walgreens weren't aware of Theranos's decision to void the Edison results until the Journal reported the move.

Walgreens was founded in Chicago in 1901 and had about 7,500 drugstores in 2010 when it decided to jazz up its image and find new technology. Walgreens had launched a health-innovations unit to make investments in startups and gain footholds in other areas of health care.

Chief Executive Officer Gregory Wasson, Chief Financial Officer Wade Miquelon and other senior Walgreens officials were enthusiastic about the possibility of a transformational deal in Silicon Valley.

A Theranos wellness center at a Walgreens store in Scottsdale, Ariz., in February 2015. Forty of Theranos's 45 blood-testing locations are at Walgreens. *PHOTO: MICHAEL CHOW/THE REPUBLIC*

After quickly building a fast-growing vaccinations operation, Walgreens saw potential in the medical-lab business, where lab-focused companies generated more than $30 billion in revenue in 2014, according to Census Bureau estimates. Walgreens believed it could upend the industry by combining its store network with Ms. Holmes's technology.

The Theranos partnership took root in 2010 after a chance meeting at a health-technology conference between Ms. Holmes and Jay Rosan, an executive in Walgreens' health-innovations unit, people who worked on the deal say. Serious talks between the companies were under way by early 2011.

As part of a May 2011 deal arranged by Dr. Rosan, a family-medicine doctor and former health-insurance executive who goes by "Dr. Jay," Walgreens agreed to pay Johns Hopkins for its expertise in evaluating prospective investments. Assessing Theranos's blood-testing technology was one of the tasks discussed.

At the meeting with the Hopkins scientist, Ms. Holmes and Theranos President Sunny Balwani agreed to provide one of its proprietary devices to his lab. But when Dr. Rosan checked in with the scientist during a later visit, he was told Theranos hadn't delivered the device, according to a person familiar with the matter.

Dr. Rosan, now a venture-capital investor in the Philadelphia area, declined to comment. Mr. Balwani, whose resignation from Theranos was announced this month, couldn't be reached.

While Theranos didn't provide a device to Hopkins, Walgreens got a prototype, and members of Dr. Rosan's team set it up in a cubicle.

The prototype came with kits to perform esoteric tests that other labs and test makers apparently didn't offer, producing results such as "low" and "high" rather than numeric values.

As a result, Walgreens couldn't compare results from the Theranos machine to any commercially available tests.

Mr. Miquelon, the Walgreens finance chief, visited Theranos's headquarters and met with Ms. Holmes and Mr. Balwani in a conference room, according to a former Theranos employee.

At least twice, including when Mr. Rust visited, Walgreens hired lab-industry veterans to evaluate Theranos's lab capabilities and business operations in Palo Alto. Other consultants reviewed the potential deal from Walgreens headquarters in Illinois.

In the summer of 2011, Walgreens sent Mr. Miquelon, Dr. Rosan and some lower-ranking employees, including an internal auditor, to Theranos headquarters with lab experts from a consulting firm called Colaborate LLC.

Walgreens and Theranos had just signed an initial letter of agreement, and the drugstore chain's executives wanted a firsthand review of Theranos's business operations and lab capabilities.

The visitors were ushered into a conference room and chaperoned throughout the visit. When a member of the Walgreens team left the meetings to use the restroom, the person was escorted by Theranos personnel.

Colaborate wasn't given access to the lab area at Theranos or its Edison technology. Another consultant affiliated with Colaborate reported shortcomings with information-management systems meant to keep track of patients.

Kevin Hunter, Colaborate's president and CEO, says he is barred from discussing his findings because of confidentiality agreements with Walgreens and Theranos.

In a report later in 2011, the consultants concluded Walgreens needed more information to assess the partnership. Those findings and reports by other consultants were kept from many Walgreens officials, including some directly involved in the negotiations with Theranos.

Walgreens Chief Executive Gregory Wasson, shown during a 2012 speech in Chicago, had his finger pricked for a cholesterol test during a visit to Theranos. Walgreens saw big potential in the growing medical-lab business. *PHOTO: BLOOMBERG*

Mr. Wasson, Walgreens' chief executive, toured the Palo Alto facility in 2012 with other Walgreens officials. His finger was pricked for blood to perform a cholesterol test, according to a person familiar with the matter. It isn't clear if his blood was tested with an Edison device. He declined to comment.

Despite their limited access, Walgreens executives decided to keep working on an agreement. Some executives were comforted when Theranos said Safeway Inc. had agreed to host blood-drawing sites at some of its supermarkets. If Safeway trusted Theranos, then Walgreens could, too, the Walgreens officials believed.

The comfort level at Walgreens rose again when CMS gave Theranos a "CLIA certificate." That meant regulators had concluded Theranos met standards to perform tests on human samples.

As the two companies neared a final agreement, Theranos asked for more control. Walgreens agreed to let Theranos run its wellness centers as independent operations. The drugstore chain's access to data from the blood-testing sites was highly limited.

Earlier, Walgreens had studied whether it could integrate its pharmacy record system with Theranos's proprietary lab-management software.

Mr. Miquelon pushed for a deal and was the top official on the Walgreens negotiating team, which also included Dr. Rosan.

The Walgreens team made concessions to Theranos. The contract signed by the companies doesn't give Walgreens the right to view Theranos's clinical data or financial records. Walgreens rarely gave up such access in investment deals it struck with other companies.

Mr. Miquelon didn't respond to requests for comment. He left Walgreens in 2014 and has sued Walgreens for defamation related to his exit. Walgreens has denied any wrongdoing.

At a ribbon-cutting ceremony to celebrate the opening of a Theranos wellness center in the Phoenix area, Mr. Wasson and Ms. Holmes each held large scissors.

In 2014, Ms. Holmes pressed Mr. Wasson to expand the Theranos wellness centers beyond initial sites in Arizona and California. The Walgreens chief executive balked, says a person familiar with the matter.

He knew Safeway had cold feet about Theranos. The Journal reported in November 2015 that Theranos had earlier missed deadlines for the blood-testing rollout at Safeway, citing current and former Safeway executives, and some Safeway executives were wary of the tests' accuracy.

Theranos has declined to comment on its discussions with Safeway.

Worried about Theranos's ability to manage operations, Mr. Wasson told Ms. Holmes that Walgreens wanted to move more slowly and would dictate the scale of the broader rollout.

In early 2014, Walgreens and Theranos were negotiating a new contract, but it wasn't signed. Mr. Wasson left in January 2015 as Walgreens merged with European pharmacy giant Alliance Boots GmbH.

Walgreens shelved the expansion plans after the Journal reported in October that Theranos did the vast majority of tests it offered to consumers on traditional lab machines. The Journal also reported that some former employees doubted the accuracy of a small number of tests run on Edison devices.

One of the most recent setbacks came in mid-April when the Journal reported that regulators had 3½ weeks earlier proposed banning Ms. Holmes from the lab-testing industry. The drugstore chain's senior executives found out from the news report.

—Michael Siconolfi contributed to this article.

EXHIBIT D

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/safeway-theranos-split-after-350-million-deal-fizzles-1447205796

BUSINESS

Safeway, Theranos Split After $350 Million Deal Fizzles

Grocery chain built clinics in more than 800 stores but never began blood tests; code-named 'T-Rex'

A Safeway store in Denver. The supermarket chain spent about $350 million to build clinics where Theranos Inc. would offer blood tests, but the partnership has foundered. *PHOTO: MATTHEW STAVER/BLOOMBERG NEWS*

By JOHN CARREYROU
Nov. 10, 2015 8:36 p.m. ET

Safeway Inc. spent about $350 million to build clinics in more than 800 of its supermarkets to offer blood tests by startup Theranos Inc.

But the tests never began, the clinics are now used largely for flu shots and travel-related vaccines, and the two companies have been negotiating to officially dissolve their partnership, according to people familiar with the matter.

Current and former Safeway executives said Theranos missed deadlines for the blood-testing rollout. They also said several Safeway executives questioned the accuracy of results Theranos gave to Safeway employees tested at a clinic in the supermarket chain's headquarters in Pleasanton, Calif.

Safeway was a big growth opportunity for Theranos, based in Palo Alto, Calif. The project, code-named "T-Rex" at Safeway, hasn't been publicly disclosed by either company but goes back to at least 2011.

Safeway's chief executive, Steven Burd, told investors and analysts in 2012 that the company was "contemplating a significant…wellness play," without identifying Theranos by name. Former Safeway executives said the CEO was referring to Theranos.

The deal was struck before Theranos announced in 2013 a different partnership to offer blood tests to the public through Walgreens drugstores. Safeway signed on as the exclusive supermarket provider of Theranos tests, and Safeway built clinics in roughly half of its stores at the time, one former executive said.

Walgreens Boots Alliance Inc. won't open any new Theranos blood-testing centers beyond the current 41 until Theranos resolves questions about its technology raised by an article in The Wall Street Journal last month, according to a Walgreens official.

That article reported that the proprietary lab instrument developed by Theranos as the anchor of its growth strategy handled just a small fraction of the tests sold to consumers at the end of 2014, according to people familiar with the matter. The article also said some of the startup's former employees were leery about the machine's accuracy.

Theranos has said its laboratory work is accurate and it has performed tests on millions of patients referred by thousands of doctors, with highly positive feedback. Theranos also has said that it is "continuing to work with" Walgreens on "future opportunities and arrangements."

RELATED

- Walgreens Scrutinizes Theranos Testing(Oct.23)
- Theranos Dials Back Lab Tests at FDA's Behest(Oct. 16)
- Hot Startup Theranos Has Struggled With Its Blood-Test Technology(Oct. 16)

In an email Tuesday, Theranos's general counsel, Heather King, said: "We don't comment on discussions with other companies. The questions and information you have presented...are inaccurate and defamatory." She declined to comment on the claims by former Safeway executives.

A Safeway spokesman declined to comment.

The valuation of Theranos, started by Elizabeth Holmes in 2003 when she was 19 and dropped out of Stanford University, jumped to $9 billion last year.

A merger earlier this year made Safeway part of Albertsons Cos., the second-largest grocery company in the U.S. behind Kroger Co. Albertsons has about 2,200 stores and is controlled by private-equity firms that include Cerberus Capital Management LP.

"T-Rex" was rooted in Mr. Burd's enthusiasm for health-care innovation, according to the former Safeway executives. They said he managed the partnership directly with Ms. Holmes. Mr. Burd declined to comment, citing a nondisclosure agreement. He retired in May 2013.

The plan called for Safeway to build upscale clinics that would house Theranos's blood analyzers and provide patients with rapid test results, according to current and former Safeway executives.

The $350 million price tag was equivalent to more than half of Safeway's net income of $596.5 million in 2012. Safeway had revenue of $44.21 billion. Safeway also invested more than $10 million in Theranos, one former Safeway executive said.

In an initial phase of the project, Safeway had Theranos conduct blood testing at the headquarters clinic, current and former Safeway executives said.

Theranos often drew the same employee's blood twice, first with blood from a finger prick and then the traditional method of a needle in the arm, according to one former Safeway executive.

The former executive said he worried that Theranos's finger-prick process was still a work in progress. "If the technology is fully developed, why would you need to do a venipuncture?" this person said, using the term for a traditional blood draw.

The concerns deepened when Theranos's test results for several Safeway employees differed from the results the same employees got from other laboratories, according to the former executive. Another former Safeway executive confirmed those recollections.

It isn't clear how many Safeway employees got blood tests from Theranos or whether the varying results came from finger-prick or venous tests.

One Safeway executive got a frighteningly high result from Theranos on a test to gauge his prostate-specific antigen, according to two former Safeway executives. They said the test suggested that the executive had prostate cancer. Retesting by another lab came back normal.

Two of the former Safeway executives said they told Mr. Burd, Safeway's chief executive, about the varying employee test results.

The former executives said Mr. Burd told them he had been reassured by Ms. Holmes. Mr. Burd continued to support the partnership with Theranos, according to the former Safeway executives.

Theranos also backed away from putting its blood analyzers in Safeway's clinics so patients could get the results quickly, the current and former executives said.

Instead, Theranos said blood samples collected at Safeway would have to be shipped to a central lab for analysis, according to the former executives.

By early 2013, some stores in California had hired phlebotomists, or the technicians who specialize in drawing blood, according to the current and former Safeway executives.

But Theranos kept delaying the rollout of its blood-testing services, those people said.

In April 2013, Mr. Burd was less enthusiastic about the financial possibilities of the Theranos partnership. Asked by an analyst about the "wellness initiative," Mr. Burd said: "It hasn't happened yet."

Mr. Burd retired the next month. After that, Theranos's Ms. Holmes stopped interacting with Safeway executives and delegated the handling of the relationship to Theranos's president and chief operating officer, Sunny Balwani, according to the former Safeway executives.

The project has been largely dormant for more than a year. Safeway's clinics remain open but are used mostly to administer vaccines, the current and former executives said. The clinics feature granite countertops, wood paneling, glass walls and flat-screen video monitors.

Write to John Carreyrou at john.carreyrou@wsj.com

EXHIBIT E

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/hot-startup-theranos-dials-back-lab-tests-at-fdas-behest-1444961864

BUSINESS

Hot Startup Theranos Dials Back Lab Tests at FDA's Behest

Firm has stopped collecting tiny vials of blood drawn from finger pricks for all but one of its tests

By JOHN CARREYROU
Updated Oct. 16, 2015 3:17 p.m. ET

Under pressure from regulators, laboratory firm Theranos Inc. has stopped collecting tiny vials of blood drawn from finger pricks for all but one of its tests, according to a person familiar with the matter, backing away from a method the company has touted as it rose to become one of Silicon Valley's hottest startups.

The move is a setback to the Palo Alto, Calif., company's ambition to revolutionize the blood-testing industry. As a result of the halt, Theranos is operating more like a traditional lab that draws blood with needles from patients' arms. Theranos is valued at $9 billion, or about as much as each of the industry's two largest companies in the U.S.

PREVIOUS COVERAGE

- Hot Startup Theranos Has Struggled With Its Blood-Test Technology

Food and Drug Administration inspectors recently showed up unannounced at Theranos, the person familiar with the matter said. The inspection was triggered by concerns the agency had about data Theranos had voluntarily submitted to the FDA in an effort to win approval for its proprietary testing methods, this person said.

During the inspection, FDA officials indicated to Theranos that the agency considers the "nanotainers" made and used by the company to collect finger-pricked blood an unapproved medical device, the person familiar with the matter said.

Theranos founder Elizabeth Holmes said in an interview on the CNBC show "Mad Money" that the company is "not even using our nanotainers except for FDA-cleared assays."

So far, the agency has approved just one of the more than 100 proprietary tests submitted by Theranos. That test detects herpes and was cleared by the FDA in July. Theranos still is allowed to use a finger prick and the nanotainers for that one test, the person familiar with the matter said.

Since the inspection by FDA officials, Theranos has also been audited by the Centers for Medicare and Medicaid Services, the main regulatory overseer of clinical labs, according to people familiar with the matter. A CMS spokeswoman declined to comment.

To resume broader use of the tiny vials, Theranos must have them vetted and officially approved by the FDA, the person familiar with the situation said.

The company's general counsel, Heather King, didn't immediately respond to questions about the inspections, but said that "Theranos has never been asked to stop using its finger stick technology." On Wednesday, Ms. King had said that "Theranos remains deeply engaged with regulators, including FDA."

