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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

L.T., on behalf of herself and all others similarly situated,

Plaintiff,

v.

THERANOS, INC. and WALGREENS BOOTS ALLIANCE, INC.,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

INTRODUCTION

1. Accurate analysis of blood samples is essential to the safe practice of medicine. Doctors rely on blood tests to detect everything from relatively mundane conditions like elevated cholesterol to serious maladies like liver disease and certain types of cancer. These results also inform doctors' therapeutic recommendations, helping them determine whether to treat a condition, what to treat it with, and how aggressively. Inaccurate blood tests, then, can contribute to serious conditions going undetected, to treatable conditions growing worse unnoticed, to patients forgoing medications they should take, or taking medications they shouldn't. An inaccurate blood test can change a patient's life.

2. For decades, blood collection and analysis have been straightforward and reliably accurate. Standard blood draw techniques involve venipuncture (drawing blood from a vein, typically in the arm), collection of a sample using vials of 5 to 10 milliliters, labeling and recording the sample, analyzing it in a lab, and then reporting the results to doctors trained to interpret them. Federal agencies regulate laboratories and lab devices so that patients and doctors can count on accurate testing. With its track record of safety and reliability, diagnostic lab testing in the United States has grown into a $75 billion per year industry.

3. Defendant Theranos, Inc. is a Silicon Valley startup that set out to "disrupt" that industry by introducing what it said was a revolutionary new way of drawing and testing blood. Instead of the large needles, tubes, and vials that phlebotomists conventionally use, Theranos claimed to have invented a system that drew blood with a mere pinprick to the fingertip, captured only a few drops in a tiny, proprietary vial, and analyzed the sample on a secret device it code-named "Edison." Edison was supposed to be able to run dozens of tests using a single miniscule sample, generate results within minutes instead of days or weeks, and deliver results right to a patient's smartphone using a Theranos-developed app.

4. Theranos's first major step toward that disruption came in fall 2013, when it announced a long-term partnership with Defendant Walgreens Boots Alliance, Inc. ("Walgreens"), operator of a nationwide drugstore chain. Walgreens was as eager to branch out into the lucrative blood-testing market as Theranos was to expand its access to the public. Top-level executives at the two corporations agreed on a scheme to open "wellness centers" that conducted blood testing inside Walgreens

pharmacies using Theranos's secret system. As a first step toward opening wellness centers in all of Walgreens' over 8,000 U.S. locations, Theranos and Walgreens opened an initial cluster of wellness centers in the Phoenix, Arizona area, along with two wellness centers in northern California near Theranos's Palo Alto headquarters. These wellness centers collected samples that were then sent to nearby Theranos-run labs, one in Scottsdale, Arizona, the other in Newark, California. Within months of announcing their partnership, Theranos and Walgreens had opened more than 40 wellness centers and begun delivering blood tests to the public. By the end of 2015, Theranos, bolstered by the enhanced retail presence and credibility that Walgreens provided, had performed roughly 1.8 million lab tests.

5. The partnership had a problem, however: Theranos's revolutionary system did not work. In October 2015, public reports began to reveal that Theranos never performed more than a small fraction of its tests using the proprietary system on which it had built its brand and, by mid-2015, had given up using Edison entirely. Instead, Theranos secretly used conventional lab machines it purchased from third parties. It even outsourced tests to university-affiliated, third-party labs. But Theranos and Walgreens nevertheless kept billing their wellness centers as offering cutting-edge, less-invasive, and highly accurate testing.

6. Theranos's problem is bigger than Edison, however, for even using conventional lab equipment it has proved incapable of providing reliable test results. In January 2016, the federal agency that oversees diagnostic laboratories released a 121-page report detailing violations of federal regulations in Theranos's Newark lab, including five major violations pertaining to hematology, analytics, and staffing. The most serious of these violations, the regulator said, posed an "immediate" risk of serious injury or death to patients. Among the report's other findings were that Theranos staffed its lab with unqualified and inadequately trained personnel; kept freezers at incorrect temperatures; neglected to calibrate machines properly or sometimes at all; and would fail its own internal quality-control checks—only then to change its quality-control standards so that they matched the data. Private investigations undertaken by independent experts in laboratory science have also confirmed that Theranos's results are consistently flawed.

