HAGENS BERMAN SOBOL SHAPIRO LLP
Shana E. Scarlett (SBN 217895)
715 Hearst Avenue
Berkeley, California 94710
Telephone: (510) 725-3000
Facsimile: (510) 725-3001
shanas@hbsslaw.com

Steve W. Berman (*Pro Hac Vice* pending)
HAGENS BERMAN SOBOL SHAPIRO LLP
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594
steve@hbsslaw.com

HAGENS BERMAN SOBOL SHAPIRO LLP
Robert B. Carey (*Pro Hac Vice* pending)
11 West Jefferson, Suite 1000
Phoenix, Arizona 85003
Telephone: (602) 840-5900
Facsimile: (602) 840-3012
rob@hbsslaw.com

Attorneys for Plaintiff

(Additional Counsel on signature page)

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CASEY JONES, individually and on behalf of all others similarly situated,

Plaintiff,

v.

THERANOS, INC., a California Corporation,

Defendant.

No. 3:16-cv-02835

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

I. INTRODUCTION

1. Used for diagnostics and prevention, accurate, reliable, timely blood tests are a critical component of a patient's healthcare. Inaccurate tests cause emotional distress, lead to unnecessary and improper medical care, and endanger patients' health and lives.

2. To avoid these problems, lab operators must follow established policies and procedures, provide accurate information about the test—so patients' decisions are grounded in fact —and ensure that test results are not needlessly inaccurate.

3. Founded in 2003 by Elizabeth Holmes, Theranos, Inc. claims to be a "consumer health technology company," one that entered the laboratory testing market and focused on blood-based tests.

4. According to its website, its "mission is to make actionable health information accessible to people at the time it matters, enabling early detection and prevention of disease, and empowering people with information to live the lives they want to live."

5. As revealed in this Complaint, Theranos was focused more on press and market value than the health of its customers, and it achieved the opposite of its mission: it obfuscated its actions and tests to where no reasonable consumer can rely on the results provided or make health care decisions based on them.

6. Plaintiff sues to address these massive failures on issues relating to customer health, including Theranos using substandard laboratory policies and procedures, failing to honor the promises it made about testing accuracy and quality, concealing and obscuring the truth about the invasiveness of the tests, providing inaccurate test results to patients and not correcting those results when possible after a reasonable person would understand the results were or could be erroneous, and misrepresenting the technological advances that Theranos allegedly developed.

II. PARTIES

7. Defendant Theranos is a California corporation with its principal place of business at 1701 Page Mill Road Palo Alto, California 94304.

8. Theranos operates blood testing labs in California and Arizona.

9. Plaintiff Casey Jones is a resident of Maricopa County, Arizona.

III. JURISDICTION AND VENUE

10. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(a) and (d). In the aggregate, Plaintiff's claims and the claims of other Class members exceed $5,000,000, exclusive of interest and costs, and numerous Class members are citizens of different states than Defendant Theranos.

11. This Court has personal jurisdiction over Plaintiff because Plaintiff submits to the Court's jurisdiction. This Court has personal jurisdiction over Defendant because Defendant is headquartered in the District and conducts substantial business in the District. Many of the actions establishing the Complaint took place in the District, to include upon information and belief the creation and final approval of the allegedly false marketing materials.

12. Venue is proper in this District under 28 U.S.C. § 1391 because Defendant, as a corporation, is "deemed to reside in any judicial district in which they are subject to personal jurisdiction," and because many decisions behind the scheme to mislead consumers regarding the accuracy, reliability, and operation of the Theranos blood tests were made in this District.

13. Because Theranos resides in the District, transacted business within the District, and a substantial part of the events establishing the claims arose in this District, venue is proper.

IV. BACKGROUND

14. For its first retail endeavor, Theranos joined with Walgreens to bring its self-proclaimed "revolutionary" blood tests directly to the public, hoping to eventually provide its services nationwide.

15. Theranos went live with its Walgreens venture in September 2013, and eventually opened 56 "Theranos Wellness Centers" in Arizona and California.

16. The Theranos Wellness Centers are physically located in Walgreens, and staffed by Theranos employees.

17. Theranos also opened two non-Walgreens based Theranos Wellness Centers, one at the downtown Phoenix campus of Arizona State University and the other at the Generations Medical Center in Tempe, Arizona.

18. In addition to providing space for the Theranos Wellness Centers, Walgreens helped fund Theranos with a $50 million financing arrangement and assisted Theranos in scheduling and collecting payments from consumers.

19. At the Wellness Centers, Theranos offered a comprehensive slate of some 200 lab tests.

theranos

the blood tests that need just a tiny sample.

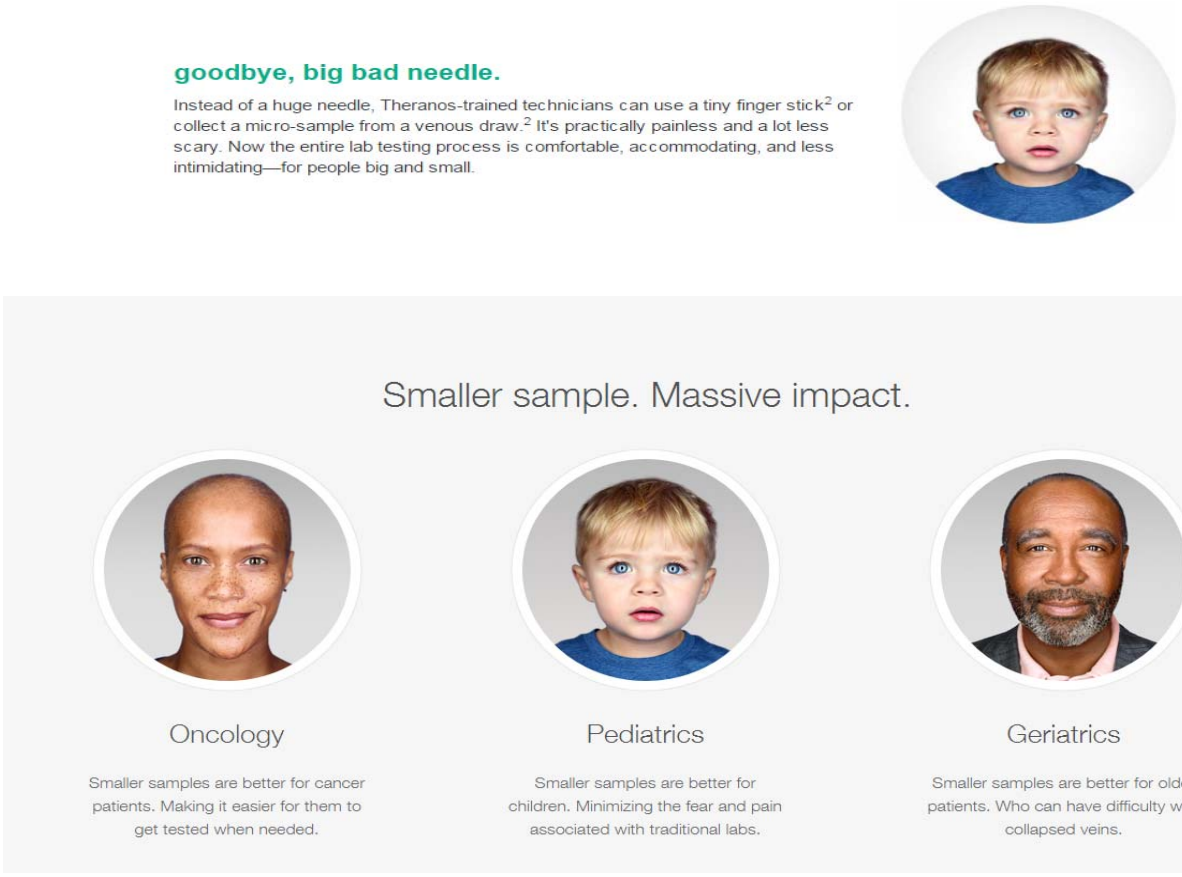
Walgreens partners with Theranos to provide lab services