A page-one article in The Wall Street Journal on Thursday detailed how the company has struggled to turn the excitement over its technology into reality. At the end of 2014, the proprietary lab instrument Theranos developed as the linchpin of its strategy handled just a small fraction of the tests then sold to consumers, according to four former employees.

Theranos has since nearly stopped using the lab instrument, named Edison after the prolific inventor, according to the person familiar with the situation. By the time of the FDA inspection, the company was doing blood tests almost exclusively on traditional lab instruments purchased from diagnostic-equipment makers such as Siemens AG, the person says.

In Thursday's article, the Journal reported that Theranos was using the Edison for just 15 tests as of the end of 2014, citing one former senior employee. The company disputed that its device did only 15 tests but declined to say how many it handled, citing "trade secrets."

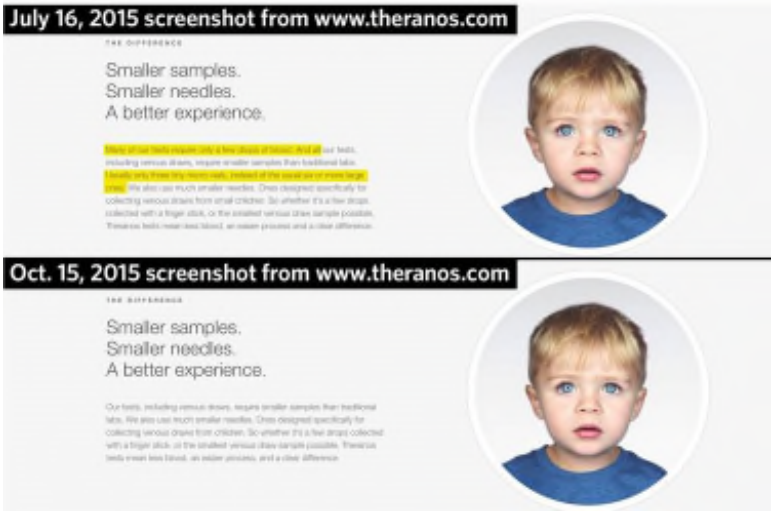
In the "Mad Money" interview, Ms. Holmes didn't quantify the number of tests run on its proprietary lab instrument when asked. She is the company's chairman and chief executive, and her ownership stake in Theranos is valued at more than $4.5 billion. Investors have pumped more than $400 million into Theranos.

Ms. Holmes has been widely hailed for her vision to create new technology that offers consumers more than 240 blood tests, ranging from cholesterol to cancer. Ms. Holmes, 31 years old, has publicly said she built Theranos around her self-professed phobia of needles.

The Journal reported Thursday that Theranos recently changed some of the wording used on its website. For instance, the company deleted a sentence that said: "Many of our tests require only a few drops of blood." Theranos also dropped a reference to collecting "usually only three tiny micro-vials" per sample, "instead of the usual six or more large ones."

Ms. King, Theranos's general counsel, said before the article was published that the wording changes were made for "marketing accuracy."

Those wording changes are consistent with the outcome of the FDA's surprise inspection. The company's outside lawyer, David Boies, said in an email Sunday that the changes "did not result from any recommendation, request or complaint about the website from any regulator."



Theranos deleted the highlighted references on its website. The changes follow an FDA inspection, according to a person familiar with the matter. Theranos said the changes were for 'marketing accuracy' and not requested by the FDA.

Most of Theranos's blood-drawing sites, which it calls "wellness centers," are located inside Walgreens Boots Alliance Inc. drugstores. Forty of the blood-drawing sites are at Walgreens stores in the Phoenix area, and two more are in Walgreens stores in northern California.

James Cohn, a spokesman for Walgreens, referred questions from the Journal about the FDA inspection and any changes in Theranos's blood-drawing methods to Theranos. A blood-drawing technician at a Walgreens in the Phoenix area, reached by phone late Thursday, said Theranos had "temporarily suspended" finger-prick draws and was only drawing blood from patients' arms with needles at that store.

Graphic

During the FDA's inspection, federal officials told Theranos that it will have to resubmit data for many of the proprietary blood tests it has previously sought clearance for from the FDA, according to the person familiar with the matter.

The FDA concluded that data Theranos submitted before the inspection and additional data gathered during the examination were insufficient to prove the accuracy of many of its tests, this person said.

Theranos has previously said it has submitted data for tests using its proprietary technology to the FDA in an effort to be rigorous and transparent.

In a news release, Theranos called the Journal article Thursday "factually and scientifically erroneous and grounded in baseless assertions." Theranos said the Journal had "declined an opportunity" to get a demonstration of the company's proprietary technology.

A Journal spokeswoman said The Wall Street Journal "fully stands by Thursday's article about Theranos, which was richly sourced and thoroughly researched." She added that the newspaper had sought permission to visit Theranos's offices to view the technology since late April.

Write to John Carreyrou at john.carreyrou@wsj.com

EXHIBIT F

two simple ways to get lab tests at theranos.

Bring a lab order from your clinician to any Theranos Wellness Center™ location.

— OR —

Order any test from our menu directly through the Theranos app or at any Theranos Wellness Center™ location. No lab order necessary.

theranos

See inside for a list of locations.

Guests may not seek reimbursement from their health insurer for any tests ordered without a clinician's order unless specified by the health insurer.

where to find us.

Walk-ins welcome. Open evenings and weekends.

theranos wellness center™ locations.

phoenix

1 **Theranos Wellness Center™ at**
ASU Health Services – Community Health Center
500 N. 3rd St., NHI Building 1, Suite 155
Corner of 3rd St & Taylor St
Located inside the building, on the first floor.
Mon-Fri 8a-5p, Sat-Sun closed

tempe

2 **Theranos Wellness Center™ at**
Generations Medical Center
6301 S McClintock, Suite 120
S McClintock & E Guadalupe Rd
Mon-Fri 7a-8p
Sat 8a-12p, Sun closed

theranos wellness center™ locations inside select Walgreens. available at the pharmacy.

apache junction

3 **Walgreens**
55 W Apache Trail
W Apache Trail & Idaho
Mon-Fri 6a-8p, Sat-Sun 8a-5p

avondale

4 **Walgreens**
1451 N Dysart Rd
N Dysart Rd & Van Buren
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

cave creek

5 **Walgreens**
29660 N Tatum Blvd
N Tatum Blvd & Cave Creek
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

chandler

6 **Walgreens**
1975 S Alma School Rd
S Alma School Rd & Germann
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

7 **Walgreens**
1919 N Dobson Rd
N Dobson Rd & Warner
Mon-Fri 6a-8p, Sat-Sun 8a-5p

8 **Walgreens**
1055 E Riggs Rd
E Riggs Rd & McQueen
Mon-Fri 9a-8p
Sat 9a-5p, Sun 10a-5p

fountain hills

9 **Walgreens**
16415 E Palisades Blvd
E Palisades Blvd & Ave of The Fountains
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

gilbert

10 **Walgreens**
785 S Cooper Rd
S Cooper Rd & Warner
Mon-Fri 6a-8p, Sat-Sun 8a-5p

11 **Walgreens**
4766 E Queen Creek Rd
E Queen Creek Rd & Power
Mon-Fri 6a-8p, Sat-Sun 8a-5p

glendale

12 **Walgreens**
21632 N 35th Ave
N 35th Ave & Deer Valley Rd
Mon-Fri 8a-8p, Sat-Sun 9a-5p

13 **Walgreens**
22280 N 67th Ave
N 67th Ave & Hillcrest
Mon-Fri 9a-8p, Sat-Sun 9a-5p

14 **Walgreens**
4965 W Bell Rd
W Bell Rd & 51st Ave
Mon-Fri 6a-8p, Sat-Sun 8a-5p

goodyear

15 **Walgreens**
3361 N Litchfield Rd
N Litchfield Rd & Indian School
Mon-Fri 6a-8p, Sat-Sun 8a-5p

mesa

16 **Walgreens**
1305 S Greenfield Rd
S Greenfield Rd & Southern
Mon-Fri 6a-8p, Sat-Sun 8a-5p

17 **Walgreens**
9230 E Main St
E Main St & Ellsworth
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

18 **Walgreens**
1135 N Mesa Dr
N Mesa Dr & Brown
Mon-Fri 6a-8p, Sat-Sun 8a-5p

19 **Walgreens**
1130 W Southern Ave
W Southern Ave & Alma School
Mon-Fri 9a-8p, Sat-Sun 10a-5p

peoria

20 **Walgreens**
9040 W Peoria Ave
W Peoria Ave & 91st
Mon-Fri 8a-8p, Sat-Sun 9a-5p

21 **Walgreens**
9050 W Union Hills Dr
W Union Hills Dr & 91st
Mon-Fri 6a-8p, Sat-Sun 8a-5p

phoenix

22 **Walgreens**
7606 S 7th St
S 7th & Baseline
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

23 **Walgreens**
7000 N 16th St
N 16th & Glendale
Mon-Fri 6a-8p, Sat-Sun 8a-5p

24 **Walgreens**
204 E Bell Rd
E Bell Rd & 3rd
Mon-Fri 6a-8p, Sat-Sun 8a-5p

25 **Walgreens**
8301 W Camelback Rd
W Camelback Rd & 83rd
Mon-Fri 9a-8p, Sat-Sun 10a-5p

26 **Walgreens**
3402 N Central Ave
N Central Ave & Osborn
Mon-Fri 6a-8p, Sat-Sun 8a-5p

27 **Walgreens**
3960 E Chandler Blvd
E Chandler Blvd & 40th
Mon-Fri 6a-8p, Sat-Sun 8a-5p

28 **Walgreens**
3450 W Dunlap Ave
W Dunlap Ave & 35th
Mon-Fri 6a-8p, Sat-Sun 8a-5p

29 **Walgreens**
4249 W Glendale Ave
W Glendale Ave & 43rd
Mon-Fri 6a-8p, Sat-Sun 8a-5p

30 **Walgreens**
5101 W Indian School Rd
W Indian School Rd & 51st
Mon-Fri 6a-8p, Sat-Sun 8a-5p

31 **Walgreens**
3605 E Thomas Rd
E Thomas Rd & 36th
Mon-Fri 6a-8p, Sat-Sun 8a-5p

32 **Walgreens**
2415 E Union Hills Dr
E Union Hills Dr & Cavecreek
Mon-Fri 6a-8p, Sat-Sun 8a-5p

33 **Walgreens**
3431 W Union Hills Dr
W Union Hills Dr & 35th
Mon-Fri 9a-6p
Sat 10a-5p, Sun closed

queen creek

34 **Walgreens**
333 E Hunt Hwy
E Hunt Hwy & Bella Vista
Mon-Fri 8a-5p
Sat 9a-5p, Sun closed

scottsdale

35 **Walgreens**
6501 E Greenway Pkwy
E Greenway Pkwy & 64th
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

36 **Walgreens**
3420 N Scottsdale Rd
N Scottsdale Rd & Osborn
Mon-Fri 6a-8p, Sat-Sun 8a-5p

37 **Walgreens**
7011 E Shea Blvd
E Shea Blvd & 70th
Mon-Fri 6a-8p, Sat-Sun 8a-5p

38 **Walgreens**
15025 N Thompson Peak Pkwy
N Thompson Peak Pkwy & Frank Lloyd Wright
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

sun city west

39 **Walgreens**
19003 N R H Johnson Blvd
N R. H. Johnson & Camino del Sol
Mon-Fri 7a-8p, Sat-Sun 9a-5p

surprise

40 **Walgreens**
15490 W Bell Rd
W Bell Rd & Reems
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

tempe

41 **Walgreens**
2000 S Mill Ave
S Mill Ave & Broadway
Mon-Fri 8a-8p
Sat 9a-5p, Sun 10a-5p

42 **Walgreens**
1745 E Southern Ave
E Southern Ave & McClintock
Mon-Fri 6a-8p, Sat-Sun 8a-5p

For all locations visit **theranos.com** or download the Theranos app.

theranos

See reverse for map of locations.

EXHIBIT G

theranos

direct testing menu

theranos

DESCRIPTION	ID	PRICE
A		
Adenovirus DNA, Quantitative	ADN1	$29.15
Alanine Aminotransferase (ALT/SGPT)	ALT1	$3.61
Albumin	ALB1	$3.37
Alkaline Phosphatase (ALP)	ALP1	$3.52
Alpha-1-Acid Glycoprotein	AAG1	$10.26
Alpha-1-Antitrypsin, Total	AAT1	$9.15
Alpha-Fetoprotein (AFP), Maternal	AFP1	$11.42
Alpha-Fetoprotein (AFP), Oncology	AFP2	$11.42
Amphetamines, Urine	AMP1	$9.90
Amylase	AMY1	$4.41
Androstenedione	AND1	$19.92
Anti-Mullerian Hormone (AMH)	AMH1	$8.81
Antibody Detection, RBC	ABD1	$25.75
Antinuclear Antibodies, Screen (ANA) with reflex to confirmation*	ANA1	$8.23
↳ Reflex to ANA confirmation		$7.60
Apolipoprotein (apo A1, apo B)	APO3	$21.10
Apolipoprotein A-1 (apo A-1)	APO1	$10.55
Apolipoprotein B (apo B)	APO2	$10.55
Aspartate Aminotransferase (AST/SGOT)	AST1	$3.52
B		
B cells, Total Count	BCC1	$25.67
Barbiturates, Urine	BAR2u	$9.90
Basic Metabolic Panel (BMP) FASTING	BMP1	$5.76
Benzodiazepines, Urine	BNZ2u	$9.90
Beta-2 Microglobulin	B2M1	$11.01
Bilirubin, Direct	BIL2	$3.42
Bilirubin, Total	BIL1	$3.42
Blood Type (ABO/RhD)	BLT1	$4.06
Blood Urea Nitrogen (BUN)	BUN1	$2.69
Borrelia Antibody (Lyme Disease)	LYM1	$9.11
Brain natriuretic peptide (BNP)	BNP1	$23.10
C		
Calcitonin	CLT1	$18.23
Calcium	CAL1	$3.51
Calcium, Urine	CAL2u	$4.11
Cancer Antigen 125 (CA 125)	CA125	$14.16
Cancer Antigen 15-3 (CA 15-3)	CA153	$14.16
Cancer Antigen 27.29 (CA 27.29)	CA27	$14.16
Cancer Antigen-GI (CA 19-9)	CA199	$14.16
Carbon Dioxide	CO21	$3.33
Carcinoembryonic Antigen (CEA)	CEA1	$12.91
Cardiolipin Antibody (ACA), IgG	ACA1	$17.31
CBC (Complete Blood Count), Auto Diff	CBC1	$5.29
CBC (Complete Blood Count), no Diff	CBC3	$4.41
CD4 Count, Absolute	CDC1	$18.22
CD4 Count, Absolute with percent	CDC2	$18.22
CD4/CD8 Count, Absolute with Ratio	CDC3	$31.97
CD4/CD8 Count, Absolute with Ratio and Percent	CDC4	$57.64
Celiac Panel	CEL1p	$31.40