7. As a result of the federal investigation, Theranos currently faces sanctions up to and including loss of the federally issued license that permits it to handle human samples, as well as a two-year ban from the blood lab industry for Theranos's founder and chief executive, Elizabeth Holmes. In an attempt to dissuade regulators from issuing these sanctions, Theranos has voided the results of all the tests it performed on its Edison devices in 2014 and 2015. Plaintiff's investigation has also revealed that Theranos, without fanfare, has sent out corrected test results to doctors in the Phoenix area, even as it continues to publicly claim that the problems the regulators found were confined to its California lab.

8. Theranos's partner, Walgreens, has been, at best, willfully indifferent to Theranos's shortcomings. Before it entered into its partnership with Theranos, Walgreens knew of, but ignored, Theranos's refusals to provide confirmation that its new, self-made devices actually worked. Walgreens never insisted on inspecting Theranos's labs or verifying Theranos's claims. And when Theranos refused to cooperate with the third-party experts that Walgreens hired to vet Theranos, Walgreens went ahead with the partnership regardless. Despite months of public reporting on Theranos's unreliability, Walgreens decided to shut down its Theranos centers only a few days ago. Even now, Walgreens has not disclosed to patients the risks of relying on Theranos tests previously sold inside its stores. Walgreens reportedly failed to take stronger action to protect patients because it feared that Theranos would sue for breach of contract.

9. Meanwhile, patients are the ones who have paid for Theranos and Walgreens' conduct. Media reports contain numerous accounts of inaccurate results for tests ranging from thyroid function to potassium levels to prostate cancer. One Arizona doctor sent her patient to a Theranos testing site for routine testing only for the results to come back so elevated that she immediately ordered her patient to the emergency room—where further, non-Theranos testing showed that the patient's results were actually normal. That patient was fortunate to suffer nothing worse than an emergency room bill of several thousand dollars. But Theranos and Walgreens, by foisting onto the public unreliable lab tests and failing, even now, to provide appropriate disclosures, continue to cheat patients and expose them to a risk of serious health consequences.

10. Plaintiff L.T.—identified here by her initials to preserve the confidentiality of her private medical information—received flawed tests from Theranos. Plaintiff bought her test at a Phoenix-area Walgreens, relying on Walgreens' reputation as a longstanding provider of safe and reliable pharmacy care. On behalf of herself and the proposed class, she brings this action for damages and injunctive relief.

JURISDICTION & VENUE

11. This Court has subject-matter jurisdiction over all the claims in this action under 28 U.S.C. § 1332(d)(2) because this is a class action wherein the amount in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, there are more than 100 members in the proposed class, and at least one member of the proposed class is a citizen of a state different from a Defendant.

12. This Court has personal jurisdiction over Defendants Theranos, Inc. and Walgreens Boots Alliance, Inc. because they conduct business in the state of Arizona and because Defendants committed the acts and omissions giving rise to Plaintiff's claims in Arizona.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this District.

THE PARTIES

I. Plaintiff

14. Plaintiff is identified herein using her initials to preserve the confidentiality of her personal medical information.

15. Plaintiff L.T. is a resident of Maricopa County, Arizona. She purchased blood testing services from Theranos at a Walgreens wellness center located in Sun City West, Arizona in 2015.

II. Defendants

16. Defendant Walgreens Boots Alliance, Inc. ("Walgreens") is a Delaware corporation headquartered at 108 Wilmot Road in Deerfield, Illinois, and the product of a 2014 merger between U.S.-based Walgreen Co. and Swiss-based Alliance Boots GmbH. Post-merger, Walgreens operates over 8,100 drugstores in the United States, offering pharmacy services alongside groceries and dry goods.

17. Defendant Theranos, Inc. ("Theranos") is a Delaware corporation headquartered at 1701 Page Mill Road in Palo Alto, California. Throughout the period described in this Complaint and up to the present, Theranos has held itself out as offering an innovative new approach to blood testing that is less intrusive and faster than conventional testing but nevertheless highly accurate. Theranos's approach, as advertised, depends on proprietary blood collection, testing, and analysis devices that Theranos designed and built, as well as proprietary software. However, Theranos has in fact used its proprietary system for only a fraction of the tests it provides, and only up until mid-2015. Theranos has instead secretly performed blood testing services on conventional lab equipment purchased from third parties. Theranos sold these services, falsely marketed as Theranos's proprietary services, to consumers at more than 40 "wellness centers" located primarily in the Phoenix metropolitan area in Arizona, with two in northern California. All but a few of the blood centers were located inside Walgreens stores. Theranos collected samples at the wellness centers, but analyzed the samples at its two off-site laboratories, one located in Newark, California, the other in Scottsdale, Arizona.