Theranos is working to shape the future of lab testing. Now, for the first time, their high-complexity CLIA-certified laboratory can perform your tests quickly and accurately using tiny samples.[1]

Learn more at Theranos.com

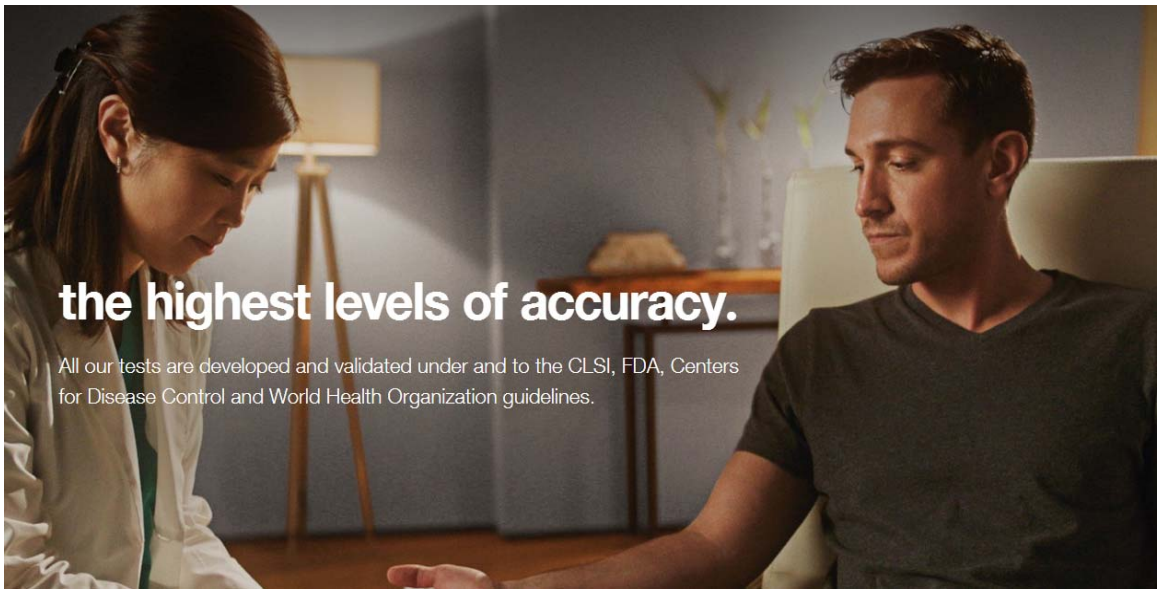
Para información en español haga clic aquí

20. The key feature Theranos used to market its tests and differentiate itself was that it brought a new technology and approach to the staid, established blood test industry. Its tagline: "one tiny drop changes everything." This theme was prominent in its advertisements: Theranos boasted it could analyze samples as small as 1/1,000 the size of the typical blood draw and perform tests on any sample type, including blood, urine, and other samples. "It's fast, easy, and the highest level of quality," Theranos informed prospective customers. Theranos stressed it used smaller samples and less invasive techniques, pushing this difference in advertisements and on company web pages:



21. It also advertised its venous blood draws used smaller needles and smaller tubes.

22. Despite using tests requiring only a little blood, Theranos promised consumers it could still deliver the best in accuracy and quality.



23. It announced that it would "realize our mission only when our tests are performed to the highest standards of quality.

24. It endorsed that getting accurate results in a timely manner is essential, declaring "what you decide about your health should be informed and timely enough to protect or improve it.

fast results. fast answers.

Theranos performs their test analyses fast, so they can return results to your clinician[3] faster than ever before.[3] That means a more timely diagnosis to support better, more informed treatment.

25. Theranos summed up its approach this way, "Our technology and our process are all configured to put you and your preventive outcomes first."

26. Theranos claimed vigilance in providing the highest quality tests. "We continuously conduct proficiency testing and participate in multiple proficiency testing programs," and all of our "tests are developed and validated under and to the CLSI, FDA, Centers for Disease Control and World Health Organization guidelines," touting that it had "processed hundreds of thousands of tests in validating our work for 10 of the 15 largest pharmaceutical companies."

27. It claimed to have performed "more than six million tests in the nearly two years since we began serving individuals and physicians through our clinical labs," and worked with over 9,000 physicians.

28. Theranos claimed it was leading the industry in transparency.

> Theranos is the first lab to commit to voluntarily submitting its laboratory developed tests to the FDA. We are working to build a model for the transition to the FDA framework. We are doing this even though we don't need to – opening up to regulators like no lab before.

29. Theranos also claims to be leading the lab industry in transparency by publishing Proficiency Testing performance statistics.

30. It boasted its consumer experience was all-around better. "Our tests use less blood to make the testing experience as wonderful as possible for everyone."

31. "Theranos' revolutionary lab services make tests more efficient, convenient, and affordable than ever before."

32. To help sell its products, Theranos preached that patients should have and deserved timely, accurate information, so they could "engage with their own health and begin working with their doctors preventatively."

33. To help further its bottom line, Theranos pushed to change Arizona law, and succeeded. Arizona became the first state to allow consumers to purchase a blood test without a provider's order and to "expressly recognize[] individual's [sic] rights to their own health information."

34. To accomplish this, Theranos worked closely with leaders in Arizona. Its assistance came from the top: Arizona Governor Doug Ducey wholeheartedly adopted Theranos' claims and pressed to change the law for Theranos to do business.