DESCRIPTION	ID	PRICE
Chlamydia Trachomatis, DNA, Qualitative	CT1u	$12.06
Chlamydia/Gonorrhea Panel, DNA, Qualitative	CG1u	$24.12
Chlamydia/Gonorrhea/HIV screen with reflex to confirmation*	CG2u	$40.51
↳ Reflex to HIV-1/HIV-2 Ab Differentiation		$15.25
↳ Reflex to HIV-1 RNA Quantitative confirmation		$57.90
Chloride	CL1	$3.13
Chloride, Urine	CL2u	$3.43
Cholesterol	CHO1	$2.96
Cholinesterase	CHL1	$5.23
Cocaine, Urine	COC1	$9.90
Complement Component 3 antigen	COM3	$8.17
Complement Component 4 antigen	COM4	$8.17
Comprehensive Metabolic Panel (CMP) FASTING	CMP1	$7.19
Cortisol, Total	CRT1u	$11.10
C-Peptide	CPP1	$14.16
C-Reactive Protein (CRP)	CRP1	$3.52
C-Reactive Protein, High Sensitivity (hsCRP)	CRP2	$8.81
Creatine Kinase	CK1	$4.43
Creatinine	CRE1	$3.49
Creatinine, Urine	CRE2u	$3.52
Cyclic Citrullinated Peptide (CCP) Antibody, IgG	CCP1	$8.81
Cyclosporine A	CYC1	$12.29
Cystatin C	CYS1	$9.25
Cytomegalovirus (CMV) Antibody, IgG	CMV1	$9.79
Cytomegalovirus (CMV) Antibody, IgM	CMV2	$11.47
D		
D-Dimer, Quantitative	DDM1	$6.93
Deamidated Gliadin Peptide (DGP) Antibody, IgA	DGP1	$7.85
Deamidated Gliadin Peptide (DGP) Antibody, IgG	DGP2	$7.85
Dehydroepiandrosterone Sulfate (DHEA-S)	DHE1	$15.13
Deoxypyridinoline (DPD) (Collagen crosslinks), Urine	DPD1u	$12.72
Double-Stranded DNA Antibody (dsDNA), IgG	DNA1	$9.35
Drug Screen Panel	DS1p	$42.00
E		
EBV (Epstein-Barr) Antibody Panel	EBV1p	$35.11
EBV Early D Antigen (EA-D) IgG	EBV4	$8.93
EBV Nuclear Antibody, IgG	EBV1	$10.41
EBV Viral Capsid Antigen (VCA) - IgG	EBV2	$12.35
EBV Viral Capsid Antigen (VCA) - IgM	EBV3	$12.35
Ecstasy (MDMA), Urine	MDM1	$9.90
Electrolytes Panel	EP1p	$4.78
Endomysial Antibody (EMA), IgA	EMA1	$8.20
Endomysial Antibody (EMA), IgG	EMA2	$8.20
Erythrocyte Sedimentation Rate (ESR/Sed Rate)	ESR1	$1.84
Estradiol	EST2	$19.01
Estriol, unconjugated	EST3	$16.46
Estrone	EST1	$16.98
Ethanol	ETH1	$7.35
Extractable Nuclear Antigen Antibodies (ENA Panel)	NAA1p	$73.26

DESCRIPTION	ID	PRICE
F		
Ferritin	FER1	$9.27
Fibrinogen	FIB1	$5.78
Folate (Folic acid)	FOL1	$10.01
Follicle Stimulating Hormone (FSH)	FSH1	$12.65
G		
Gamma-Glutamyltransferase (GGT)	GGT1	$4.90
Gastrin	GAS1	$12.00
Glucose FASTING	GLU1	$2.67
Glucose Tolerance Test (GTT), Gestational Screen, 1hr, 50g	GTT1	$3.23
Glucose Tolerance Test (GTT), 2hr, 75g FASTING	GTT2	$8.76
Glucose Tolerance Test (GTT), 3hr, 100g FASTING	GTT3	$11.43
N. Gonorrhea, DNA, Qualitative	GC1	$12.06
Growth Hormone (HGH)	HGH1	$11.35
H		
Haptoglobin	HAP1	$8.56
hCG - Chorionic Gonadotropin (Maternal), Blood Quantitative	HCG2	$10.25
hCG - Chorionic Gonadotropin, Pregnancy Test, Urine Qualitative	HCG1u	$4.31
Helicobacter Pylori (H. Pylori), IgG	HPY1	$9.87
Hematocrit (HCT)	HCT1	$1.62
Hemoglobin (HGB)	HGB1	$1.62
Hemoglobin A1c (HbA1c)	HBA1	$6.61
Hemogram 2	HEM2	$3.24
Hepatic Function Panel	HF1p	$5.56
Hepatitis A Antibody, IgM	HAV1	$7.66
Hepatitis A Antibody, Total	HAV2	$8.43
Hepatitis B Core Antibody, IgM	HBC1	$8.02
Hepatitis B Core Antibody, Total	HBC2	$8.20
Hepatitis B Surface Antibody (HBsAb), Total	HBS1	$7.31
Hepatitis B Surface Antigen (HBsAg) with reflex to confirmation*	HBS3	$7.03
↳ Reflex to HBsAg confirmation		$7.03
Hepatitis B, DNA, Quantitative	HBD1	$29.15
Hepatitis C Antibody Screen	HCV1	$9.71
Hepatitis C Antibody Screen with reflex*	HCV2	$9.71
↳ Reflex to HCV RNA Quantitative		$29.15
Hepatitis C Antibody Screen with reflex*	HCV3	$9.71
↳ Reflex to HCV RNA Quantitative		$29.15
↳ Reflex to HCV Genotype		$117.96
Hepatitis C Virus Genotype	HCV6	$117.96
Hepatitis C Virus RNA with reflex*	HCV4	$29.15
↳ Reflex to HCV Genotype		$117.96
Hepatitis C, RNA, Quantitative	HCV5	$29.15
Hepatitis Panel, Acute with reflex to confirmation*	HEP1p	$31.58
↳ Reflex to HBsAg confirmation		$7.03
Hepatitis Panel, Acute with reflex to confirmation and Hepatitis C RNA Quantitative*	HEP2p	$31.58
↳ Reflex to HBsAg confirmation		$7.03
↳ Reflex to HCV RNA Quantitative		$29.15

DESCRIPTION	ID	PRICE
Herpes Simplex 1 (HSV1), IgG	HSV1	$8.98
Herpes Simplex 2 (HSV2), IgG	HSV2	$13.17
High-density Lipoprotein (HDL)	HDL1	$5.57
HIV screen - HIV-1/2 Ag/Ab Combo with reflex to confirmation*	HIV1	$16.39
↳ Reflex to HIV-1/HIV-2 Ab Differentiation		$15.25
↳ Reflex to HIV-1 RNA Quantitative confirmation		$57.90
HIV-1/HIV-2 Antigen/Antibody Combo with reflex to confirmation and HIV-1 viral load*	HIV3	$16.39
↳ Reflex to HIV-1/HIV-2 Ab Differentiation		$15.25
↳ Reflex to HIV-1, RNA, Quantitative viral load		$57.90
HIV-1, RNA, Quantitative	HVR1	$57.90
Homocysteine	HC1	$11.48
I		
IgA, IgG, IgM	IMM1	$18.99
IgA	IGA1	$6.33
IgE	IGE1	$11.21
IgG	IGG1	$6.33
IgM	IGM1	$6.33
Insulin	INS1	$7.78
Insulin-like Growth Factor 1 (IGF-1)	IGF1	$14.47
Iron	IRN1	$4.41
Iron and Total Iron Binding Capacity (TIBC)	TBC1	$10.36
L		
Lactate Dehydrogenase	LDH1	$4.11
Lead	LED1	$8.24
Lipase	LIP1	$4.69
Lipid Panel FASTING	LP1p	$9.11
Lithium	LIT1	$4.50
Low-density Lipoprotein (LDL)	LDL1	$6.50
Luteinizing Hormone (LH)	LUT1	$12.60
Lymphocyte Subset Panel 1 - Lymphocyte Enumeration	LPC1p	$108.98
M		
Magnesium	MGN1	$4.56
Marijuana (THC), Urine	THC1	$9.90
Measles (Rubeola) Antibody, IgG	MEA1	$8.77
Measles, Mumps, and Rubella (MMR) Immunity	MMR1p	$27.85
Methadone (Dolophine), Urine	MET1	$9.90
Microalbumin, Urine	MAL1u	$3.94
Microalbumin/Creatinine Urine Random	MCR1u	$7.46
Mumps Antibody, IgG	MUM1	$8.88
Myoglobin	MYG1	$8.79
N		
Natural Killer Cells, Total Count	NKC1	$25.67
Nuclear Antigen Antibody, Jo-1	NAA1	$12.21
Nuclear Antigen Antibody, RNP	NAA2	$12.21
Nuclear Antigen Antibody, Scl-70	NAA3	$12.21
Nuclear Antigen Antibody, Sm	NAA4	$12.21

DESCRIPTION	ID	PRICE
Nuclear Antigen Antibody, SSA	NAA5	$12.21
Nuclear Antigen Antibody, SSB	NAA6	$12.21
O		
Obstetric Panel with reflex to confirmation*	OB1p	$30.07
↳ Reflex to HBsAg confirmation		$7.03
↳ Reflex to Rapid Plasma Reagin (RPR) confirmation		$2.91
↳ Reflex to TP-PA confirmation		$9.01
Obstetric Panel with HIV screen with reflex to confirmation*	OB2p	$46.46
↳ Reflex to HBsAg confirmation		$7.03
↳ Reflex to HIV-1/2 Ab Differentiation		$15.25
↳ Reflex to HIV-1 RNA Quantitative confirmation		$57.90
↳ Reflex to Rapid Plasma Reagin (RPR) confirmation		$2.91
↳ Reflex to TP-PA confirmation		$9.01
Occult Blood Diagnostic, Fecal (FOBT), 1 card	FOB1	$2.22
Occult Blood Screen, Fecal (FOBT), 3 cards	FOB2	$2.22
Opiates, Urine	OPI1	$9.90
Ova & Parasites	OVP1	$6.06
Oxycodone, Urine	OXY1	$9.90
P		
Parathyroid Hormone (PTH)	PTH1	$28.09
Partial Thromboplastin Time (PTT)	PTT1	$4.09
Phencyclidine (PCP), Urine	PCP1	$9.90
Phosphorus, Inorganic	PHS1	$3.23
Platelets, Automated	PLT1	$3.05
Potassium	POT1	$3.13
Potassium, Urine	POT2u	$2.93
Prealbumin	PAL1	$9.92
Progesterone	PRG1	$14.20
Prolactin	PRL1	$13.19
Propoxyphene, Urine	PRX1	$9.90
Prostate Specific Antigen (PSA), Free	PSA2	$12.52
Prostate Specific Antigen (PSA), Total	PSA1	$12.52
Protein, Total	PRT1	$2.50
Protein, Urine	PRT2u	$2.50
Prothrombin Time (PT/INR)	PTR1	$2.68
R		
RBC, Automated	RBC1	$2.06
Renal Function Panel	RF1p	$5.91
Reticulocyte Count, Automated	RET1	$2.72
Rheumatoid Factor, Total	RHF1	$3.86
Rubella Antibody, IgG	RUB1	$10.20
Rubella Antibody, IgM	RUB2	$9.79
Rubeola (Measles) Antibody, IgG	MEA1	$8.77
S		
Sex Hormone-binding Globulin (SHBG)	SHB1	$14.79
Sodium	SOD1	$3.28
Sodium, Urine	SOD2u	$3.31
Streptolysin O Antibody, Titer (ASO)	ASO1	$4.97
Syphilis Screen (Treponema Pallidum Antibody) with reflex to confirmation*	SYP1	$9.01
↳ Reflex to Rapid Plasma Reagin (RPR) confirmation		$2.91
↳ Reflex to TP-PA confirmation		$9.01
T		
T cells, Total Count	TCC1	$25.67
T3, Free - Triiodothyronine, Free	FT3	$11.53
T3, Reverse - Triiodothyronine, Reverse	T3R1	$10.73
T3, Total - Triiodothyronine, Total	TT3	$9.65
T4, Free - Thyroxine, Free	FT4	$6.14
T4, Total - Thyroxine, Total	TT4	$4.68
Testosterone, Free	TES1	$17.33
Testosterone, Total	TES2	$17.57
Thyroglobulin	TGB1	$10.93
Thyroglobulin Antibodies (TAA)	TAA1	$10.83
Thyroid Peroxidase Antibody (TPO)	TPO1	$9.90
Thyroid Stimulating Hormone (TSH)	TSH1	$11.44
Thyroid Stimulating Hormone (TSH) with reflex*	TSH2	$11.44
↳ Reflex to T4 Free		$6.14
Thyroid Uptake	THU1	$4.41
Thyroxine Binding Globulin (TBG)	TBG1	$10.06
Tissue Transglutaminase (tTG) Antibody, IgA	TTG1	$7.85
Tissue Transglutaminase (tTG) Antibody, IgG	TTG2	$7.85
Toxoplasma IgG	TOX1	$9.79
Toxoplasma IgM	TOX2	$9.80
Transferrin	TFR1	$8.69
Triglycerides FASTING	TRG1	$3.91
Troponin I (tCNI)	TRO1	$6.70
Tuberculosis QuantiFERON TB Gold In-Tube Test	TBQ1	$42.18
U		
Uric Acid	URI1	$3.08
Urinalysis, Complete	UAC1u	$2.16
Urinalysis, Complete with reflex*	UAC2u	$2.16
↳ Reflex to culture & susceptibility		$5.50
Urine culture	URC1u	$5.50
*Additional charges may apply if urine culture tests positive.		
V		
Varicella-Zoster Antibody	VZV1	$8.77
Vitamin B-12	VTB1	$10.26
Vitamin D 25-OH	VTD1	$20.15
W		
WBC Count, Automated Differential	WBC2	$4.41
WBC, Automated	WBC1	$1.73

FASTING = Fasting recommended.
*Ordered reflex tests only performed when medically appropriate.
Additional charges apply if reflex is performed. Test menu and prices valid as of March 2016.
Visit theranos.com or log in to the Theranos app for current information.

panels with components

All tests available on an individual basis.