SUBSTANTIVE ALLEGATIONS

I. Theranos Attempts to "Disrupt" the Established Blood Testing Industry.

18. Elizabeth Holmes was 19 years old and a sophomore at Stanford when, in 2003, she saw an opening into the United States' multibillion-dollar lab testing market. Driven, she has said, by her phobia of needles, Holmes dropped out of Stanford and founded Theranos, a company that has sought to "disrupt" the established model of diagnostic blood sample collection and analysis by developing a less invasive alternative to conventional venipuncture.

19. By 2008, Theranos had developed the linchpin of its strategy, a technology it dubbed "Edison": a machine that used samples of no more than a few drops, obtained with a finger prick and collected in tiny vials that Theranos branded "nanotainers." Theranos boasted that Edison could perform hundreds of tests on each miniscule sample of blood (or, for some tests, urine), run them faster than standard tests, and deliver them for a fraction of the price. Theranos made a key selling point of the transparency of its pricing for its lab tests, which it posted on its website.[1]

[1] Theranos.com, "Test Menu," https://www.theranos.com/test-menu (last visited June 8, 2016).

20. But even as Theranos touted transparency to the marketplace, it enforced strict secrecy around Edison. Theranos refused to submit the Edison device to inspection. Theranos likewise refused to subject any of its other technology or processes to peer review. Theranos refused even to allow the Edison device to be photographed. Theranos claimed it wanted to keep potential competitors from learning how to replicate its technological breakthroughs.

21. Edison was not the only means by which Theranos sought to disrupt the lab testing industry. Theranos also sought to disrupt the industry's market structure. The lab testing market was dominated by the "Big Two" of Quest Diagnostics Inc. ("Quest") and Laboratory Corporation of America ("LabCorp"). These and smaller companies like them sold lab testing services directly to doctors, who in turn received results, interpreted them for patients, and prescribed appropriate therapies (such as medication). The market for lab testing services, in other words, was between testing labs and doctors.

22. Theranos, however, sought to sidestep doctors and their traditional gatekeeping function by marketing, selling, and delivering its services directly to patients. Theranos even developed

smartphone apps to deliver test results, so that patients would receive (and have to interpret) test results themselves.

23. To help achieve its goal of direct-to-patient testing, Theranos lobbied the Arizona Legislature to make patient-ordered lab tests legal. Its efforts were successful, and in the April 2015 Arizona House Bill 2645 became law, authorizing patients to order lab tests directly. *See* Ariz. Rev. Stat. § 36-468. As a result, Theranos could dispense with competing for doctors' business against Quest, LabCorp, and other established companies, and instead sell directly to Arizona patients. Theranos used this access to draw patients away from the established companies and convert their patients into Theranos patients.

II. Theranos and Walgreens Partner to Bring Theranos's Testing to the Public.

24. As the next step in its plan to reach the broadest possible market of patients, Theranos began to seek out partnerships with nationwide retailers.

25. At the same time, Walgreens was seeking opportunities to capture new revenue streams by branching out beyond traditional drugstore offerings. For example, in 2009, following a severe flu season, Walgreens and other pharmacy chains lobbied state legislatures to permit pharmacists to begin administering injections of flu vaccine. By 2012, Walgreens was giving more than 6 and a half million flu shots per year and reaping month-after-month revenue increases as a result.

26. Not satisfied with the success of its newly minted vaccination business, Walgreens began to seek out partnerships with Silicon Valley companies who could help it strike even more lucrative deals.

27. In 2010, Theranos's founder Holmes met an executive from Walgreens' newly created healthcare innovation unit, Dr. Jay Rosan, at a healthcare technology conference. By early 2011, Walgreens and Theranos were in talks to deliver direct-to-consumer blood-testing services in Theranos-branded and operated wellness centers located within Walgreens stores.

28. By spring of 2011, the parties' talks had become serious. Walgreens started making plans to vet Theranos. Walgreens, however, never followed through on its plans. Fearful that Theranos would strike a deal with one of its competitors instead, Walgreens looked past Theranos's failure to

provide access to promised data and information, accepted incomplete information, and failed to adequately test and inspect Theranos's equipment and capabilities.

29. For example, in May 2011, Walgreens hired the Johns Hopkins University to evaluate prospective investments, including a contemplated investment in Theranos. Later that spring, as part of this evaluation process, Holmes and other Theranos executives met with Johns Hopkins scientists. Holmes brought with her an Edison device and binders of data that, she said, demonstrated Edison's accuracy. Theranos promised at that meeting to provide an Edison device to Johns Hopkins for testing. However, when Dr. Rosan of Walgreens later asked a Johns Hopkins representative whether Theranos had provided the device, the representative informed him that Theranos had not.