35. Theranos' lobbying resulted in Ducey having a favorable impression: "My administration is focused on making Arizona the easiest and most attractive place in the nation for 21st-century companies like Theranos to operate and grow. By reducing burdensome regulations and red tape, this law not only shows innovative companies we're open and ready for business, it also gives Arizonans access to more efficient, cost-effective services while promoting preventive health care and price transparency. That's good for business, good for patients and providers, and good for taxpayers – an all-around win for Arizona."

36. Later, Elizabeth Holmes in a letter to the editor of the Arizona Republic on December 1, 2015, reiterated Theranos' commitment to the highest standards for testing and quality: "Theranos fought for direct access in Arizona to bring high-quality … lab testing to everyone. We have fought—and always will fight—for the highest quality standards for Arizonans…."

37. In lobbying to change the law, Theranos disseminated claims of astonishing advancements in the lab testing industry.

38. "We can perform hundreds of tests, from standard to sophisticated, from a pinprick and tiny sample of blood, and we have performed more than 70 tests from a single tiny sample," said a Theranos representative.

39. According to Holmes, the claim went even further—Theranos' new technology applied across the board: "Every test that we offer in our lab can be run on our proprietary devices." Espousing this claim—that the Edison machines can run all tests Theranos submitted to the FDA—on a nationally syndicated financial TV program helped bolster Theranos' prospects and reputation with many stakeholders.

40. At some point, money came easy to Theranos as its reputation grew. According to CrunchBase, Theranos raised:

Funding Rounds (8) - **$686.3M** UPDATE

Date	Amount / Round	Valuation	Lead Investor	Investors
Mar, 2015	$348.5M / Private Equity	—	—	0
Feb, 2014	$198.9M / Private Equity	—	—	0
Sep, 2013	$50M / Undisclosed	—	Walgreens	1
Jul, 2010	$45M / Venture	—	—	0
Nov, 2006	$28.5M / Series C	—	—	4
Feb, 2006	$9.1M / Series B	—	—	1
Feb, 2005	$5.8M / Series A	—	—	0
Jun, 2004	$500k / Seed	—	Draper Fisher Jurvetson (DFJ)	1

41. Theranos adeptly spun its storyline about its successes and "revolutionary" testing. It pushed and embraced positive, glowing reports of the company's "transformative" nature and industry-changing technologies. These efforts spanned the media spectrum—old and new, big and small—including The Wall Street Journal, Business Insider, San Francisco Business Times, Fortune, Forbes, Medscape, and Silicon Valley Business Journal. The reports adopt Theranos' assessment that its work is novel and the coming of a "golden idea":

- "Theranos: The Biggest Biotech You've Never Heard of."
- San Francisco Business Times, August 30, 2013.
- "Elizabeth Holmes: The Breakthrough of Instant Diagnosis."
- Wall Street Journal, September 8, 2013.
- "Creative disruption? She's 29 and Set to Reboot Lab Medicine."
- MedPageToday, November 18, 2013.

- "This CEO is Out for Blood."
- Fortune, June 12, 2014.
- "Bloody Amazing."
- Forbes, 7/2 and 7/21, 2014.
- "Meet Elizabeth Holmes, Silicon Valley's Latest Phenomenon."
- San Jose Mercury News, July 15, 2014.
- "This Woman's Revolutionary Idea Made Her A Billionaire—And Could Change Medicine."
- Business Insider, September 29, 2014.
- "She's America's Youngest Female Billionaire - And a Dropout."
- CNN/Money, October 16, 2014.
- "Here's How the World's Youngest Self-Made Female Billionaire Shows People She's In Charge."
- Business Insider, December 8, 2014.
- "Top 10 Most Innovative Companies in Health Care, 2015: #7, Theranos."
- Fast Company, February 2015.
- "Theranos CEO: Avoid Backup Plans."
- INC., Stanford Business School, February 10, 2015.
- "Elizabeth Holmes: 2015 Horatio Alger Award Winner."
- Horatio Alger Association, March 9, 2015.
- "Theranos One Step Closer to Consumerizing Health."
- Decibio, April 8, 2015.
- "Elizabeth Holmes." 100 Most Influential People edition.
- TIME, April 16, 2015.
- "World's Youngest Billionaire - Another Steve Jobs?"
- CNBC, April 27, 2015.
- "Airbnb Chesky, Theranos Holmes among presidential entrepreneurs."
- USAToday, May 11, 2015.
- "Personalized Technology Will Upend the Doctor-Patient Relationship""

- Harvard Business Review, June 19, 2015.
- "Disruptive Diagnostics Firm Theranos Gets Boost from FDA."
- Fortune, July 2, 2015.
- "Theranos' Holmes Marks 50th Anniversary of Medicare and Medicaid with Vision for Next 50 Years."
- Business Wire, July 30, 2015.
- "Elizabeth Holmes on Using Business to Change the World."
- Forbes, October 5, 2015.
- "How Theranos is Disrupting the Health Care Industry."
- Bloomberg, October 6, 2015.
- "Theranos Founder Elizabeth Holmes to Deliver Keynote Address at 2015 Medical Innovation Summit."
- Crain's Cleveland Business, October 7, 2015.
- "Theranos' Elizabeth Holmes Call on Women to Help Each Other."
- Fortune, October 12, 2015.
- "CME Group Announces Elizabeth Holmes as the 2015 Melamed-Arditti Innovation Award Recipient."
- MarketWatch, October 12, 2015.

42. The result of Theranos' promotional efforts: a market value over $9 billion by 2014 and a CEO widely acclaimed as one of the most successful entrepreneurs in the world—and one of the youngest billionaires ever.

43. Theranos purposely ginned up excitement and funding, pushed it was disrupting an antiquated, stodgy industry, and shrouded its product in secrecy. Theranos, however, didn't keep its promises that its services allow consumers to proactively engage in their own healthcare decisions using accurate, timely information provided by Theranos. As one health reporter said, "New innovations can't simply surf on excitement when people's lives are at stake."

44. Theranos also advertised its tests on Walgreen's website promising a test that would support "better, more informed treatment":

Theranos Lab Testing at Walgreens

- the lab test, reinvented.

At Theranos, we're working to bring about a day when lab testing is accessible and affordable for everyone. So people can engage with their health and their physicians like never before, and no one has to say goodbye too soon.