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DESCRIPTION	ID	PRICE
Basic Metabolic Panel (BMP) FASTING	BMP1	$5.76
Blood Urea Nitrogen (BUN) • Calcium • Carbon dioxide • Chloride • Creatinine • Glucose • Potassium • Sodium		
Celiac Panel	CEL1p	$31.40
Deamidated Gliadin Peptide (DGP) Antibody, IgA • Deamidated Gliadin Peptide (DGP) Antibody, IgG • Tissue Transglutaminase (tTG) Antibody, IgA • Tissue Transglutaminase (tTG) Antibody, IgG		
Chlamydia/Gonorrhea Panel, DNA, Qualitative	CG1u	$24.12
Chlamydia Trachomatis, DNA, Qualitative • N.Gonorrhea, DNA, Qualitative		
Chlamydia/Gonorrhea/HIV with reflex to confirmation*	CG2u	$40.51
↳ Reflex to HIV-1/2 Ab Differentiation		$15.25
↳ Reflex to HIV-1 RNA Quantitative confirmation		$57.90
Chlamydia Trachomatis, DNA, Qualitative • N. Gonorrhea, DNA, Qualitative • HIV screen - HIV-1/HIV-2 Antigen/Antibody Combo		
Complete Blood Count (CBC), no Diff	CBC3	$4.41
Complete Blood Count (CBC), Auto Diff WBC	CBC1	$5.29
Hematocrit • Hemoglobin • Platelets Automated • RBC Automated • WBC Automated		
Comprehensive Metabolic Panel (CMP) FASTING	CMP1	$7.19
Albumin • Alanine Aminotransferase (ALT) • Alkaline Phosphatase (ALP) • Aspartate Aminotransferase (AST) • Bilirubin Total • Blood Urea Nitrogen (BUN) • Calcium Total • Carbon dioxide • Chloride • Creatinine • Glucose • Sodium • Potassium • Protein, Total		
Drug Screen Panel	DS1p	$42.00
*Please note that our Drug Screen Panel is not for legal, forensic, or employment drug testing. Amphetamines • Barbiturates • Benzodiazepines • Cocaine • Marijuana (THC/Cannabinoids) • MDMA (Ecstasy) • Methadone (dolophine) • Opiates • Oxycodone • Phencyclidine (PCP) • Propoxyphene		
Electrolytes Panel	EP1p	$4.78
Carbon dioxide • Chloride • Potassium • Sodium		
Epstein-Barr (EBV) Antibody Panel	EBV1p	$35.11
EBV Nuclear Antibody, IgG • EBV Viral Capsid Antigen (VCA) - IgG • EBV Viral Capsid Antigen (VCA) - IgM		
Extractable Nuclear Antigen Antibodies (ENA Panel)	NAA1p	$73.26
Nuclear Antigen Antibody, Jo-1 • Nuclear Antigen Antibody, RNP • Nuclear Antigen Antibody, Scl-70 • Nuclear Antigen Antibody, Sm • Nuclear Antigen Antibody, SSA • Nuclear Antigen Antibody, SSB		

DESCRIPTION	ID	PRICE
Hemogram 2	HEM2	$3.24
Hematocrit (HCT) • Hemoglobin (HGB)		
Hepatic (Liver) Function Panel	HF1p	$5.56
Albumin • Alanine Aminotransferase (ALT) • Alkaline Phosphatase (ALP) • Aspartate Aminotransferase (AST) • Bilirubin Direct • Bilirubin Total • Protein Total		
Hepatitis Panel, Acute with reflex to HBsAg confirmation*	HEP1p	$31.58
↳ Reflex to HBsAg confirmation		$7.03
Hepatitis Panel, Acute with reflex to HBsAg confirmation* and HCV RNA Quantitative*	HEP2p	$31.58
↳ Reflex to HBsAg confirmation		$7.03
↳ Reflex to HCV RNA Quantitative		$29.15
Hepatitis A Antibody, IgM • Hepatitis B Core Antibody, IgM (HBcAb) • Hepatitis B surface antigen (HBsAg) • Hepatitis C Antibody Screen		
Lipid Panel FASTING	LP1p	$9.11
Cholesterol • High-density Lipoprotein (HDL) • Low-density Lipoprotein (LDL) • Triglycerides		
Lymphocyte Subset Panel 1–Lymphocyte Enumeration	LPC1p	$108.98
B cells, Total Count • CD4/CD8 Count, Absolute with Ratio and Percent • Natural Killer cells, Total Count • T cells, Total Count		
Measles, Mumps, and Rubella (MMR) Immunity	MMR1p	$27.85
Measles (Rubeola) Antibody IgG • Mumps Antibody IgG • Rubella Antibody IgG		
Obstetric Panel with reflex to confirmation*	OB1p	$30.07
↳ Reflex to HBsAg confirmation		$7.03
↳ Reflex to Rapid Plasma Reagin (RPR) confirmation		$2.91
↳ Reflex to TP-PA confirmation		$9.01
Obstetric Panel with HIV screen with reflex to confirmation*	OB2p	$46.46
↳ Reflex to HBsAg confirmation		$7.03
↳ Reflex to HIV-1/2 Ab Differentiation		$15.25
↳ Reflex to HIV-1 RNA Quantitative Confirmation		$57.90
↳ Reflex to Rapid Plasma Reagin (RPR) confirmation		$2.91
↳ Reflex to TP-PA confirmation		$9.01
ABO/RhD Blood Typing • Antibody Detection, RBC • CBC with Auto Diff • Hepatitis B surface antigen (HBsAg) • Rubella IgG • Syphilis Screen (Treponema Pallidum Antibody)		
Renal (Kidney) Function Panel FASTING	RF1p	$5.91
Albumin • Blood Urea Nitrogen (BUN) • Calcium Total • Carbon Dioxide • Chloride • Creatinine • Glucose • Phosphorus Inorganic • Potassium • Sodium		

FASTING = Fasting recommended.

*Ordered reflex tests only performed when medically necessary. Test menu and prices valid as of March 2016. Visit theranos.com or log in to the Theranos app for current information.

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BasicHealth™ menu All tests available on an individual basis.

	ID	PRICE
BasicHealth™ starter FASTING Blood Count (CBC with diff) • Comprehensive Metabolic Panel (CMP) • HbA1c • Lipid Panel FASTING	BS1p	$28.19
BasicHealth™ for women FASTING Blood Count (CBC with diff) • Comprehensive Metabolic Panel (CMP) • HbA1c • Lipid Panel FASTING • Thyroid Stimulating Hormone (TSH) • Urinalysis Complete	BW1p	$41.78
BasicHealth™ for men FASTING Blood Count (CBC with diff) • Comprehensive Metabolic Panel (CMP) • HbA1c • Lipid Panel FASTING • PSA Total • Thyroid Stimulating Hormone (TSH) • Urinalysis Complete	BM1p	$54.30

core health menu All tests available on an individual basis.

Anemia Assessment Blood Count (CBC with diff) • Ferritin • Iron • Iron Binding Capacity (TIBC) • Reticulocyte Count Automated	BH1p	$27.64
Diabetes Assessment FASTING Glucose FASTING • HbA1c • Lipid Panel FASTING	DB1p	$18.39
STD Assessment Chlamydia, DNA, Qualitative • N. Gonorrhea, DNA, Qualitative • Hepatitis B Surface Antigen (HBsAg) with reflex to HBsAg confirmation* (+$7.03) • Herpes Simplex 2 (HSV2), IgG • HIV screen with reflex to confirmation* - HIV-1/HIV-2 Antigen/Antibody Combo with reflex to HIV-1/2 Ab Differentiation* (+$15.25) with reflex to HIV-1 RNA Quantitative confirmation* (+$57.90) • Syphilis screen with reflex to confirmation* - TP Ab with reflex to RPR Ab Confirmation* (+$2.91) with reflex to TP-PA confirmation* (+$9.01)	STI2p	$69.72
Thyroid Assessment T3 Free • T4 Free • T4 Total • Thyroid Stimulating Hormone (TSH)	TY1p	$33.77

Test results are not a guarantee of your health status or a substitute for conversations with a physician. Please do not make the decision to start or stop medication or forego medical tests or treatments until you have reviewed your test results with a physician. Your physician may recommend additional testing to confirm your results.

Tests are available without a physician's order in Arizona only. Guests may not seek reimbursement from their health insurer for any tests ordered without a physician's order.

Lab services provided by Theranos, Inc., a CLIA-certified laboratory. Theranos is an independently owned and operated company, and is not an affiliate of Walgreen Co.

FASTING = Fasting recommended.

*Ordered reflex tests only performed when medically appropriate. Additional charges apply if reflex is performed. Test menu and prices valid as of March 2016.

Visit theranos.com or log in to the Theranos app for current information.

EXHIBIT H

theranos direct testing order form

Select any of the tests below or from over 200 tests on the Theranos Test Menu. A complete list of tests, descriptions, and prices can be found at **theranos.com** or on the Theranos app.

BasicHealth™ menu routine tests to help you track your overall health. All tests available on an individual basis.

- ◯ **BasicHealth™ starter** FASTING — $28.19 CBC with diff • CMP • HbA1c • Lipid Panel
- ◯ **BasicHealth™ for women** FASTING — $41.78 CBC with diff • CMP • HbA1c • Lipid Panel • TSH • Urinalysis Complete
- ◯ **BasicHealth™ for men** FASTING — $54.30 CBC with diff • CMP • HbA1c • Lipid Panel • TSH • Urinalysis Complete • PSA Total

core health menu

- ◯ **Anemia Assessment** $27.64 CBC with diff • Ferritin • Iron • Iron Binding Capacity (TIBC) • Reticulocyte Count Automated
- ◯ **Diabetes Assessment** FASTING $18.39 Glucose • HbA1c • Lipid Panel.
- ◯ **STD Assessment** $69.72 Chlamydia DNA Qualitative • N. Gonorrhea DNA Qualitative • Hepatitis B (HBsAg) with confirmation* • Herpes Simplex 2 • HIV screen with confirmation* • Syphilis Screen with confirmation*
- ◯ **Thyroid Assessment** $33.77 T3 Free • T4 Free • T4 Total • TSH

common tests

- ◯ **Blood Count** (CBC with diff) _____ $5.29
- ◯ **Blood Type** (ABO/RhD) _____ $4.06
- ◯ **Comprehensive Metabolic Panel** (CMP) FASTING ____ $7.19
- ◯ **Cortisol, Total** _____ $11.10
- ◯ **Estradiol** _____ $19.01
- ◯ **Glucose** FASTING _____ $2.67
- ◯ **HbA1c** _____ $6.61
- ◯ **Hepatitis C** _____ $9.71
- ◯ **hsCRP** _____ $8.81
- ◯ **Lipid Panel** FASTING _____ $9.11
- ◯ **PSA Total** _____ $12.52
- ◯ **Thyroid Stimulating Hormone** (TSH) _____ $11.44
- ◯ **Urinalysis, complete** _____ $2.16
- ◯ **Testosterone, Total** _____ $17.57
- ◯ **Vitamin B-12** _____ $10.26
- ◯ **Vitamin D 25-OH** _____ $20.15

other selections from the theranos test menu provide the name or Theranos test ID for tests you wish to order.

◯ _____ ◯ _____ ◯ _____ ◯ _____

◯ _____ ◯ _____ ◯ _____ ◯ _____

your information

last name	first name	m.i.	DOB mm/dd/yy	phone	sex

address	city	state	zip	email

By signing this form, I authorize Theranos to collect sample(s) for the purpose of clinical laboratory tests.
I understand the risk(s) of the sample collection process are minimal, but may include discomfort, bleeding, bruising, or fainting.

own your health

It is the responsibility of the person who was tested to arrange with the person's health care provider for consultation and interpretation of the test results.

Test results are not a guarantee of your health status or a substitute for conversations with a physician. Please do not make the decision to start or stop medication or forego medical tests or treatments until you have reviewed your test results with a physician. Your physician may recommend additional testing to confirm your results.

_____ _____ _____

printed name of guest/guardian **signature** **date**

FASTING It is recommended that you have no food or liquids, other than water, for at least 8 hours prior to your test.

*Additional charges apply if confirmation is medically appropriate. See Theranos test menu for more information.

For use only by guests in Arizona who are ordering tests without a physician's order. Guests may not seek reimbursement from a health insurer for tests ordered using this form.
Lab services provided by Theranos, Inc., a CLIA-certified laboratory. Theranos is an independently owned and operated company, and is not an affiliate of Walgreen Co.

sample collection date/time

DA_1.5

EXHIBIT I

a guide to direct testing

For the first time ever in Arizona, you can now get any lab test without a lab order at Theranos.

theranos

At Theranos, we're pioneering a new era of preventive care. Where you can take a proactive role in your health and engage with your physician early. And thanks to direct testing, that's now easier than ever.

Direct testing means you are in control. And can now order lab tests without a lab order. No permission slips necessary, no insurance eligibility needed. Just walk into a Theranos Wellness Center™ location, get any test on our menu, and own your health like never before.

What does this mean for physicians?

With direct testing it's easier for people, especially those without health insurance or with high deductibles, to get vital information about their health when it matters most, before they are already sick. So people can become better informed earlier and can work with their physician to be proactive and address potential problems sooner.

Will my insurance pay for direct testing?

While some insurance companies will cover some aspects of preventive care, most direct testing is not covered by insurance. But unlike in the past, when lab testing was so expensive that paying out of pocket was often impossible, Theranos prices are a fraction of traditional labs, and often less than insurance co-pays. Meaning paying directly is an easy option for most people.

Who should I talk to about what tests I should get?

While you don't need a physician written lab order to take advantage of direct testing, if you have questions about what tests you should consider, or about your test results once you receive them, you should consult with your physician. You can also visit theranos.com, click on MD Connect, and find a physician in your area.

Where can I get direct testing?

Direct testing is available at any Theranos Wellness Center™ location in Arizona. To find a Theranos Wellness Center™ near you, visit theranos.com.

What kind of lab tests can I get through direct testing?

Any of the hundreds of tests that your physician would order through Theranos are also available to you through direct testing. So routine tests, as well as those to monitor your thyroid, blood glucose, sexual health, and more are available directly to you.

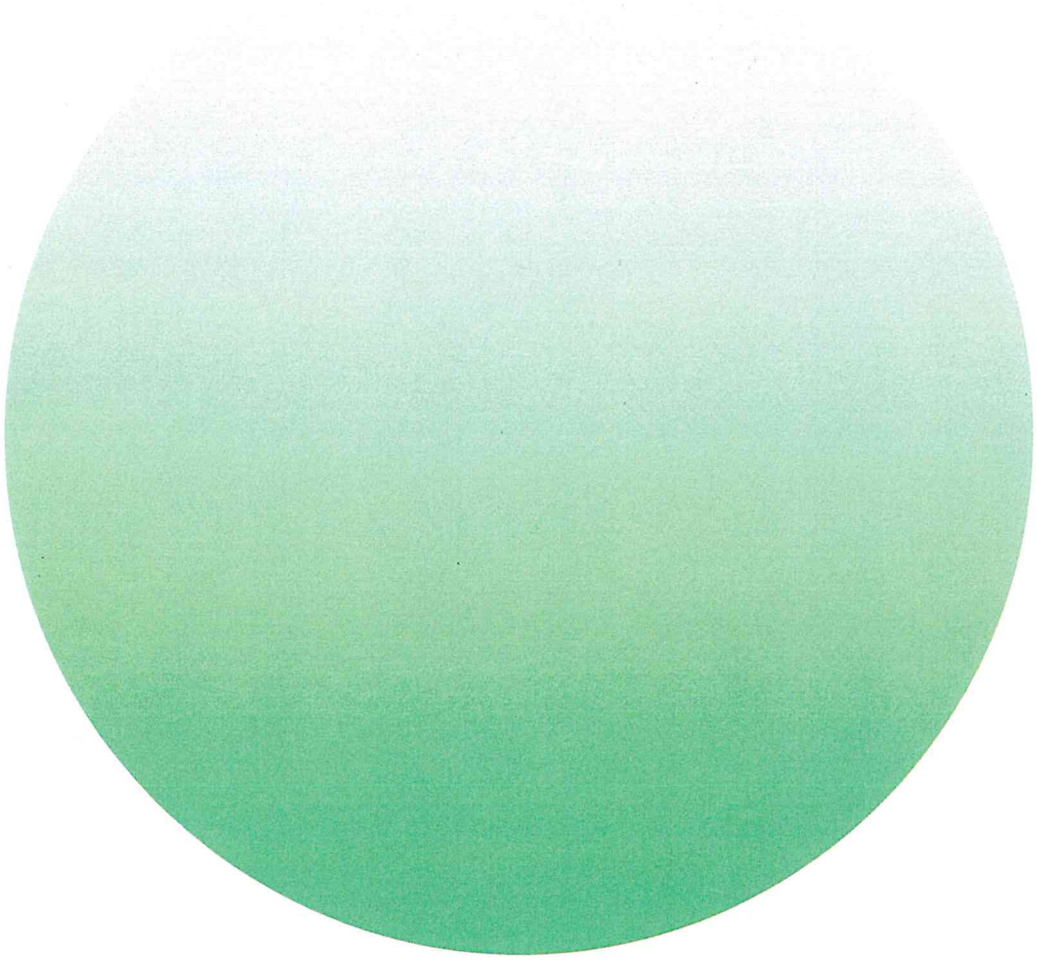
How does direct testing affect me?