30. Instead of insisting that Theranos keep its promise, Walgreens obtained a prototype of the Edison device. And rather than providing this device to Johns Hopkins, Walgreens had its employees set up the prototype in a cubicle and began trying to verify its accuracy themselves. They discovered, however, that the test results delivered by the prototype could not be compared to those of conventional labs, as the prototype reported results using values like "high" or "low" instead of the numeric values that conventional labs use, and only performed unusual tests that conventional labs do not offer. Despite these incomplete and inconclusive efforts, Walgreens did not halt the deal with Theranos.

31. Similarly, Walgreens satisfied itself with its deal with Theranos without ever examining Theranos's lab facilities. It sent executives and consultants on a junket to Theranos's headquarters but allowed Theranos to sequester them in conference rooms and chaperone them if they ventured elsewhere.

32. For example, in summer 2011, when Walgreens and Theranos had already signed an initial letter of agreement, Walgreens sent consultants from a firm called Colaborate LLC, a laboratory testing and evaluation firm, to Theranos's headquarters in Palo Alto. Accompanying the consultants were Dr. Rosan, Wade Miquelon (Walgreens' former chief financial officer), and other Walgreens employees. Throughout the visit, Theranos kept Colaborate and the Walgreens representatives in a conference room. Theranos declined to show them the laboratory and even escorted them when they visited the restroom. Neither did Theranos provide Colaborate with access to an Edison machine.

Colaborate eventually issued a report telling Walgreens that it lacked sufficient information to consummate the Theranos deal, but Walgreens pushed ahead with it regardless.

33. Similarly, in October 2012, Walgreens sent two executives and a consultant, Paul Rust, a retired Quest executive, to review quality-control data at Theranos. According to published reports, Theranos provided Rust with data but did not confirm that it came from Edison devices. Neither would Theranos permit Rust or the others into its laboratory. Later, when Rust sought to confirm that Walgreens representatives had been inside Theranos's lab, he learned that they hadn't. Yet despite not having properly inspected Theranos's laboratories or vetted its quality-control data, Walgreens moved forward with its deal with Theranos.

34. Publicly available information alone should have led Walgreens to conclude that it needed further confirmation of Theranos's reliability and accuracy entering into any deal that would expose patients to Theranos's testing methods. For example, Walgreens should have known and appreciated the importance of Theranos's improper staffing of its laboratories. The director of Theranos's Scottsdale lab is Daniel Young, a mechanical engineer with no medical degree. The director of Theranos's Newark lab was, until recently, Sunil Dhawan, a dermatologist with no degrees or certification in pathology or laboratory science who worked for Theranos only part-time. It was Dhawan's directorship of the Newark lab that constituted one of the five major violations at the Newark lab identified by federal regulators and led to the threatened sanctions Theranos now faces. According to public reports, Dhawan's name was listed on the Newark lab's license.

35. The failure of a proposed deal between Theranos and a Walgreens competitor, the grocery chain Safeway, also illustrates Walgreens' pursuit of profits over patient safety. As Walgreens was courting Theranos, Theranos simultaneously was in talks with Safeway to provide lab testing services in Theranos-dedicated clinics embedded within Safeway stores. Safeway invested $10 million in Theranos and sank $350 million into constructing the clinics.

36. According to public reports, however, Safeway pulled out of its deal with Theranos after its due diligence raised questions about the accuracy of the testing Theranos sought to offer. For example, Safeway executives had their own blood tested by both Theranos and another, conventional lab. The test results differed significantly. One executive's results from Theranos showed such highly

elevated quantities of prostate-specific antigen (PSA) as to suggest he had prostate cancer. Conventional lab testing, however, confirmed that his PSA levels were normal. Easily discovered discrepancies like these contributed to Safeway's reluctance to move forward with offering Theranos testing to the public.

37. Safeway also was concerned because Theranos balked at placing its blood analyzers inside Safeway stores, and instead insisted on having samples shipped to one of its off-site labs. This allowed Theranos to use conventional testing machines and even outsource testing to third-party labs rather than using the much-hyped Edison device, all while benefiting from advertising buzz around the latter.

38. Safeway also grew concerned by Theranos's repeated failure to meet deadlines and to deliver on promises to divulge information needed to verify Theranos's claims.