Learn more at theranos.com ›

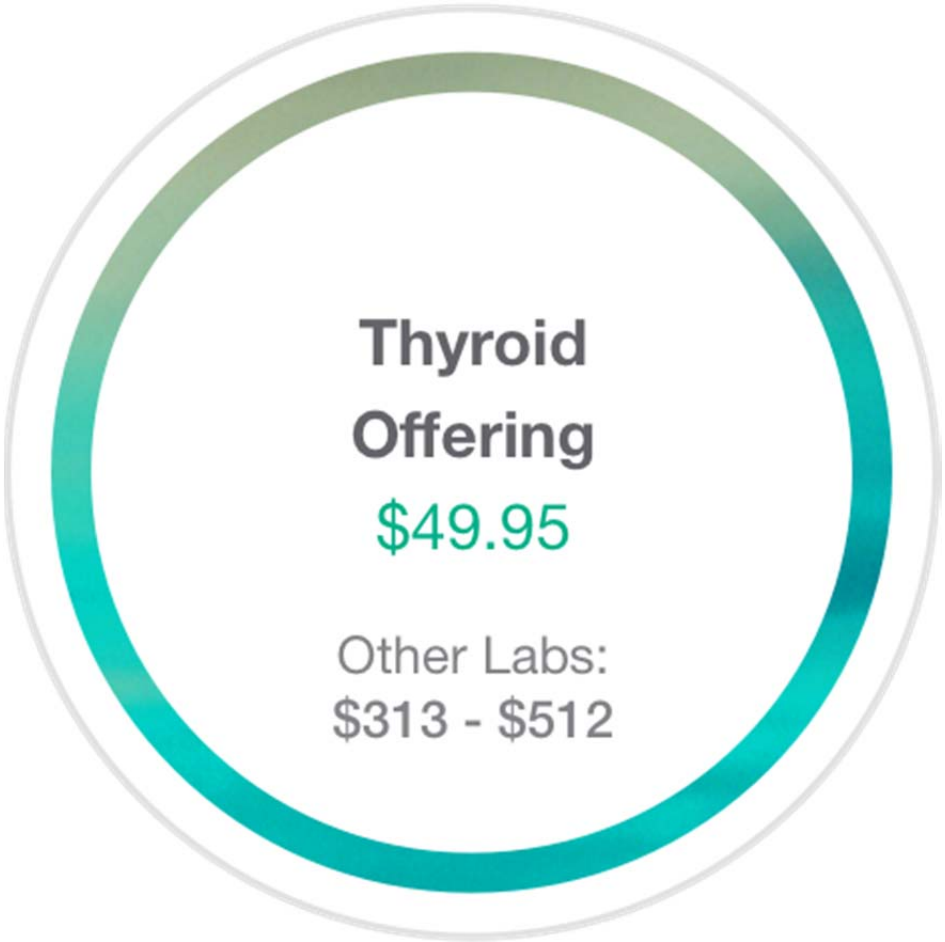
- Visiting or living in Arizona?

Learn more about Direct Access testing at Theranos Wellness Centers ›

- **Theranos is easy to find.**

You can find Theranos Wellness Center™ locations inside select Walgreens in the greater Phoenix, AZ area. With extended hours, including nights and weekends it's easy to fit your tests into your busy schedule.

To evaluate organ function and check for conditions such as diabetes, liver disease, and kidney disease


Thyroid
Offering
$49.95
Other Labs:
$313 - $512
To evaluate
thyroid function


STI Comprehensive Offering
$59.95
Other Labs:
$924 - $1,019
To screen for and diagnose sexually transmitted infections

To help evaluate
insulin production

- Fast results. Fast answers.

At Theranos, we've dramatically reduced the time it takes to analyze samples. So you and your physician get your results faster than ever before.[1] Which means a more timely diagnosis to support better, more informed treatment. So you can engage with your physician, and your health, like never before.[1]

45. Behind the claims of revolution and disruption, there were unfounded, false, deceptive, and misleading claims of superiority over existing systems and practices.

46. First, Theranos' labs were negligently maintained and operated and it did not follow proper procedures and policies.

47. On March 18, 2016, Centers for Medicare & Medicaid Services wrote Theranos to notify it of proposed sanctions against Theranos' Clinical Laboratory Improvement Amendments of

1988 (CLIA) certificate. CLIA is a federal regulatory standards program whose goal is to ensure accuracy, reliability and timeliness of test results, regardless of where the test was performed, for all clinical laboratory tests on humans.

48. CMOS conducted a CLIA recertification and complaint survey at Theranos' laboratory, completing its onsite portion on November 20, 2015 and concluding the survey on December 23, 2015.

49. Based on this survey, Theranos was out of compliance with five CLIA Condition-level requirements, including (a) D5024: 42 C.F.R. § 493.1215; (b) D5400: 42 C.F.R. § 493.1250; (c) D6076: 42 C.F.R. § 493.1441; (d) D6108: 42 C.F.R. § 493.1447; and (e) D6168: 42 C.F.R. § 493.1487.

50. In a January 25, 2016, letter, CMS outlined these deficiencies and notified Theranos of the seriousness of the deficiencies under 42 C.F.R. § 493.1215, which resulted in a finding of immediate jeopardy to patient safety and health, and demanded immediate action to remove the jeopardy and come into compliance.

51. Theranos, after requesting an extension, responded on February 12, 2016.

52. After reviewing Theranos' response, CMS concluded that Theranos' response did not "constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015, and does not demonstrate that the laboratory has come into Condition-level compliance and abated immediate jeopardy."

53. A credible allegation of compliance is a statement or document that is (1) made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required; (2) realistic in terms of the possibility of corrective action being accomplished between the survey and the date of the allegation; and (3) indicates resolution of the problem.

54. The report found that Theranos' blood tests often failed to meet the lab's own standards, and that Theranos employed unqualified staff to review patient test results.

55. According to the Wall Street Journal, which viewed an unredacted report, 13 tests conducted on Theranos' inventions performed poorly. Examples include (1) 29 percent of the quality control checks performed on the company's inventions in October 2014 fell outside the normal range; (2) a hormone test run on Theranos' proprietary machines failed 87 percent of quality control checks; and (3) a test used to detect prostate cancer failed quality control verifications 22 percent of the time between April and May 2015.

56. Second, Theranos pushed its revolutionary, fast, minimally invasive techniques on cutting edge technology, yet that is not what consumers received when they went to the Walgreens stores.

57. Theranos' new technology did not extend to its entire product line and, even where it did, it was not always used.

58. Theranos told regulators it used the Edison, its proprietary device, for 12 types of tests out of over 200 types offered to consumers and stopped using the devices altogether in late June 2015.

59. Consumers arrived expecting to have minimal blood drawn and small needles or finger pricks, but they got conventional venous blood draws.

60. Likewise, the tests were often then run on standard testing equipment (operated incorrectly or with inadequate training), not the novel technology touted in the promotional efforts or marketing material.

61. Even when the technology existed, it wasn't used. Theranos consequently halted its finger-stick draws, collected in a small tube called a nanotainer, after the FDA declared the container was a medical device that should be regulated. Theranos ceased using its proprietary technology, nicknamed Edison, in June 2015.

62. Theranos' Arizona lab handled the vast majority of blood samples collected at Arizona-based Walgreens locations and at Arizona State University's clinic and the Generations Medical Center.