With direct testing, it's easier for you and your family to get lab tests. Just go to any Theranos Wellness Center™ location, order the tests you are interested in, and get tested. It's that simple.

How do I get started?

To get started, just visit a Theranos Wellness Center™ location and order the tests you're interested in. You can also pre-order them with the Theranos app. To find a location near you and see a complete list of our tests and prices, visit theranos.com.

Guests may not seek reimbursement from their health insurer for any tests ordered without a health care provider's order unless specified by the health insurer. The option to order lab tests without a health care provider's order is limited to Arizona locations.



theranos

theranos.com

EXHIBIT J

Theranos Whistleblower Shook the Company—and His Family

Tyler Shultz says he wanted to shield reputation of former Secretary of State George Shultz, a Theranos director and his grandfather; $400,000 in legal fees

By John Carreyrou

After working at Theranos Inc. for eight months, Tyler Shultz decided he had seen enough. On April 11, 2014, he emailed company founder Elizabeth Holmes to complain that Theranos had doctored research and ignored failed quality-control checks.

The reply was withering. Ms. Holmes forwarded the email to Theranos President Sunny Balwani, who belittled Mr. Shultz's grasp of basic mathematics and his knowledge of laboratory science, and then took a swipe at his relationship with George Shultz, the former secretary of state and a Theranos director.

"The only reason I have taken so much time away from work to address this personally is because you are Mr. Shultz's grandson," wrote Mr. Balwani to his employee in an email, a copy of which was reviewed by The Wall Street Journal.

Mr. Shultz quit the same day. As he was leaving Theranos's headquarters in Palo Alto, Calif., he says he got a frantic cellphone call from his mother, who told him Ms. Holmes had just called the elder Mr. Shultz to warn that his grandson would "lose" if he launched a vendetta against the blood-testing startup.

❝

The only reason I have taken so much time away from work to address this personally is because you are Mr. Shultz's grandson.

—Theranos President Sunny Balwani to Tyler Shultz in a 2014 email

Tyler Shultz, now 26 years old, was among several Theranos employees who tried to voice concerns inside the company about what they saw as troubling practices, and Mr. Shultz was the first to blow the whistle to a state regulator. He says he wanted to expose the problems to protect the health of patients and his grandfather's reputation.

The elder Mr. Shultz, 95, was President Richard Nixon's Treasury and labor secretary, the first Office of Management and Budget director, and secretary of state for President Ronald Reagan, with whom he had a close relationship. In 1989, Mr. Reagan awarded Mr. Shultz the Medal of Freedom, the U.S.'s highest civilian honor.

Using an alias, Tyler Shultz contacted New York state's public-health lab and alleged Theranos had manipulated a process known as proficiency testing, relied on by federal and state regulators to monitor the accuracy of lab tests. That was the first known regulatory complaint about Theranos's lab practices. In early 2015, Mr. Shultz began speaking to a Journal reporter as a confidential source.

Theranos accused him of leaking trade secrets and violating an agreement to not disclose confidential information. Mr. Shultz says lawyers from the law firm founded by David Boies, one of the country's best-known litigators and

Elizabeth Holmes, Theranos's founder and chief executive, in September 2015. *PHOTO: DAVID ORRELL/GETTY IMAGES*

who later became a Theranos director, surprised him during a visit to his grandfather's house.

They unsuccessfully pressured the younger Mr. Shultz to say he had talked to the reporter and to reveal who the Journal's other sources might be. He says he also was followed by private investigators hired by Theranos.

The tension opened a rift in the Shultz family. While growing up, Tyler played in the pool at his grandfather's house, and he often dropped by the elder Mr. Shultz's home or his office at the Hoover Institution think tank while attending Stanford University.

In the past year and a half, the grandson and grandfather have rarely spoken or seen one another, communicating mainly through lawyers, says Tyler Shultz. He and his parents have spent more than $400,000 on legal fees, he says. He didn't attend his grandfather's 95th birthday celebration in December. Ms. Holmes did.

"Fraud is not a trade secret," says Mr. Shultz, who hoped his grandfather would cut ties with Theranos once the company's practices became known. "I refuse to allow bullying, intimidation and threat of legal action to take away my First Amendment right to speak out against wrongdoing."

Theranos and Ms. Holmes declined to comment for this article, and Mr. Balwani couldn't be reached. He left the company earlier this year.

> ***Fraud is not a trade secret. I refuse to allow bullying, intimidation and threat of legal action to take away my First Amendment right to speak out against wrongdoing.***
>
> —Tyler Shultz about his ordeal after quitting his job at Theranos

The elder Mr. Shultz joined Theranos's board of directors in 2011. Former Secretary of State Henry Kissinger, former Secretary of Defense William Perry, and former Sen. Sam Nunn, all fellows with Mr. Shultz at the Hoover Institution, joined the Theranos board around the same time. They couldn't be reached for comment.

The unusually high-profile board gave Theranos an aura of power, connections and gravitas as it raised money from investors and developed the blood-testing devices Ms. Holmes touted as revolutionary.

After the Journal published in October 2015 its first article detailing problems at Theranos, the company announced that all four men had been moved from the board of directors to a newly formed board of counselors.

Tyler Shultz is cooperating with an investigation of Theranos by federal prosecutors, according to people familiar with the matter. Theranos is the subject of criminal and civil investigations by the U.S. attorney's office in San Francisco and the Securities and Exchange Commission, which are trying to determine if the company misled investors and regulators about its technology and operations. Theranos has said it is cooperating.

Mr. Shultz's allegations that Theranos's proprietary Edison machines frequently failed quality-control checks and produced widely varying results

RELATED COVERAGE

- Walgreens Claims Theranos Voided 11.3% of Test Reports
- Walgreen Terminates Partnership With Theranos (June 13, 2016)
- Craving Growth, Walgreens Dismissed Its Doubts About Theranos (May 25, 2016)
- Theranos Voids Two Years of Edison Blood-Test Results (May 18, 2016)
- Theranos Executive Sunny Balwani to Depart Amid Regulatory Probes (May 12, 2016)
- U.S. Health Regulators Release Lightly Redacted Theranos Letter, Inspection Report (Apr. 25, 2016)
- Hot Startup Theranos Has Struggled With Its Blood-Test Technology (Oct. 16, 2015)

were corroborated in inspection results released in March by the federal Centers for Medicare and Medicaid Services. In April, Theranos told regulators it had voided all test results from Edison machines for 2014 and 2015, as well as some other tests it ran on conventional machines.

Theranos is appealing sanctions proposed by regulators, including a ban on Ms. Holmes from the blood-testing industry for at least two years. Last month, the company shut down all its blood-testing facilities and said it would focus on developing products that could be sold to outside labs, hospitals and doctors' offices.

The younger Mr. Shultz and Ms. Holmes met in late 2011 while he was visiting his grandfather's house next to the Stanford campus. Tyler Shultz was a junior at Stanford majoring in mechanical engineering.

Former Secretary of State George Shultz at a Senate committee hearing in January 2015. *PHOTO: ANDREW HARRER/BLOOMBERG NEWS*

He says he "fell in love with her vision" of instant and painless blood tests run on tiny samples of blood collected from fingertips. "I knew I had to be part of this," he recalls thinking.

Mr. Shultz interned at Theranos that summer and went to work there full-time in September 2013. He had just graduated after changing his major to biology to better prepare for a career at the startup, he says.

Theranos began offering blood tests to the public in late 2013. The company soon achieved a valuation of $9 billion from investors, with Ms. Holmes owning a majority stake. She also is chief executive of Theranos.

The new employee was assigned to the assay validation team, which was responsible for verifying and documenting the accuracy of blood tests run on Edison machines before they were deployed in the lab for use with patients.

Mr. Shultz says he found that results varied widely when tests were rerun with the same blood samples. To reduce that variability, Theranos routinely discarded outlying values from validation reports it compiled, he says.

One validation report about an Edison test to detect a sexually-transmitted infectious disease said the test was sensitive enough to detect the disease 95% of the time. But when Mr. Shultz looked at the two sets of experiments from which the report was compiled, they showed sensitivities of 65% and 80%.

That meant that if 100 people infected with the disease were tested only with the Edison device, as many as 35 of them would likely incorrectly conclude they were disease-free.

A few months later, Mr. Shultz moved to Theranos's production team, where

he quantified by how much patient tests should be allowed to vary during daily quality-control checks. Under federal rules, labs are allowed to set those parameters on their own within the bounds of accepted industry guidelines.

He says he noticed Edison machines often flunked Theranos's quality-control standards. He says Mr. Balwani, the No. 2 executive at the company, pressured lab employees to ignore the failures and run blood tests on the machines anyway, contrary to accepted lab practices.

Mr. Shultz says he took his concerns directly to Ms. Holmes. When they met in early 2014, she encouraged him to talk to Daniel Young, a Theranos vice president in charge of biostatistics.

According to Mr. Shultz, Mr. Young said the differences with the sexually-transmitted infectious disease test occurred because some results fell inside an "equivocal zone," meaning they were unclear at first but clarified later through other methods.

Theranos wouldn't make Mr. Young available for comment, and he couldn't be independently reached.

Mr. Shultz wasn't satisfied. In March 2014, he anonymously emailed his complaint to New York officials who administered a proficiency-testing program in which Theranos was enrolled.

The director of the lab's clinical-lab evaluation program replied that the practices sounded like "a form of PT cheating," using an abbreviation for proficiency testing. New York officials decline to comment.

After emailing Ms. Holmes in April 2014 about the allegedly doctored research and quality-control failures, Mr. Shultz heard nothing for several days.

Then Mr. Balwani's response arrived. It began: "We saw your email to Elizabeth. Before I get into specifics, let me share with you that had this email come from anyone else in the company, I would have already held them accountable for the arrogant and patronizing tone and reckless comments."

Ms. Holmes never replied, says Mr. Shultz, who decided it was time to quit his job. He says his mom called while he was on his way out and implored: "Stop whatever you're about to do!"

Mr. Shultz says he was startled. He went directly to his grandfather's office. George Shultz had his assistant photocopy the email from Mr. Balwani and put it in an office safe but seemed skeptical of his grandson's story, says Tyler Shultz.

❝

I am sorry if this email seems attacking in any way, I do not intend it to be, I just feel a responsibility to you to tell you what I see so we can work towards solutions.

—Tyler Shultz in an April 11, 2014, email to Theranos founder Elizabeth Holmes

They agreed to talk again at Mr. Shultz's house that evening. Tyler Shultz brought along a Theranos colleague who shared his misgivings, he says, but it felt to him like his grandfather's allegiance to the company had grown.

As household staff served them dinner in the formal dining room, the elder Mr. Shultz said Ms. Holmes had told him Theranos's blood-testing devices worked so well that they were being used in medevac helicopters and hospital operating rooms, Tyler Shultz recalls. He and his colleague knew

that wasn't true.

His grandfather urged them to move on with their lives. So Mr. Shultz did.

Seven months later, he and his parents showed up for Thanksgiving dinner at his grandfather's house. Ms. Holmes was there with her parents. Over turkey and stuffing, they discussed California's drought and the bulletproof windows on Theranos's new headquarters as if nothing had happened.

Mr. Shultz listened awkwardly as Ms. Holmes stood up and gave a toast expressing her appreciation for every member of the Shultz family, he says.

Tyler Shultz near his home in Los Altos Hills, Calif., earlier this month. *PHOTO: JASON HENRY FOR THE WALL STREET JOURNAL*

In March 2015, Tyler Shultz was contacted by a Journal reporter through the professional network LinkedIn. He called the reporter several weeks later with a prepaid phone, reasoning it would be harder to track than a conventional mobile phone. They met at a Mountain View, Calif., beer garden in May 2015.

A few weeks later, Mr. Shultz was confronted by his father after arriving for dinner with his parents at their home in Los Gatos, Calif. His grandfather had called to say Theranos suspected he had talked to the Journal reporter. Theranos's lawyers wanted to meet with him the next day.

He says he called his grandfather and asked if they could meet without lawyers. The elder Mr. Shultz agreed and invited his grandson to his house. The mood was tense but cordial, Tyler Shultz recalls, and he denied talking to any reporters. He says his step-grandmother was present during the conversation.

> ***We saw your email to Elizabeth. Before I get into specifics, let me share with you that had this email come from anyone else in the company, I would have already held them accountable for the arrogant and patronizing tone and reckless comments.***
>
> —Theranos President Sunny Balwani to Tyler Shultz in a 2014 email

His grandfather asked if he would sign a one-page confidentiality agreement to give Theranos peace of mind. According to Tyler Shultz, when he said yes, his grandfather revealed that two lawyers were waiting upstairs with the agreement.

Michael Brille and Meredith Dearborn, partners at the law firm Boies, Schiller & Flexner LLP, then came downstairs, says the younger Mr. Shultz. Mr. Brille said he was trying to identify the Journal's sources. He handed the young man a temporary restraining order, a notice to appear in court and a letter signed by Mr. Boies alleging the former employee had leaked Theranos trade secrets.

Tyler Shultz says his grandfather protested to the lawyers that this wasn't what he and Ms. Holmes had agreed to earlier, but that Mr. Brille kept pressing the younger Mr. Shultz to admit he had spoken to the Journal.

He wouldn't. "This conversation needs to end," the young man eventually declared. He says his grandparents ushered the two lawyers out of the house.

"My recollections of the events are very different than Tyler's," Mr. Brille says. "Our engagement with Tyler Shultz was at the invitation of his grandfather George. We engaged with Tyler in an effort to understand the extent to which he had disclosed trade secrets to third parties."

An assistant to George Shultz said he "does not agree with Mr. Brille's recollection."

Tyler Shultz says his grandfather called Ms. Holmes to complain about how his grandson was treated, and they reached a compromise. It called for Theranos to deliver the one-page confidentiality agreement the next morning so he could sign it. Ms. Holmes was asked to send a different lawyer.

The next day, though, Mr. Brille returned with a new document that contained another surprise, says the younger Mr. Shultz. The document was an affidavit stating that he had never spoken to the Journal or any third party about Theranos. It also said he would pledge to name every current and former employee he suspected of having done so.

His grandfather told his grandson to sign it if it was true he hadn't spoken to a reporter. The young man says he declined unless Theranos promised not to sue him.

With a pencil, the elder Mr. Shultz jotted a sentence at the bottom stating that Theranos wouldn't sue his grandson for two years. Tyler Shultz says he told his grandfather that he wanted the company to promise it would never sue him.

After the elder Mr. Shultz and Mr. Brille conferred in another room, the lawyer agreed to the grandson's condition, the younger Mr. Shultz says. By then, though, he had second thoughts and said he wanted his own lawyer.

His grandmother fished out a phone number for the elder Mr. Shultz's longtime lawyer and gave it to her grandson. That afternoon, Tyler Shultz met with his grandfather's lawyer and a partner at the same law firm and decided not to sign anything.

Mr. Brille warned that Theranos would have no choice but to sue Mr. Shultz, he recalls. He went home expecting to be summoned to court the next day. That night, though, Mr. Brille sent an email to the elder Mr. Shultz's lawyer saying the company was holding off to give both sides more time to negotiate.

With advice from a new lawyer, Tyler Shultz began settlement talks with Theranos but couldn't persuade himself to accept the conditions sought by the company.