39. These failings on Theranos's part caused Safeway to walk away from its deal with Theranos. Walgreens, exposed to nearly identical warning signs, instead invested $50 million into Theranos and joined Theranos in its plan to seize an outsized portion of the lucrative nationwide lab testing industry and capture a nationwide market of patients.

III. Theranos and Walgreens Open Their Wellness Centers

40. Theranos and Walgreens took the first major step of their long-range plan in September 2013, when they announced their partnership and opened the first of more than 40 wellness centers, mostly clustered in the Phoenix metropolitan area and nearly all of which were inside Walgreens stores.

41. In the advertising for their new wellness centers, Theranos and Walgreens boasted of the transformative, cutting-edge technology they offered the public.

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42. Theranos and Walgreens emphasized that their testing would be less invasive than conventional testing, with imagery that conveyed to patients that they would have a needle-free experience. In a joint press release announcing their partnership, Theranos and Walgreens boasted that their "less invasive" testing used samples "as small as a few drops, or 1/1,000 the size of a typical blood draw" and claimed that Theranos's finger-prick or venous microsamples "eliminat[ed] the need for larger needles and numerous vials of blood required for most diagnostic lab testing."

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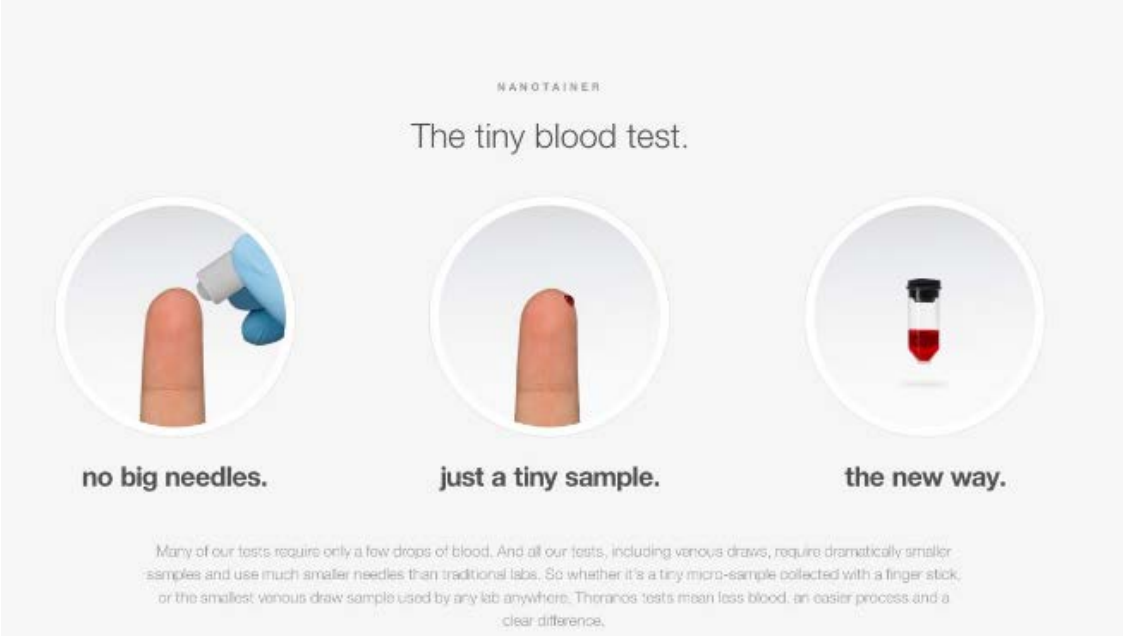
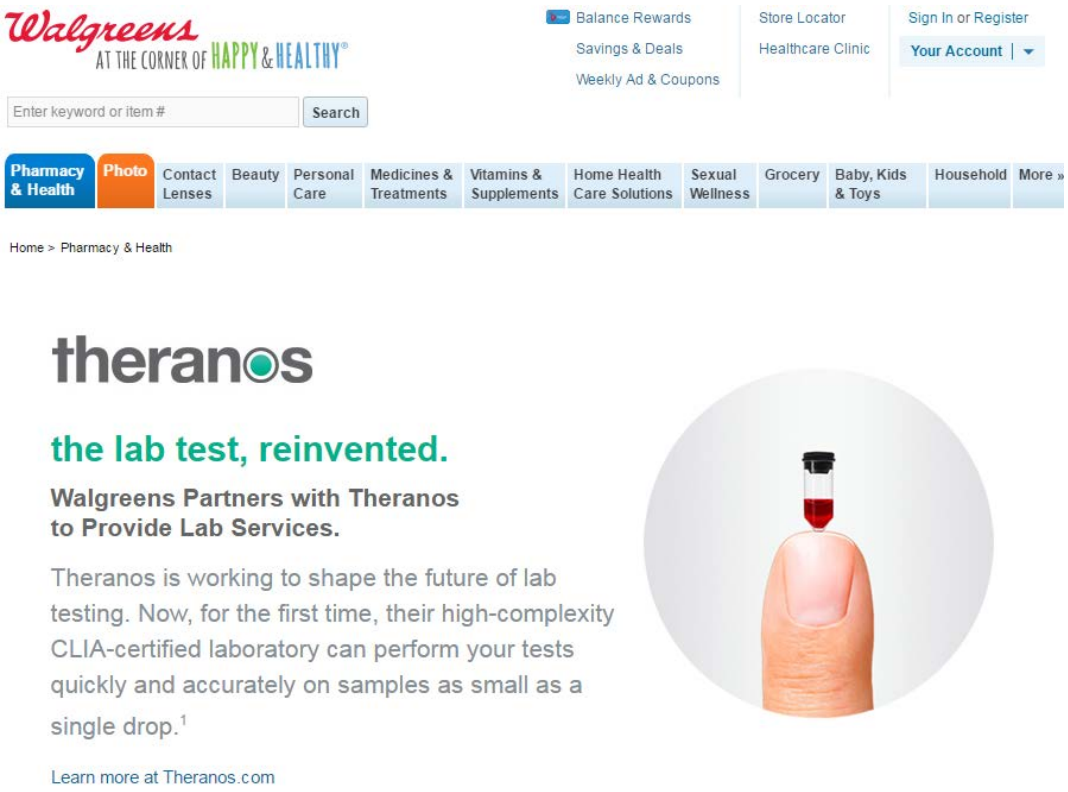