63. The June 2015 decision to cease using Edison did not affect the company's Arizona lab because it exclusively used traditional FDA-approved blood analyzers and instruments made by companies such as Siemens and Olympus.

64. Arizona patients could have blood drawn through capillary draw or venous draw, and the samples would be sent to the applicable lab by Theranos. But Theranos did not inform consumers it had new technology only for twelve of the 200 tests and that conventional equipment would be used for many tests. Nor did Theranos advise that the blood draw might not be the minimally invasive draw, a fact consumers learned only during the blood draw.

65. Third, contrary to its mission statement, Theranos did not strive to provide accurate information to its consumers so they could make an informed choice.

66. Its path to success was far from open and public. Despite its claims of transparency, Theranos kept information about its technology and blood tests secret.

67. Holmes most descriptive statements, was that Theranos uses "the same fundamental chemical methods" as existing labs do, and its advances relate to "optimizing the chemistry" and "leveraging software" to permit those conventional methods to work with tiny sample volumes.

68. Nor has Theranos engaged the scientific community. Theranos, to this day, has not published on its work in peer-reviewed biomedical literature. Reportedly, by January 5, 2015, a search for Theranos in PubMed returned only two unrelated articles co-authored by Theranos employees, neither of which offered insights about the company.

69. Holmes has said the company has proof its tests are as accurate as traditional ones, but has provided no support for the statement.

70. To allay criticism of Theranos' tests, its spokesperson promised that Theranos planned to publish data "in the near future. Stay tuned!" Despite its promise, no data have been forthcoming on this topic.

71. Theranos did not even disclose its methodologies to its medical services partners. As part of a "long-term strategic alliance" to use Theranos' technology, the Cleveland Clinic and Theranos agreed to a joint study that would compare the effectiveness of Theranos' approach to traditional approaches. In January, three Cleveland Clinic scientists visited Theranos' headquarters,

where they were shown the company's Edison devices but Theranos did not show the scientists how the devices worked or provide written materials on how exactly the machines operated.

72. Because details of the Theranos technology have not been disclosed, peers cannot evaluate or comment on its claims. As a leading physician has noted, "The quality of the results are [sic] not known since the Theranos system has not been independently evaluated, nor do any published results exist to compare with conventional technologies. New diagnostic tests must be evaluated for their accuracy, precision, specificity and long-term robustness. Trueness and precision (accuracy) must be maintained over months or years, and monitored by external quality assurance programs, so that patient's data can be directly compared over long periods of time. Without independent validation, Theranos technology's quality and robustness will remain in question."

73. Without such review and assessment, patients receive the opposite of what was promised. They must manage their health based on assumptions and promises, not timely, accurate information.

74. Fourth, Theranos' promises of the highest levels of accuracy and quality are unfounded, false and misleading.

75. A study showed that Theranos' results are not as accurate as the two dominant players in the industry. In March 2016, Theranos' results were compared to those from LabCorp and Quest Diagnostics in a study funded by Icahn Institute for Genomics and Multiscale Biology and the Harris Center for Precision Wellness at the Icahn School of Medicine at Mount Sinai.

76. The percentages for measurements outside their normal range were 8.3%, 7.5%, and 12.2% for LabCorp, Quest, and Theranos, respectively. Although LabCorp and Quest showed no significant difference in the rates of their tests outside the reference range, the odds ratio that Theranos reported a measurement outside its normal range compared with the other services was 1.6.

77. This increase in abnormal test results can have negative consequences for medicine—usually extra testing, additional patient visits to clinics or hospitals, and added doctor services, all of which result in additional costs and burdens to patients or to the healthcare system and are potentially harmful where the abnormal tests were misdiagnoses (*i.e.*, false positives).

78. Nor did Theranos' labs meet state and federal standards—all of which are designed to protect patients.

79. Arizona inspectors claimed that Theranos could not provide back-up data showing that it had fully validated three lab instruments used to analyze test samples despite federal regulations requiring labs to furnish such data.

80. Theranos also failed to meet proficiency testing and lab-instrument validation requirements, which are key to ensuring patients and doctors get accurate results.

81. During a separate inspection, the Federal Drug Administration issued 14 "observations" after a review of Theranos' testing facilities in California from Aug. 25 through Sept. 16. Most findings addressed problems with quality-control issues, but notably the FDA determined Theranos' nanotainer was an unapproved medical device.

82. Fifth, consumers are not getting what they paid for when they receive blood tests from Theranos.

83. In May 2016, Theranos voided two years of test results—comprising tens of thousands of tests—from 2014 and 2015, and corrected some results and did not revise others, leaving the void results as the only result the consumer received.

84. These tests were conducted on both Edison equipment and conventional tests, and at multiple labs.

85. It was reported that the Arizona lab performed the blood-coagulation tests with a traditional machine from Siemens AG programmed to the wrong settings by Theranos, and failed several tests to gauge the purity of the water it used in its Siemens machines, which could affect the accuracy of some blood tests run on the devices.

86. Brooke Buchanan, a Theranos spokeswoman, confirmed that Theranos "made mistakes in the past in the Newark" lab, which housed the Edison.

87. Based on reports, both Theranos laboratories have been identified as operationally deficient in material ways.

88. Theranos' cure for deficient results was to re-run tests using conventional means with either the residual blood from the minimal draw or with blood already tested (presumably an amount

that wouldn't work with traditional machines, since Theranos' approach was the "first time" testing was accomplished using small amounts of blood), calling into question the reliability of any re-testing program.

89. Theranos has also misrepresented the import of the timeliness of its results.

90. Theranos claims the usual delay of testing in centralized laboratories is approximately three days and that they will generate and deliver their data much faster (*e.g.*, within four hours).

91. But according to a leading practitioner, the three-day delay claim is not accurate. The bulk of laboratory testing in centralized laboratories is completed within an hour or two (calculated from time of sample collection to time of results posting for physician review). For these tests, the claim that Theranos gets results faster is false. While there may be some tests that takes days, not hours, those are typically situations where time is not critical for adjusting patient care and faster analysis will not assist patient management or outcomes.

V. FACTUAL ALLEGATIONS CONCERNING PLAINTIFF

92. On September 2, 2015, Casey Jones visited a Theranos Wellness Center at the Walgreen's located at 3960 E Chandler Blvd, Phoenix, AZ 85048, on orders from his physician, Dr. Matthew Anastasi, to obtain a blood panel as part of a routine annual physical.

93. One reason Mr. Jones considered having the blood tests performed at the Theranos Wellness Center was that he and his wife were trying to get pregnant at the time and the store had several advertisements regarding the ability to order additional labs by simply checking extra boxes on the requisition form.

94. One additional, voluntary test was titled "reproductive health." Because Mr. Jones and his wife were concerned with his reproductive health, Mr. Jones had the reproductive health test performed at the Theranos Wellness Center.