He says he was told by his parents that Ms. Holmes called the elder Mr. Shultz in the summer of 2015 to complain that their son was being unreasonable. Tyler Shultz says he also got a tip that private investigators were watching him.

In a conversation in his parents' kitchen, they pleaded with him to agree to whatever Theranos wanted, he says. Even though his heart sank when they discussed selling their house to cover the costs of defending him against a potential Theranos lawsuit, Mr. Shultz didn't make a deal with the company.

His parents said in a statement: "Tyler has acted exactly like the man we raised him to be, and we are extraordinarily proud of him."

Tyler Shultz says he hasn't seen his grandfather since July. *PHOTO: JASON HENRY FOR THE WALL STREET JOURNAL*

The younger Mr. Shultz says he stopped hearing from Mr. Brille and Theranos after the Journal's first article was published in October 2015. The article included a description of the regulatory complaint Mr. Shultz had filed under the alias Colin Ramirez but didn't identify him by his real name.

An assistant to George Shultz said he was unavailable to comment but "wishes you to know that he deeply loves and respects his grandson Tyler, is very proud of Tyler and all he has accomplished and will accomplish, and knows Tyler to be a man of great integrity. Mr. Shultz is deeply sorry that Tyler's experience at Theranos was so unsatisfactory for Tyler."

After leaving Theranos, Tyler Shultz worked briefly for a biotechnology company and now is collaborating with a team of researchers to try to build a portable device capable of diagnosing a dozen diseases from a person's blood, saliva and vital signs. The team is vying for a multimillion-dollar cash prize in the prestigious Qualcomm Tricorder XPrize competition.

Mr. Shultz visited his grandfather in July. They hadn't spoken for seven months. He says he told his grandfather he was disappointed about not getting more support from him throughout the ordeal. He asked the elder Mr. Shultz to publicly distance himself from Theranos.

"I am pleading with you as your grandson," Tyler Shultz recalls saying, "please do the right thing." His grandfather, still on Theranos's board of counselors, remained noncommittal. They haven't seen each other since.

Write to John Carreyrou at john.carreyrou@wsj.com

Theranos Whistleblower Shook the Company—and His Family
By **JOHN CARREYROU**
Updated Nov. 18, 2016 11:17 a.m. ET

EXHIBIT K

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/u-s-probes-theranos-complaints-1450663103

TECH

U.S. Probes Theranos Complaints

Blood-testing startup's practices investigated over concerns about accuracy, protocol

CEO Elizabeth Holmes, shown in October, has defended Theranos's testing. *PHOTO: NIKKI RITCHER FOR THE WALL STREET JOURNAL*

By JOHN CARREYROU
Dec. 20, 2015 8:58 p.m. ET

U.S. health regulators are investigating complaints about laboratory and research practices at Theranos Inc. by two former employees of the blood-testing startup company, according to people familiar with the inquiries.

A complaint filed in September by a former Theranos lab employee to the Centers for Medicare and Medicaid Services alleged that management instructed lab employees to keep testing patients with the company's blood-analysis devices despite indications of "major stability, precision and accuracy" problems with those devices.

The second complaint was sent to the Food and Drug Administration earlier this month by another ex-employee, who alleged that the study submitted by Theranos last year to win the agency's approval for a herpes test was tainted by breaches in research protocol.

Copies of both complaints were reviewed by The Wall Street Journal. Last week, an FDA scientific reviewer interviewed the person who filed the complaint with that agency, according to a person familiar with the matter. CMS auditors inspected Theranos's lab in Newark, Calif., in November as part of a regularly scheduled audit that the company says is continuing.

A spokeswoman for Theranos, Brooke Buchanan, said the company hasn't been provided with "a copy of any alleged complaint, so we have no basis to evaluate what is in it or even if a complaint has been filed."

She added: "Agencies have a process for evaluating complaints, and many complaints are not substantiated. We trust our regulators to properly investigate any complaints, and we look forward to continuing our strong and productive relationships with them."

CMS and FDA spokeswomen declined to comment.

Theranos, based in Palo Alto, Calif., was valued at $9 billion in a funding round last year, making the company one of the highest-valued startups in Silicon Valley.

A Journal article in October said the lab instrument developed as the linchpin of Theranos's strategy handled just a fraction of the tests sold to consumers at the end of 2014, citing four former employees. The vast majority of tests were done with traditional lab instruments, the former employees said.

October's article also said some employees were leery about the accuracy of Theranos's in-house machine, called the Edison, noting that some doctors and patients also were concerned about test results.

Theranos has said that all its lab work is accurate and reliable. In recent weeks, Elizabeth Holmes, the company's founder and chief executive, has defended Theranos in public appearances and pledged to publish peer-reviewed data on its tests. Ms. Buchanan, the spokeswoman, said the data aren't ready and declined to specify when the information will be published.

In response to questions from the Journal, Theranos last week made available three senior company scientists, who discussed their work and certain documents and regulatory submissions by Theranos. However, the company said the documents couldn't be disclosed by the Journal or reflected in this article because they contained confidential information and trade secrets.

In the complaint to CMS, the former lab employee alleged that Theranos managers were made aware of accuracy problems with its Edison devices in 2013 and 2014 but pressured lab employees to keep processing patient samples without taking corrective actions.

Edison machines would sometimes produce "radically different results" for the same patients, the former employee alleged. Referring to a thyroid test known as thyroid-stimulating hormone, the employee wrote that "a patient would swing between" hypothyroidism and hyperthyroidism, or too little of the hormone and too much, when the test was repeated the same day.

Daniel Young, a Theranos vice president and director of its Arizona laboratory, said he is "not aware of any pressure from upper management to release errors or unreliable results. That goes against everything I know about how Theranos operates."

He said Theranos has performed internal validation studies in which tests were run on both its proprietary technology and FDA-approved machines. The validation studies proved the accuracy of Theranos's proprietary tests, he added.

The ex-employee also echoed an allegation made by a Theranos employee to New York regulators last year. That employee had claimed the company might have manipulated the process known as proficiency testing that is used by CMS to monitor the accuracy of labs.

Dr. Young said Theranos uses alternative assessment procedures for proficiency testing and has briefed regulators on these procedures. "I have full confidence that our procedures are sound," he said.

The former employee who filed the complaint with CMS also sent the agency a follow-up email in October that alleges the company did a category of tests known as general chemistry tests by diluting tiny samples of blood collected from patients' fingers and running them on traditional lab machines.

Quality-control checks of that testing method often failed, especially on tests designed to measure levels of carbon dioxide, calcium, sodium or potassium in the blood, according to the former Theranos employee.

Another former Theranos lab employee says the company kept using the dilution practice until May. Outside lab experts say diluting blood samples increases the risk of errors.

Dr. Young declined to comment about alleged dilution, saying prior statements by Theranos adequately and fully address the matter.

Ms. Holmes, Theranos's chief executive, has denied diluting blood samples from patients' fingers to run them on traditional machines. "I bet you if you tried that, it wouldn't work because it's just not possible to dilute a sample and put it on to a commercial analyzer," she said at the WSJDLive conference in October. "I mean, there are so many things that are wrong with that."

The complaint to the FDA alleged that Theranos hadn't fully assembled the proprietary machines used for the herpes study when the experiments began. The former employee also alleged that the company underreported the rate at which the machines broke down during the study.

The employee also alleged that some crucial parts of the devices, including polystyrene tips that drop into blood samples, were modified to improve their accuracy. Scientists disapprove of making changes during a study because that can taint the integrity of the resulting data, according to outside experts.

Theranos denied the allegations and said its herpes study adhered to accepted scientific protocols and that the information it submitted to the FDA was truthful and complete.

The FDA approved Theranos's herpes test in July. The company has cited that approval as evidence that its proprietary blood-testing technology is reliable and fit for widespread use.

Theranos's spokeswoman, Ms. Buchanan, said Theranos believes that the former employee who filed the FDA complaint is "uninformed" and "disgruntled." The FDA's approval was "hard earned and the product of significant efforts by dozens of exemplary scientists and engineers—honest, hardworking, highly qualified individuals."

In September, the FDA declared the tiny vials used by Theranos to collect finger-pricked blood an "uncleared medical device" after inspecting the company's California facilities. Following the inspection, Theranos narrowed its use of the "nanotainers" to just the FDA-approved herpes test. In October, Ms. Holmes said the company was in a "pause period" while it awaits the agency's approval of the firm's other proprietary tests.

Write to John Carreyrou at john.carreyrou@wsj.com

EXHIBIT L

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/theranos-is-subject-of-criminal-probe-by-u-s-1461019055

TECH

Theranos Is Subject of Criminal Probe by U.S.

Federal prosecutors are investigating whether the blood-testing company misled investors about the state of its technology and operations

Elizabeth Holmes, founder and CEO of Theranos, in October. *PHOTO: NIKKI RITCHER/THE WALL STREET JOURNAL*

By CHRISTOPHER WEAVER, JOHN CARREYROU and MICHAEL SICONOLFI
April 18, 2016 6:37 p.m. ET

Federal prosecutors have launched a criminal investigation into whether Theranos Inc. misled investors about the state of its technology and operations, according to people familiar with the matter.

Walgreens Boots Alliance Inc. and the New York State Department of Health have received subpoenas in recent weeks seeking documents and testimony about representations made to them by the Palo Alto, Calif., blood-testing company, some of the people said.

Walgreens has been Theranos's main conduit to consumers since the companies announced a partnership in 2013 that now includes 40 Theranos wellness centers at drugstores in Arizona. The New York agency received an application from Theranos for a laboratory license in the state.

People familiar with the matter said the subpoenas seek broad information about how Theranos described its technologies and the progress it was making developing those technologies.

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- At Theranos, Many Strategies and Snags (Dec. 27)
- Hot Startup Theranos Has Struggled With Its Blood-Test Technology (Oct. 16)

Investigators are also examining whether Theranos misled government officials, which can be a crime under federal law, some of the people said.

Such subpoenas don't necessarily mean prosecutors are actively seeking an indictment. People familiar with the matter said the investigation is at an early stage.

In addition to the criminal probe, the Securities and Exchange Commission is examining whether Theranos made deceptive statements to investors when it solicited funding, according to people familiar with the matter. Theranos was valued at $9 billion in a funding round in 2014 and the majority stake of Elizabeth Holmes, the startup's founder and chief executive, at more than half that.

In a statement, Theranos said: "The company continues to work closely with regulators and is cooperating fully with all investigations."

SEC spokeswoman Judith Burns declined to comment, as did Justice Department spokesman Peter Carr and Abraham Simmons, an assistant U.S. attorney in San Francisco, where the federal investigation is being conducted.

Interactive

Companies valued at $1 billion or more by venture-capital firms

Walgreens spokesman Michael Polzin also declined to comment. New York health-department spokesman J.P. O'Hare didn't respond to requests for comment.

Since launching Theranos in 2003, Ms. Holmes has set out to revolutionize the blood-testing industry. Before the company made changes to its website earlier this year, the website cited "breakthrough advancements" that made it possible to run "the full range" of lab tests on a few drops of blood pricked from a finger.

In October, The Wall Street Journal reported that Theranos did the vast majority of more than 200 tests it offered to consumers on traditional lab machines purchased from other companies. The Journal also reported that some former employees doubted the accuracy of a small number of tests run on the devices Theranos invented, code-named Edison.

Theranos has declined to say how many tests or which ones it runs on commercial machines. The company has said its technology has the capability to handle a broad range of tests.

Federal officials began requesting information about Theranos in January and February, according to the people familiar with the matter. Those informal requests were followed by grand-jury subpoenas from a federal court in San Francisco in March, the people said. Agents from the Federal Bureau of Investigation and U.S. Postal Inspection Service are assisting in the investigation, the people said.

The news release issued when the Walgreens deal was announced said consumers "will be able to access less invasive and more affordable clinician-directed lab testing, from a blood sample as small as a few drops, or 1/1,000 the size of a typical blood draw."

As part of the deal, Walgreens has invested at least $50 million into Theranos, according to people familiar with the matter.

In January, though, Walgreens notified Theranos that it intends to terminate the partnership unless the company quickly fixes problems found in a federal inspection completed in November at Theranos's lab in Newark, Calif.

Last month, federal health regulators proposed banning Ms. Holmes from the blood-testing business for at least two years after concluding that the company failed to resolve what officials have called major problems found during the inspection.

Theranos spokeswoman Brooke Buchanan said the company has submitted a response addressing the concerns and hopes to avert the sanctions. The sanctions haven't been imposed. If they are, Theranos can appeal.

The company began running some tests on Edisons in its California lab in late 2013, according to some former employees and the federal inspection report.

Theranos's lab-license application in New York said the company planned to test patients' blood on traditional lab machines and didn't mention any proprietary testing devices, said someone with knowledge of the application.

Theranos also enrolled in the New York agency's proficiency-testing program, in which regulators monitor a lab's accuracy by sending it samples of preserved blood with known characteristics and asking the lab to test them.

If the lab's results are in line with those reported by a peer group, it receives a passing grade.

In March 2014, a Theranos employee alleged to the agency in an email that Theranos was manipulating its proficiency-testing program by reporting back results obtained from traditional lab machines for some tests, instead of the Edison devices with which it was running those tests on live patient samples.

Theranos said it uses an alternative process for proficiency testing. The process "has been disclosed to and discussed with regulators," said Ms. Buchanan, the Theranos spokeswoman. "Theranos' proficiency testing process meets the regulatory requirements."

State records show Theranos never obtained a New York license. The person with knowledge of the company's application said it was shelved when Theranos's lab director at the time wrote to the agency to inform it he had resigned and wanted his name taken off the application.

The SEC has been paying closer attention recently to ensuring that large private technology firms properly inform investors about their finances and valuations. In a speech at Stanford University late last month, SEC Chairwoman Mary Jo White said: "The risk of distortion and inaccuracy is amplified because start-up companies, even quite mature ones, often have far less robust internal controls and governance procedures than most public companies."

—Jean Eaglesham contributed to this article.

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EXHIBIT M

Agony, Alarm and Anger for People Hurt by Theranos's Botched Blood Tests

They led to changes in medical treatment and a scramble for answers; some patients weren't told for months about unreliable results

By Christopher Weaver

Sheri Ackert worried she might have a new tumor. Steve Hammons stopped taking his blood-thinning medication. Kimberly Toy emptied the pasta and sweets from her cupboards and said: "I can't believe this happened."

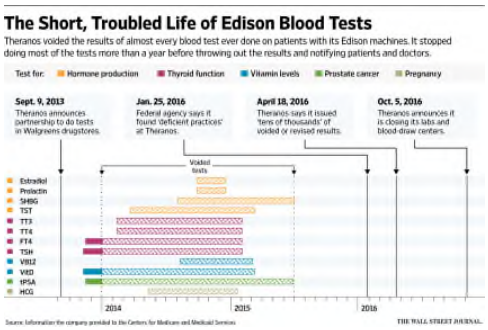
What they have in common are dubious test results from Theranos Inc. A review of regulatory records and interviews with patients shows the Palo Alto, Calif., company didn't just burn investors who bought into its promise to revolutionize the world of blood testing. It also left a trail of agonized patients who had been drawn to Theranos by its claims of convenience, low cost and reliability.

While inaccurate tests can occur at any laboratory, Theranos failed to maintain basic safeguards to ensure consistent results, according to regulators, independent lab directors and quality-control experts.

Questionable test results from Theranos caused some patients to become alarmed and others to adjust the amount of medicine they were taking. Rattled patients who told The Wall Street Journal they sought more information about their results said they got no response, and weeks or months passed before Theranos told many patients that their results were unreliable.

Mr. Hammons, a retired marketer who lives in Peoria, Ariz., and had heart surgery last year, found out only last Friday that Theranos had corrected a September 2015 test showing his blood taking more than six times longer than normal to clot.

The results from five different visits to Theranos in six weeks varied so much that Mr. Hammons said he was told by his doctor to stop taking his blood thinner, called warfarin, and switch to a less potent medicine. Theranos sent him the corrected report for the one test after the Journal asked the company about his results.



Theranos founder Elizabeth Holmes and the company declined to comment for this article. In April, the company told federal health regulators it had voided all test results from its proprietary Edison devices from 2014 and 2015, as well as some other tests it ran on conventional machines.

In all, Theranos said it issued "tens of thousands" of voided or revised test results to doctors or patients.

According to Theranos, the voided results add up to 1% of all the tests run by the company, which has said it stands by its other test findings. Theranos has said it is not aware of patients being harmed as a result of operational problems. It has said all affected patients were notified by the company.

Theranos is fighting the federal government's decision in July to revoke the company's license to run a lab in California because of unsafe practices and to ban Ms. Holmes from the blood-testing business for at least two years. The company has said it accepted "full responsibility for the issues" at its California lab.

Earlier this month, Theranos shut down all its blood-testing facilities and said it will focus on developing products that could be sold to outside labs.

The federal Centers for Medicare and Medicaid Services, which inspected the California lab last fall, said in July that Theranos failed to explain how it came to its conclusions about patient outcomes for some tests at the lab or how Theranos made sure that affected patients were notified.

The Journal interviewed more than a dozen patients who got improbable test results from the California lab or Theranos's other lab in Arizona, including some relating to tests that haven't been voided or revised. Patients are still grappling with unanswered questions about their results.

The Journal also reviewed undisclosed regulatory documents that quantify the severity of Theranos's accuracy problems.

Notes from the CMS inspection show that 834 out of 2,890 quality-control checks run on the Edison in October 2014, or 29%, exceeded the company's threshold of two standard deviations from its average result. Standard deviation is a statistical measurement of variation.

In addition, 80% of the 834 quality-control checks that raised a red flag under Theranos's internal standards were more than three standard deviations from its average result, the inspection notes show. Theranos has told regulators it used the Edison from November 2013 to June 2015.

"It doesn't give me a lot of confidence the patients' results could be right," said James Westgard, a scientist who developed widely used quality-control rules for the lab-testing industry.

After the Journal described the inspection notes to Mr. Westgard, he said of Theranos: "They were just going through the motions."

Theranos's blood tests ranged from routine lab services relating to cholesterol and pregnancy to a rarely used procedure tracking the level of the antibiotic gentamicin. The company offered a complete blood count, which screens for overall health and a variety of disorders, for $5.35. That's about half as much as the federal Medicare agency pays labs on average for the same blood screening.

In Arizona, Theranos successfully lobbied for a law allowing laboratories to provide blood tests directly to patients without involvement by doctors, who are trained to question unusual results.

Gov. Doug Ducey signed the law at Theranos's lab in Scottsdale in April 2015, and his prepared remarks cited Ms. Holmes's "devotion to serving and empowering patients with new and improved technology."

Spokesman Daniel Scarpinato said Arizona's governor "continues to support citizens having access to their personal medical information, and other providers are currently operating under this reform."

Federal rules allow labs to set their own quality standards. Inspectors have said Theranos wrongly released test results to patients even when its quality-control checks violated the company's own requirements.

Theranos patients have filed at least 10 lawsuits against the company in

federal courts in California and Arizona, seeking class-action status. The allegations include fraud by Theranos for advertising it could accurately perform tests. Theranos has denied the allegations and said it will fight them.

Kimberly Toy, shown at home in Phoenix, was shocked by the diabetes-test result she got from Theranos because it was much higher than another lab's earlier test. *PHOTO: MARK PETERMAN FOR THE WALL STREET JOURNAL*

Ms. Toy, who sued Theranos in June, got a diabetes test last year at Sonora Quest Laboratories. It showed a hemoglobin A1c level of 5.7%. That was high enough for her doctor to worry that she was at risk of becoming diabetic. She changed her diet, exercised more, lost 15 pounds and decided to monitor her health with follow-up blood tests.

One of those tests was at Theranos in February. It showed a hemoglobin A1c level of 6.4%. That finding shocked Ms. Toy, 55 years old, who runs a cleaning service in Phoenix. Doctors diagnose diabetes based on a level of 6.5% or more.

Several weeks later, she repeated the test at Sonora Quest, which showed 5.8%. The reading declined to 5.3% in July.

Pallav Sharda, 39, a Menlo Park, Calif., technology entrepreneur and medical doctor with a family history of diabetes, got a hemoglobin A1c result of 6% from Theranos in July 2015, according to a lab report. Two days later, he had the test repeated elsewhere. That result of 5.4% put him in the normal range.

High results can lead doctors to prescribe medication aimed at helping to prevent the onset of diabetes. Side effects of the main medication recommended by the American Diabetes Association include muscle pain, vomiting, diarrhea and respiratory illness. Dr. Sharda and Ms. Toy weren't prescribed drugs because their follow-up tests showed that wasn't necessary.

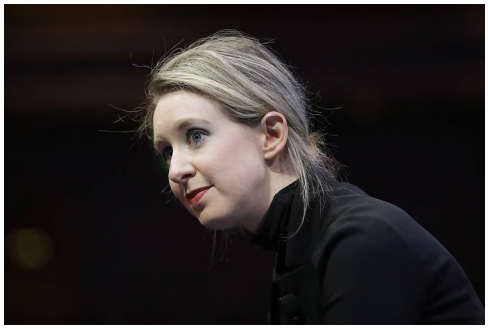
Endocrinologists and lab experts said it is implausible for results of the hemoglobin A1c test to change as much as they did with Dr. Sharda and Ms. Toy because the A1c reading reflects average blood-sugar levels over several months.

In January, federal inspectors said some practices at Theranos put patients in "immediate jeopardy." Inspectors singled out a blood-coagulation test that Theranos ran despite flunking quality-control checks.

The test is used to monitor effects of warfarin. Too much of the blood thinner can cause dangerous bleeding, while too little can lead to strokes.

It took Theranos nearly two months to warn a California man's doctor not to rely on the blood-coagulation test result he got Sept. 17, 2015.

Federal inspectors found numerous problems with how Theranos was doing blood-coagulation tests on a type of Siemens AG machine during the inspection that began Sept. 22, 2015, according to a person familiar with the matter and regulatory records. Theranos used the same type of machine to test the California man's blood, his report shows.



Elizabeth Holmes, Theranos's founder and chief executive, at the 2015 Fortune Global Forum in San Francisco. *PHOTO: JEFF CHIU/ASSOCIATED PRESS*

Theranos stopped using the Siemens machine during the inspection and later told regulators it voided all coagulation tests run on the device from October 2014 to Sept. 17, 2015.

The man's doctor wasn't told until Nov. 16, 2015, that "there may have been issues with the quality of the result and this result should not be used out of an abundance of caution," according to his medical records. The next day, inspectors returned to finish their inspection of Theranos's lab.

It isn't clear why he wasn't warned sooner about the bad test result. In July, regulators told Theranos that the company didn't provide an "acceptable explanation" for the lag. Theranos hasn't responded publicly to the accusation.

In the case of Mr. Hammons, 64, whose tests were run at Theranos's Arizona lab, the report he got last week from the company revised a measurement doctors use to compare warfarin patients to a lab's typical patient.

That ratio was 27% higher in the revised report, putting Mr. Hammons even deeper in the range that worries doctors.

Doctors said either reading would likely cause a patient's doctor to recommend seeking medical attention because their blood was clotting too slowly, but results on his four other Theranos tests showed the warfarin wasn't thinning his blood enough. He doesn't recall any troubling symptoms.

In March, Theranos sent Greg Waldorf what it called "corrected results" for three tests conducted in October 2014 for thyroid hormones. At the time, Theranos used the Edison for the particular thyroid tests he got.

Mr. Waldorf, 48, a Silicon Valley entrepreneur, has had thyroid cancer and gets the tests done each year, he said. The original test result for the hormone thyroxine was four times higher than the upper limit of what is considered normal. According to doctors, patients at that level would show clear symptoms of hyperthyroidism, such as heart palpitations, but Mr. Waldorf had none.

Follow-up tests days later at Stanford Hospital were normal. After getting the revised report from Theranos nearly a year and a half after his tests there, Mr. Waldorf said he called the company and was told his results were voided due to the quality-control efforts.

Patients and doctors told the Journal they were shocked when Theranos produced hard-to-explain results that could signal serious or even life-threatening problems.

Ms. Ackert, 60, a health-care administrator who lives in Apache Junction, Ariz., went to Theranos for tests ordered by one of her doctors to assess possible side effects related to her breast-cancer treatment. After her diagnosis in 2013, she had a double mastectomy and a year of chemotherapy.

Last

Theranos headquarters in Palo Alto, Calif. The company shut down all its blood-testing facilities earlier this month. *PHOTO: THERANOS*

November, Theranos's lab report arrived in her email's inbox with a surprise: A level of an estrogen hormone called estradiol was exceedingly high for a patient her age. She knew she should have little or no estrogen in her blood because she is past menopause.

If the result was accurate, it might mean Ms. Ackert had a rare adrenal tumor that can secrete estradiol or an elevated risk of breast-cancer recurrence, doctors said. "I wanted to know why, and did she have a tumor?" said her oncologist, Santosh Rao of Banner MD Anderson Cancer Center in Gilbert, Ariz.

He suggested that she repeat the test. Sonora Quest drew her blood from a vein, just as Theranos had done a week earlier.

"She wasn't the same Sheri," said her sister, Denise Thorson, who arrived from Minnesota with her husband for a weekend trip to watch a Nascar race. Ms. Ackert made agitated calls to her doctor's office before leaving on the trip and checked her phone throughout the weekend.

"How could they put her through this?" said her husband, Doug Hawthorne.

Four days after the follow-up test, Ms. Thorson walked into a room at Ms. Ackert's house and saw her and her husband embracing. They were crying. The doctor's office had reported her estradiol level in the second test was so low that it couldn't be measured precisely.

The reading was less than 2 picograms per milliliter, compared with 313.5 picograms in Theranos's test result. That was the level her doctors had expected in the first place.

—John Carreyrou and Lisa Schwartz contributed to this article.

Agony, Alarm and Anger for People Hurt by Theranos's Botched Blood Tests
By **CHRISTOPHER WEAVER**
Updated Oct. 20, 2016 9:52 p.m. ET

EXHIBIT N

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/walgreen-terminates-partnership-with-blood-testing-firm-theranos-1465777062

BUSINESS

Walgreen Terminates Partnership With Blood-Testing Firm Theranos

Move by drugstore chain shuts off Silicon Valley firm's primary revenue source

Walgreen Co. said it was shutting down Theranos lab-testing services in all its Walgreens locations. *PHOTO: CHARLES KRUPA/ASSOCIATED PRESS*

By MICHAEL SICONOLFI, CHRISTOPHER WEAVER and JOHN CARREYROU

Updated June 13, 2016 10:19 a.m. ET

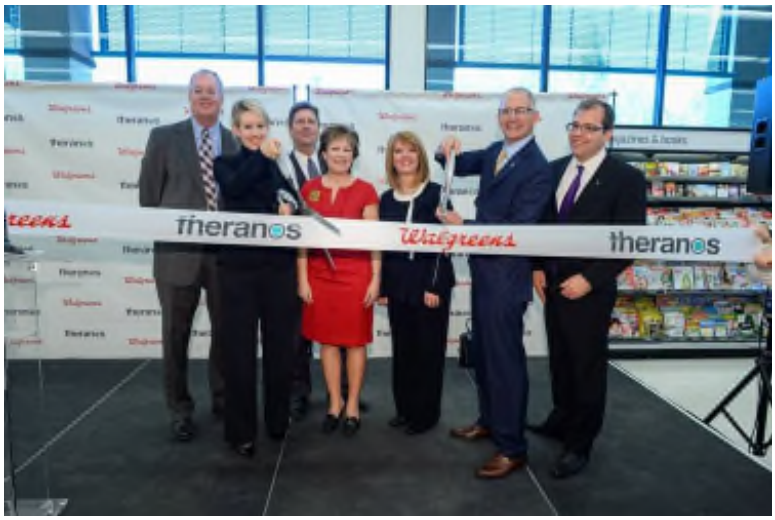
Drugstore operator Walgreen Co. formally ended a strained alliance with Theranos Inc. as regulators near a decision on whether to impose sanctions against the embattled Silicon Valley firm.

Some officials at the Walgreens Boots Alliance Inc. unit had grown frustrated at not getting more details and documentation from Theranos after learning it had corrected tens of thousands of blood tests, including many performed on samples collected from patients at Walgreens pharmacies, according to people familiar with the partnership.

In a news release late Sunday, Walgreens said it had told Theranos it was terminating their nearly three-year-old partnership, effective immediately, and that it was shutting down Theranos lab-testing services in Walgreens locations. It said it would work over the next several days to help transition its customers.

"In light of the voiding of a number of test results, and as the Centers for Medicare and Medicaid Services has rejected Theranos's plan of correction and considers sanctions, we have carefully considered our relationship with Theranos and believe it is in our customers' best interests to terminate our partnership," Brad Fluegel, Walgreens' senior vice president and chief healthcare commercial market development officer, said in a statement.

The move is a significant blow to Theranos. The 40 Theranos blood-draw sites inside Walgreens stores in Arizona, which the company calls "wellness centers," have been the primary source of revenue for Theranos and its conduit to consumers, analysts say. The tie-up also has given the blood-testing firm a stamp of credibility since it was publicly announced in September 2013.



Theranos CEO Elizabeth Holmes, left, in 2013 marking the company's partnership with Walgreens. *PHOTO: WALGREENS*

Walgreens leaders decided to end the partnership after regulators disclosed problems at Theranos in late January, but held off on finalizing the separation because the company feared Theranos might sue, said people familiar with the matter.

Without Walgreens, Theranos would no longer be competing with major labs. To regain its access to consumers, it would have to forge a new retail partnership, offer its blood-testing services directly to more doctors' offices or open its own blood-draw sites, among other options. It already has moved to open a blood-testing center in Arizona. Recently, the company has been exploring a tie-up with another pharmacy or supermarket, according to a person familiar with the matter.

Michael Polzin, a Walgreens spokesman, declined to comment beyond the news release.

Theranos spokeswoman Brooke Buchanan said, "Quality and safety are our top priorities, and we are working closely with government officials to ensure that we not only comply with all federal regulations but exceed them."

Ms. Buchanan added, "We are disappointed that Walgreens has chosen to terminate our relationship and remain fully committed to our mission to provide patients access to affordable health information and look forward to continuing to serve customers in Arizona and California through our retail locations."

RELATED

- Craving Growth, Walgreens Dismissed Its Doubts About Theranos (May 25)
- Theranos Voids Two Years of Edison Blood-Test Results (May 18)
- Theranos Executive Sunny Balwani to Depart Amid Regulatory Probes (May 12)
- U.S. Health Regulators Release Lightly Redacted Theranos Letter, Inspection Report (Apr. 25)

CMS, the agency that inspected Theranos's Newark, Calif., lab last fall, will inform Theranos in roughly the next two weeks about its determination on sanctions, said a person familiar with the matter. A CMS spokeswoman declined to comment

In recent days, some Walgreens officials became more convinced that Theranos would face painful CMS sanctions, according to people familiar with the matter. The agency previously said it had found major deficiencies at the California lab, including at least one it said posed an immediate threat to patients.