95. When Mr. Jones' doctor provided him with the lab order, he explained he could go to any lab he desired and provided him with maps to LabCorp and Theranos.

96. Dr. Anastasi spoke highly of Theranos as a new technology that is minimally invasive, requiring only a small "prick" of blood to perform the panel of tests. He also noted they are conveniently located in Walgreen's stores and are open for walk-in appointments.

97. Besides the information he received from his doctor, Mr. Jones learned about Theranos from the heavy media coverage and business press about their founder and CEO and the self-proclaimed remarkable changes they were making to the industry.

98. An additional benefit in choosing Theranos was the option to have results delivered immediately upon the completion of the tests via an Android app. Mr. Jones downloaded the app and received his lab results electronically.

99. Based the ease of draw, convenience, implied accuracy and credibility of Theranos' new technology, and ability to obtain additional tests, Mr. Jones chose the option of having his tests performed at the Theranos Wellness Center.

100. Convenience was important to Mr. Jones because the lab was in his neighborhood and he was about to leave town for a trip.

101. Because some tests were ordered by his physician and others by Mr. Jones, the physician ordered tests were billed to his insurance and the tests ordered by Mr. Jones were paid by him personally that day.

102. Mr. Jones paid $77.70 for the tests he personally opted to have performed by Theranos.

103. Theranos conducted approximately 69 tests: six tests were performed at the Theranos lab at 7373 Gateway Boulevard, Newark California, 94560 and approximately 63 tests were performed at the Theranos lab at 1365 N. Scottsdale Rd., Scottsdale Arizona 85257.

104. Upon arriving at Walgreens, Mr. Jones' experience differed greatly from what was promoted. He had several large vials of blood drawn—upon information and belief the same as what he would have had drawn at any other lab. There was no disclaimer made to Mr. Jones about this apparent change in the blood draw procedure.

105. The final report from Theranos, dated September 4, 2015.

106. Shortly after the blood draw, Mr. Jones read that Theranos (a) has a technology that does not work and (b) has serious quality control problems in their labs.

107. Because of the reported issues with Theranos, Mr. Jones has serious concerns about the lab results he received, including concerns regarding the reliability and accuracy of the tests.

VI. CLASS ALLEGATIONS

108. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiff seeks certification of the following class:

109. All consumers who purchased a Theranos blood test in California or Arizona.

110. Plaintiff also seeks certification of the following subclass.

111. Arizona Subclass: All consumers who purchased a Theranos blood test in Arizona.

112. Excluded from the Classes are Defendant; the officers, directors or employees of Defendant; any entity in which Defendant has a controlling interest; and any affiliate, legal representative, heir or assign of Defendant. Also, excluded from the Class are any federal, state or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

113. Plaintiff does not know the exact number of Class members. But Theranos claims to have conducted millions of tests, meaning there are at least tens of thousands of Class members such that joinder of all Class members is impracticable.

114. The Class is easily determined by objective criteria using Defendant's own records, which by law must exist. Theranos knows where each test was performed, by whom, for whom, and when.

115. There are questions of law and fact common to the Class. Defendant's illegal business practices and unlawful omissions similarly impact Class members, all of whom purchased a Theranos blood test.

116. Plaintiff asserts claims that are typical of the Class. Plaintiff and all Class members have been subjected to the same wrongful conduct because they all purchased a Theranos blood test marketed and sold by Theranos using the same marketing or substantively similar marketing materials or received a test conducted or handled in a similar way. And like other members of the Class, Plaintiff purchased and paid for a Theranos blood test which he otherwise would not have paid for had the test been properly marketed based on truthful and accurate information or did not receive the test promised or due as a matter of law.

117. As a purchaser of Theranos' services, Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff and the Class are represented by counsel competent and experienced in both consumer protection and class action litigation.

118. Class certification is appropriate because common questions of law and fact substantially predominate over questions that may affect only individual members of the Class, including:

a. Whether Theranos' blood tests were suitable or merchantable.

b. Whether Theranos' methodologies and equipment complied with industry, state, and federal standards.

c. Whether Theranos' blood tests were as represented or promised.

d. Whether Theranos' blood tests were of the highest accuracy and quality.

e. Whether Theranos misrepresented its tests were minimally invasive, accurate, and reliable.

f. Whether Theranos' conducted violation the UCL.

g. Whether Theranos' conducted violated California's false advertising laws.

h. Whether Theranos' conduct violated the Arizona Consumer Fraud Act.

i. Whether the challenged practices harmed Plaintiff and members of the Class; and

j. Whether Plaintiff and members of the Class are entitled to damages, restitution, equitable relief, and/or injunctive relief.

119. A class action is superior to other available methods for the fair and efficient adjudication of this controversy, since joinder of all the individual Class members is impracticable. Because the restitution and/or damages suffered, and continue to be suffered, by each individual Class member may be relatively small, the expense and burden of individual litigation would make it very difficult, if not impossible, for individual Class members to redress the wrongs done to each individually and the burden imposed on the judicial system would be enormous.

120. A class action is manageable, conserves judicial resources and the parties' resources, and protects the rights of each putative class member.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION
(BREACH OF CONTRACT)

121. Plaintiff incorporates the allegations in the above paragraphs as if fully set forth herein.

122. Defendant Theranos entered uniform or substantially similar contracts with class members to provide blood tests.

123. Theranos assured its customers it had the expertise and capability to provide accurate and reliable blood tests. Theranos promised that its tests were the most accurate and highest quality tests in the market.

124. For monetary consideration, Theranos agreed to provide blood testing using its proprietary system.

125. Plaintiff and putative Class members each paid money for the blood tests offered by Theranos. Plaintiff paid $77.70 for the Reproductive Health blood tests and his insurer paid for routine blood work related to his annual physical.

126. Theranos breached its contract with Plaintiff and putative class members by (1) providing tests that were not of the promised high level of accuracy and quality, (2) conducting tests using traditional blood testing methodologies and equipment instead or its self-proclaimed minimally invasive state-of-the art proprietary system, (3) not drawing blood in the minimally invasive way advertised, (4) not ensuring its equipment met its own quality standards, (5) not ensuring its services were tendered with reasonable care and workmanlike effort, including failing to ensure its equipment met industry, state, or federal standards and failing to ensure lab staff was properly trained and monitored, and (7) failing to act in good faith and deal fairly with class members by acting to deprive class members of the justified expectations they were to receive under the contract, including failing to notify class members in a timely fashion of the deficiencies and problems with the tests or their results and not clarifying that certain services were conventional and no different than other blood tests on the market.

127. In May 2016, Theranos invalidated the results of all tests conducted using its Edison system between 2014 and 2015. Each class member who had a test conducted using the Edison system did not receive the benefit of its bargain—a reliable, accurate blood test.