It proposed in a March letter closing the laboratory down and barring Theranos founder Elizabeth Holmes from the industry for at least two years.

"Due to the comprehensive nature of the corrective measures we've taken over the past several months, which has been affirmed by several experts, we are hopeful that CMS won't impose sanctions," Theranos's Ms. Buchanan has said. "But if they do, we will work with CMS to address all of their concerns."

Senior Walgreens officials believe that any significant sanctions would give them a defense if Theranos were to sue Walgreens for breach of contract, people familiar with the matter said.

Top Walgreens leaders previously worried they could face litigation seeking massive damages if they unilaterally closed Theranos's testing sites at their Arizona stores, according to people with knowledge of the thinking inside Walgreens.

Walgreens managers also grew increasingly frustrated in recent weeks with Theranos as they sought information about the extent of test reports it had corrected or voided.

The drugstores' senior leadership team learned Theranos had told regulators it was voiding or correcting tens of thousands of reports in mid-April. In early May, Walgreens asked Theranos to provide details of the corrected reports, according to people familiar with matter.

Theranos told Walgreens the corrections were part of the normal process of coming back into compliance with regulators and only involved tests performed in the California lab, according to people familiar with the matter.

On May 18, The Wall Street Journal reported that Theranos had voided all results for tests run on its proprietary Edison device in 2014 and 2015, and that it had also corrected some blood coagulation tests performed in a second laboratory it operates in Scottsdale, Ariz.

Since then, Theranos hasn't provided Walgreens some specific information and documentation about blood tests voided for its customers, including which specific customers and tests, according to a person familiar with the matter. The issue is important because any erroneous results could throw off health decisions patients make with their doctors. Theranos has said it voided the tests out of an abundance of caution, and doesn't think any patients were affected.

In recent weeks, Walgreens also was named as a co-defendant in one of three civil lawsuits filed by consumers against Theranos. The suits, which seek class-action status, allege that Theranos misled the public about the nature and accuracy of its blood-testing technology.

Walgreens declined to comment. Theranos said the suits are without merit and that it would vigorously defend itself against them.

Current and former Walgreens officials say Theranos veiled its technology and operations in secrecy from the early days of the relationship between the two companies.

Some of the officials said Theranos told Walgreens' team it could accurately perform dozens of tests on just a drop of blood using its proprietary testing system, the Journal reported in late May.

The company later told regulators it had performed just 12 tests using the device and that by late last summer, it used conventional devices made by companies like Siemens AG to perform all of its tests.

In exiting the partnership, Walgreens doesn't expect to recoup its investment of at least $50 million in Theranos, according to people familiar with the thinking of some officials at the drugstore chain.

Write to Michael Siconolfi at michael.siconolfi@wsj.com, Christopher Weaver at christopher.weaver@wsj.com and John Carreyrou at john.carreyrou@wsj.com

EXHIBIT O

THE WALL STREET JOURNAL.

http://www.wsj.com/articles/u-s-regulator-bans-theranos-ceo-elizabeth-holmes-from-operating-labs-for-two-years-1467956064

BUSINESS

Theranos Dealt Sharp Blow as Elizabeth Holmes Is Banned From Operating Labs

Company also remains subject of criminal probe into whether it misled investors

By JOHN CARREYROU, MICHAEL SICONOLFI and CHRISTOPHER WEAVER
Updated July 8, 2016 7:22 p.m. ET

Silicon Valley startup Theranos Inc. is fighting for its life after regulators decided to revoke its license to operate a lab in California because of unsafe practices and to ban founder Elizabeth Holmes from the blood-testing business for at least two years.

The sanctions were laid out in a letter to Theranos released Friday by the agency that oversees U.S. labs, the Centers for Medicare and Medicaid Services. Theranos said it is still seeking to resolve its issues with the regulator.

One sanction, a monetary fine of $10,000 a day until all deficiencies have been corrected, goes into effect July 12. The most serious sanctions, such as the ban of Ms. Holmes, won't go into effect for 60 days.

If it fails to reach a settlement with the government, Theranos's options are limited. Almost any course it takes will dramatically reshape the company that Ms. Holmes founded in 2003 as a Stanford University dropout and grew to a valuation of more than $9 billion in a 2014 fundraising round.

The company could appeal the sanctions to an administrative judge, which would put some on hold. Its odds of winning would be slim, according to legal experts and government data. Or it could withdraw from the lab-testing business altogether, focusing on developing devices. That would significantly change its mission.

A third option is for Ms. Holmes, who couldn't own equity in or operate any lab for at least two years under the sanctions, to walk away from the enterprise built largely on her personality and vision of revolutionizing medicine with a way to cheaply perform dozens of tests with just a droplet of blood.

The company faces other threats, including a criminal probe by federal prosecutors of whether it misled investors and regulators, according to people familiar with the matter. Theranos also lost its main retail partner, the Walgreens drugstore chain, last month.

Theranos declined to comment beyond its news release and statements. In one, it said: "We accept full responsibility for the issues at our laboratory in Newark, California, and have already worked to undertake comprehensive remedial actions," including, it added, shutting down that lab, adding new medical experts and lab staff and improving its quality and training procedures and systems.

The sanctions could force the board to make some tough decisions.

"The ban is a blessing. It gives the company a way to go forward without Holmes, whose lack of credibility in the financial and clinical communities is sinking the company," said Erik Gordon, a professor at Ross School of Business at the University of Michigan. "If the company appeals the ban, it will destroy its claims that it is cooperating and is more likely to end in bankruptcy than a turnaround."

RELATED READING

- Read the full letter from CMS
- Hot Startup Theranos Has Struggled With Its Blood-Test Technology (Oct. 16, 2015)
- Theranos Is Subject of Criminal Probe by U.S. (April 18)

A person close to the matter said Ms. Holmes was unlikely to resign. Some at the company believe its survival chances are better with her than without her, the person said, adding that Theranos is likely to seek to work with the lab regulator, CMS, to resolve its problems before the sanctions take effect.

In a statement issued late Friday, Theranos said: "The company will continue to carry out its mission under the leadership of its founder and CEO."

A spokesman for CMS said the company can approach regulators to begin negotiations. Agency officials would take into account the ability of the lab to mitigate any danger to patients, the accuracy of records and its overall compliance history in assessing whether any agreement is appropriate.

In a July 7 letter to Theranos imposing the sanctions, CMS said the company continued to put patients in "immediate jeopardy," had provided conflicting information about when it stopped using its proprietary blood-testing system last summer, and kept inconsistent records of patient test results it voided or corrected.

"There is a possible patient impact for every test reported from the laboratory's [proprietary] instruments," the letter quoted Theranos's own corrective plan as saying.

Theranos voided all results from its proprietary device for 2014 and 2015, The Wall Street Journal reported in May.

In one of its statements Friday, Theranos played down any impact on patients, saying, "As of now, we have not been made aware—by CMS, physicians or patients—of any harm to patient health resulting from our tests."

The ban on Ms. Holmes would take effect at the same time as the lab's license revocation and be subject to the same appeals process.

Theranos was built around Ms. Holmes's self-described phobia of needles. She left Stanford at 19 with hopes of creating a company that would do for lab testing what Apple did to the personal-device industry. She attracted titans of industry and government to her board and was profiled often in magazines.

The Journal's reporting, beginning with an October report detailing former Theranos employees' concerns about the true capabilities and accuracy of its proprietary Edison device, challenged that narrative.

In January, CMS said the company's California lab posed an "immediate jeopardy to patient health and safety." In March, CMS proposed its sanctions, after rejecting a company plan to fix its problems.

Theranos said it has stopped all patient testing at the lab in California, though it won't be required to until its lab-testing license is revoked effective Sept. 5. Theranos hopes to continue operating its lab in Arizona.

If the sanctions are imposed, Ms. Holmes could no longer own equity in any private company operating any laboratories. She could remain at the helm only if the company shut all its labs, including the one in Arizona and a third it plans to open in Pennsylvania.

The appeals process could take months, and such appeals have rarely succeeded. A list of decisions on the agency's website shows it didn't lose a single such case from 2001 through 2010.

Jane Pine Wood, a partner at law firm McDonald Hopkins LLC who specializes in lab issues, called the situation "one where everything is pretty much stacked up against the lab."

Regulatory experts said the determination by CMS was highly unusual for a lab of such prominence. "I can't think of anything this severe ever happening to a clinical laboratory of this size and scale," said Geoffrey Baird, associate professor in the laboratory medicine department at the University of Washington.

In an acknowledgment its future might not include lab operations, Theranos said late Friday that labs form just one of its business units. It said its research and development arm doesn't depend on them, and it could continue "to build infrastructure and build on its mission of improving access through affordable diagnostic testing, and its proprietary technologies and accessible business model."

A criminal federal probe the Journal reported in April is continuing, people close to the matter said. It is examining whether Theranos misled investors and government officials, among other things, the people said, and investigators have interviewed several former employees.

Federal investigators have sought and obtained documents, including Theranos's initial contract with Walgreens and marketing material back to September 2010 saying Theranos could run "370+" tests through finger sticks, according to people familiar with the matter.

The letter CMS released Friday afternoon shows Theranos used its proprietary testing system on 12 different types of tests from 2013 to 2015.

Theranos issued a statement in April saying it continued to work closely with regulators and was cooperating fully with all investigations.

Write to John Carreyrou at john.carreyrou@wsj.com, Michael Siconolfi at michael.siconolfi@wsj.com and Christopher Weaver at christopher.weaver@wsj.com

EXHIBIT P

KELLER ROHRBACK L.L.P.

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IAN S. BIRK ❸
KENNETH A. BLOCH ❸
KAREN E. BOXX ❸
GRETCHEN FREEMAN CAPPIO ❸
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T. DAVID COPLEY ①⑩❸
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LAURA R. GERBER ❸
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KARIN B. SWOPE ❸
PAUL A. TONELLA ❸
HAVILA C. UNREIN ②⑨❸
GABE E. VERDUGO ❸
AMY WILLIAMS-DERRY ⑥❸
MICHAEL WOERNER ❸
BENSON D. WONG ❸
EDWIN G. WOODWARD ❸

① ADMITTED IN ARIZONA
② ADMITTED IN CALIFORNIA
③ ADMITTED IN COLORADO
④ ADMITTED IN IDAHO
⑤ ADMITTED IN ILLINOIS
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❷ ADMITTED IN OREGON
❸ ADMITTED IN WASHINGTON
❹ ADMITTED IN WASHINGTON, D.C.
❺ ADMITTED IN WISCONSIN

November 22, 2016

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Theranos, Inc.
Theranos Corporate Headquarters
1701 Page Mill Road
Palo Alto, CA 94304

Walgreens Boots Alliance, Inc.
Corporate Headquarters
200 Wilmot Road
Deerfield, IL 60015

Elizabeth A. Holmes, CEO
Theranos Corporate Headquarters
1701 Page Mill Road
Palo Alto, CA 94304

Re: *Notice of Claim – California Consumer Legal Remedies Act*

Dear Sir/Madam:

PLEASE TAKE NOTICE: This letter constitutes notice under California Civil Code § 1782, of violations of the California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.* by Theranos, Inc. ("Theranos"), Walgreens Boots Alliance, Inc. ("Walgreens"), and Elizabeth Holmes ("Holmes") (collectively, "Defendants").

This letter constitutes FURTHER NOTICE that Defendants' conduct also constitutes violations of California's Business and Professions Code §§ 17200 and 17500 (Unfair Business Practices and False Advertising) as unfair business acts and practices.

Please be aware that a prospective class of consumers demands that you remedy such violations within the time limits set forth in the above-referenced statutes.

BACKGROUND

We represent the Plaintiffs in a consolidated action filed on behalf of a prospective class of consumers who purchased Theranos lab tests ("Theranos Tests"). Many class members purchased Theranos Tests at a retail Walgreens location. The Theranos Tests were manufactured, marketed, distributed, promoted, and/or sold by Defendants. Defendants knowingly placed the Theranos Tests into the stream of commerce and purposefully misleadingly marketed and promoted its product to residents in the state of California, as well as other states.

Defendants marketed the Theranos Tests as "[t]he tiny blood test" and "the lab test, reinvented" that "can perform [ ] tests quickly and accurately on samples as small as a single drop." Defendants' marketing, representations, and/or statements misled and/or deceived consumers into believing Theranos Tests would provide accurate test results. However, Defendants have concealed and/or failed to disclose that Theranos Tests were, in fact, inaccurate. Rather, Defendants chose to engage in deliberately deceptive and unlawful practices designed to hide the truth. Defendants' representations were and continue to be misleading, deceptive, or false.

Plaintiffs and the consumers in the prospective class reasonably relied upon, and were reasonably deceived by, Defendants' representations regarding the Theranos Tests. As a direct and proximate result of Defendants' misrepresentations and unlawful and unconscionable commercial practices, Plaintiffs and the prospective class lost the money they paid for the Theranos Tests, were subjected to a blood draw process that was not what Defendants advertised, received unreliable test result, and faced the added cost of retesting.

DEMAND

Defendants have failed to honor their consumer protection obligations. We hereby demand that Defendants and each of them correct, replace, or otherwise rectify the Theranos Tests. We hereby notify you that a Consolidated Complaint seeking an injunction against Defendants has been filed, enclosed herein.

Please be advised that your failure to comply with this request within the time limits set forth in the statute above may subject you to the following remedies, as provided by applicable law:

1. The actual damages suffered;
2. Statutory and/or punitive damages;
3. An injunction;
4. Restitution of property;
5. Any other relief which the court deems proper; and
6. Court costs and attorneys' fees.

This letter is not meant to be a complete statement of facts or demands. Nor should anything contained herein be deemed a waiver of our clients' rights, defenses, or claims, all of which are expressly reserved.

Sincerely,

T. David Copley
Interim Co-Lead Plaintiffs' Counsel

Enclosure

cc: (via email)
Amy J. Mauser
Evan Edmund North
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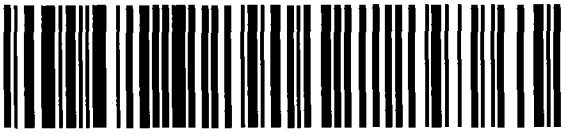

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EXHIBIT Q

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Interim Co-Lead Plaintiffs' Counsel

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In re: Arizona THERANOS, INC., Litigation	**No. 2:16-cv-2138-HRH** **(Consolidated with)** **No. 2:16-cv-2373-HRH** **No. 2:16-cv-2660-HRH** **-and-** **No. 2:16-cv-2775-HRH** **CONSUMER LEGAL REMEDIES ACT VENUE AFFIDAVIT OF PLAINTIFF A.R. [CCP § 1780(d)]**

I, A.R., hereby declare and state as follows:

1. I am over the age of 18 and a Plaintiff in this action. The facts contained in this declaration are based on my personal knowledge and information and I have gathered that is available to me, and if called upon to do so, I could and would testify to the matters stated herein.

2. I make this affidavit as required by California Civil Code § 1780(d).

3. The complaint in this action is filed in the proper place for trial of this action because Defendants have conducted and continue to conduct business in the State of Arizona, and because Defendants have committed acts and omissions complained of herein in the State of Arizona.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on November 21, 2016.

DocuSigned by:
Plaintiff A.R.
F01F0A66158D412...
Plaintiff A.R.