128. Theranos claims it is issuing corrected results, but upon information and belief it is impossible re-test samples and give accurate and reliable updated results from samples taken in 2014 and 2015, especially when the blood draws should have been minimally invasive, small sample sizes according to Defendant's own advertisements. Even if the samples could be re-tested, there is no reason to believe that the new results would be accurate or reliable, nor are they useful to consumers months or even years after the date.

129. Because of Defendant's conduct, Plaintiff and Class members have been injured.

SECOND CAUSE OF ACTION

(ARIZONA CONSUMER FRAUD)
(ARIZONA SUBCLASS ONLY)

130. Plaintiff incorporates by reference the allegations in the above paragraphs as if fully set forth.

131. Defendant's advertising and website made use of deception, deceptive acts, unfair acts, fraud, false pretenses, false promises, misrepresentations, concealments, suppression of material facts, and/or omission of material facts in connection with the sale and advertisement of its services in violation of the Arizona Consumer Fraud Act, Arizona Revised Statute § 44-1522 (A).

132. These acts include, but are not limited to:

- Advertising its tests are the most accurate in the industry when they are the least accurate.
- Advertising its proprietary Edison machine can test blood accurately and reliably using smaller quantities of blood than traditional methods even though each claim is false. By Defendant's own admission, all tests conducted using the Edison machine between 2014 and 2015 are invalid and should be voided.
- Advertising that many of its tests are minimally invasive, requiring a skin prick or small vial of blood when in reality the tests require a traditional blood draw by the same size needle and vial used by its competitors.
- Advertising its proprietary technology as if it exists and is used for all Theranos tests when it only exists for a small fraction of the tests Theranos markets and sells.

- Advertising it performs the highest quality testing in the industry when its testing procedures and equipment are flawed and fail to meet its own standards, standards set by the manufacturer, and industry, state, or federal standards.
- Advertises its goal is to give consumers actionable information but conceals and obfuscates on the methodologies of its tests.
- Failing to notify consumers in a timely manner that its tests were inaccurate and voidable despite knowing that the tests were not reliable or accurate.

133. Theranos intended that others rely on the concealment, suppression or omission of material facts by, among other things, promising to disclose the results of independent testing of its equipment and methodology but failing to do so.

134. Theranos has engaged in a pattern or practice of misrepresentation and deceptive conduct in the sale of blood testing services to consumers.

135. Theranos' actions were willful because it knew or should have known that the practices described in this Complaint violated the Consumer Fraud Act.

THIRD CAUSE OF ACTION

(VIOLATION OF THE UNFAIR COMPETITION ACT, CALIFORNIA BUSINESS & PROFESSIONS CODE § 17200, *ET SEQ.*)

136. Plaintiff incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

137. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair, or fraudulent business act or practice."

138. Theranos' conduct, as alleged in the Complaint, constituted and constitutes unfair, unlawful and fraudulent business practices in violation of Section 17200, et seq. of the California Business and Professions Code.

139. The conduct is unfair, unlawful, and fraudulent because Theranos breached its contract with Plaintiff and putative class members and engaged in false advertising under Section 17500, *et seq*. of the California Business and Professions Code.

140. Defendant's conduct is unfair because it impairs competition within the market for blood tests. Theranos falsely advertises and claims its blood tests are minimally invasive, accurate, and reliable. Theranos' conduct prevents consumers from making fully informed decisions

regarding where to have their blood tests performed and by whom. Reasonable consumers are likely to be deceived by Defendant's false statements.

141. Defendant's conduct also offends established public policy supporting truth in advertising to consumers.

142. Defendant's conduct is unlawful because Theranos breached its contract with Plaintiff and putative class members and engaged in false advertising under Section 17500, *et seq*. of the California Business and Professions Code.

143. Defendant has violated the fraudulent prong of section 17200 because it misrepresentation and material omissions are likely to deceive a reasonable consumer and the facts would be material to a reasonable consumer.

144. Theranos' advertisements and public statements create the false impressions its blood tests are minimally invasive, reliable, and accurate when they are not.

145. Consumers can choose their blood test provider. Given that Theranos' blood tests are equally invasive to traditional tests, unreliable, and inaccurate, the economic harm to consumers who had their tests performed by Theranos over its competitors is obvious.

146. Theranos' misrepresentations and omissions were material, and likely to deceive reasonable consumers.

147. Theranos knew or should have known that the marketing and sale of its blood tests as minimally invasive, reliable, and accurate was deceptive.

148. Theranos had a duty to disclose the inherent flaws and limitations in its tests, and any inaccuracy and reliability problems before the tests were performed. Theranos also had a duty to disclose in a timely manner the fact that the tests were inaccurate and voidable. Theranos failed to fulfill these obligations.

149. Plaintiff and putative class members have suffered injury, including the loss of money, as result of Defendant's unlawful, unfair, and/or deceptive practices. Plaintiff and putative class members are accordingly entitled to disgorgement of Theranos' profits, plus interest and attorneys' fees, under California Code of Civil Procedure § 1021.5.

FOURTH CAUSE OF ACTION

(CONSUMER LEGAL REMEDIES ACT.)
(CAL. CIV. CODE § 1750, *ET SEQ.*)

150. Plaintiff incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

151. Defendant is a "person" under Cal. Civ. Code § 1761(c).

152. Plaintiff and putative class members are "consumers," as defined by Cal. Civ. Code § 1761(d), who purchased blood tests from Theranos.

153. The blood tests are "goods or services" under Cal. Civ. Code § 1770(a).

154. Cal. Civ. Code § 1770(a)(5) prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have…."

155. Cal. Civ. Code § 1770(a)(7) prohibits "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

156. Theranos violated these CLRA provisions by it misrepresentations and omissions regarding the sponsorship, approval, certification, characteristics, benefits, standards, and quality of its blood testing in its advertising.

157. As alleged in the Complaint, Theranos creates the impression that it is providing consumers with the most advanced, accurate, least invasive, and highest quality testing available in the market. Theranos omits and fails to disclose that (1) its labs were negligently maintained and operated, and did not follow proper procedures and policies; (2) consumers did not receive revolutionary, fast, minimally invasive techniques on cutting edge technology promised by Theranos; (3) Theranos did not strive to provide accurate information to its consumers so they could make an informed choice despite promises to do so; (4) its promises that its tests are of the highest levels of accuracy and quality are unfounded, false and misleading; and (5) consumers are not getting what they paid for when they receive blood tests from Theranos.

158. Theranos' omissions are material. Reasonable consumers would consider the promise of minimally invasive, accurate, and reliable blood tests—indeed, the most accurate and highest quality tests according to Defendant— to be important in determining whether or not to purchase blood tests from Theranos or another provider.

159. Reasonable consumers were likely to be deceived, and were in fact misled, by Defendant's misrepresentations and omissions.

160. Theranos knew or reasonably should have known that the marketing and sale of its blood tests was and is deceptive.

161. Plaintiff and putative class members were directly and proximately injured by Theranos' conduct and lost money as a result of, and in reliance on, Defendant's misrepresentations and omissions, because they would not have purchased or paid as much for the Theranos blood tests had they been told the truth.

162. All of the wrongful conduct alleged herein occurred, and continues to occur, in the conduct of Defendant's business. Defendant's wrongful conduct is part of a general practice that is still being perpetuated and repeated.

163. In accordance with Civil Code § 1780 (a), Plaintiff and putative class members seek injunctive and equitable relief for Defendant's violations of the CLRA, including an injunction to enjoin Theranos from continuing its deceptive advertising and sales practices.

164. In accordance with Civil Code § 1782 (a) of the CLRA, Civ. Code § 1782(a), on May 26, 2016, Plaintiff's counsel served Defendant with notice of their alleged violations of the CLRA by certified mail, return receipt requested. After 30 days of the date of such notification, Defendant intends to amend his Complaint to maintain an action for damages under Section 1780 of the CLRA, Civ. Code § 1780.

FIFTH CAUSE OF ACTION

(VIOLATION OF THE UNFAIR COMPETITION ACT, CALIFORNIA BUSINESS & PROFESSIONS CODE § 17500, *ET SEQ.*)

165. Plaintiff incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

166. California Business & Professions Code §§ 17500, et seq. (the "FAL") broadly proscribes deceptive advertising in this State. Section 17500 makes it unlawful for any corporation intending to sell products or perform services to make any statement in advertising those products or services concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by exercising reasonable care would be known, to be untrue or misleading, or not to sell those products or services as advertised at the price stated therein, or as so advertised.

167. Theranos' advertising creates the impression that its blood tests are minimally invasive, reliable, and highly accurate. Theranos claims its tests are the highest quality, most advanced tests available. All these statements are false.

168. Theranos fails to disclose its tests are equally invasive as its competitors' tests, unreliable, and inaccurate. Theranos itself voided all tests performed by its proprietary Edison system between 2014 and 2015, as inaccurate and unreliable.

169. Theranos had a duty to disclose its tests were equally invasive as its competitors' tests, unreliable, and inaccurate before they were offered to consumers. Theranos failed to fulfill this duty.

170. Theranos had a duty to disclose its labs did not meet all industry, state, and federal standards before the tests were offered to consumers. Theranos failed to fulfill this duty.

171. Theranos' omissions are material. Consumers are given the choice to have their blood tested at any facility. Reasonable consumers would consider the omitted facts to be important in determining whether to have their blood tested at a Theranos facility or elsewhere.

172. Reasonable consumers were likely to be deceived, and were misled, by Defendant's misrepresentations and omissions.

173. Theranos knew or should have known that the marketing and sale of its blood tests was deceptive.

174. Plaintiff and putative class members have suffered injury, including the loss of money, because of Defendant's conduct. Plaintiff and putative class members were directly and proximately injured by Defendant's conduct and lost money because of, and in reliance on,

Defendant's misrepresentations and omissions, because they would not have purchased or paid as much for a Theranos blood test had they known that the tests were equally invasive, unreliable, and inaccurate.

175. All of the wrongful conduct alleged in the Complaint occurred, and continues to occur, in the conduct of Defendant's business. Defendant's wrongful conduct is part of a general practice that is still being perpetuated and repeated throughout the State of California and nationwide.

176. Plaintiff requests this Court enter such orders or judgments as may be necessary to enjoin Defendant from continuing its unfair and deceptive business practices, to restore to Plaintiff and putative class members any money that Defendant acquired by unfair competition, and to provide such other relief as set forth below.

SIXTH CAUSE OF ACTION

(UNJUST ENRICHEMENT)

177. Plaintiff incorporates the allegations in the above paragraphs as if fully set forth herein.

178. In the event that there is no legal contract between Theranos and putative class members, Plaintiff alleges the following, in the alternative to the breach of contract claim alleged in Count I, on behalf of himself and the putative class.

179. As the intended and expected result of its conscious wrongdoing as set forth in this Complaint, Theranos has profited and benefited from the unlawful sale of its misleading, unreliable, and inaccurate blood tests.

180. To the detriment of Plaintiff and putative class members, Theranos has been and continues to be unjustly enriched as a result of the unlawful and/or wrongful conduct alleged herein.

181. Theranos has voluntarily accepted and retained the fees paid by Plaintiff and putative class members with full knowledge and awareness that as a result of its unlawful conduct, Plaintiff and the putative class paid substantial monies to Theranos to which it was not lawfully entitled.

182. Plaintiff and putative class members paid for minimally invasive, accurate, and reliable blood tests, but received invasive, inaccurate and unreliable tests.

183. Between Theranos and Plaintiff/putative class members, it would be unjust for Theranos to retain the benefits attained by its wrongful actions.

184. Theranos has been unjustly enriched at the expense of Plaintiff and putative class members who are entitled in equity to disgorgement and restitution of Defendant's wrongful profits, revenue, and benefits, to the extent, and in the amount deemed appropriate by the court, and any other relief the court deems just and proper to remedy Defendant's unjust enrichment.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and for members of the Class, respectfully request that the Court enter judgment in their favor and against Defendant, as follows:

A. Certification of the proposed Class, including appointment of Plaintiff's counsel as Class Counsel and Plaintiff as class representative;

B. An order temporarily and permanently enjoining Defendant from continuing the unlawful, deceptive, fraudulent, and unfair business practices alleged in this Complaint;

C. Costs, restitution, damages, including punitive damages, and disgorgement in an amount to be determined at trial;

D. An order requiring Defendant to pay both pre- and post-judgment interest on any amounts awarded;

F. An award of costs and attorneys' fees; and

G. Such other or further relief as may be appropriate.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial for all claims so triable.

DATED: May 26, 2016

HAGENS BERMAN SOBOL SHAPIRO LLP

By */s/ Shana E. Scarlett*

Shana E. Scarlett (SBN 217895)
715 Hearst Avenue
Berkeley, California 94710
Telephone: (510) 725-3000
Facsimile: (510) 725-3001
shanas@hbsslaw.com

Robert B. Carey (*Pro Hac Vice pending*)
Leonard Aragon (*Pro Hac Vice pending*)
Michella Kras (*Pro Hac Vice pending*)
11 West Jefferson, Suite 1000
Phoenix, Arizona 85003
Telephone: (602) 840-5900
Facsimile: (602) 840-3012
rob@hbsslaw.com

Steve W. Berman (*Pro Hac Vice pending*)
1918 8th Avenue, Suite 3300
Seattle, Washington 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594
steve@hbsslaw.com

Attorneys for Plaintiff