43. Similarly, the Walgreens website told consumers they could say "goodbye, big bad needle" because Theranos-trained technicians could "use a tiny finger stick or collect a microsample from a venous draw" instead of using a "huge needle." Theranos boasted they could run over 200 different tests using these abnormally small samples, thanks to their revolutionary testing equipment.



44. Theranos and Walgreens also claimed to offer industry-leading accuracy and speed with their tests. Their joint press release boasted that Theranos's "proprietary laboratory infrastructure" would "minimize[] human error through extensive automation to produce high quality results," and that those results would be "available to physicians in a matter of hours, enabling fast diagnoses to help informed treatment choices."

45. Theranos's website continues to claim "the highest levels of accuracy," explaining that "[a]ll our tests are developed and validated under and to the CLSI, FDA, Centers for Disease Control[,] and World Health Organization guidelines."

46. Theranos's website also misleadingly boasts of its practice of submitting all of its "Laboratory Developed Tests" to the Food and Drug Administration ("FDA") for clearance and approval. None of Theranos's tests is FDA-approved except for one that tests for the herpes simplex 1 virus IgG (HSV-1). Moreover, the FDA has characterized Theranos's nanotainers as an uncleared medical device, forcing Theranos to cease to use the nanotainer device for all its tests but one. Further, according to published reports, a former Theranos employee has disclosed that Theranos modified its machines in the midst of the herpes tests that led to FDA approval and underreported to the FDA how often the machines broke down during the study.

47. At the heart of all Theranos's promises lay Theranos's brand identity, that of an epoch-making Silicon Valley revolutionary that had reinvented lab testing. This image is one Walgreens was happy to promote and yoke itself to. Former Walgreens CFO Miquelon boasted of Theranos founder Holmes's "disruptive force," stating that she had discovered how to do lab testing "much cheaper, more accurately and in a shorter period of time. . . . She has made the process better."

48. But while Theranos and Walgreens sold the public on Theranos's revolutionary new testing methods, in reality Theranos hardly used the Edison devices at the heart of its "disruptive" testing model. Theranos has disclosed that its Scottsdale lab was equipped only with conventional laboratory machines that Theranos bought from Siemens—not the Edison machines central to Theranos's brand. And while the Newark lab had Edison machines as well as conventional Siemens machines, Theranos has disclosed that its Scottsdale lab conducted over 90 percent of its testing. Theranos has further disclosed that it outsources "highly complex" tests to third-party, university-

affiliated labs, despite its public statements that it is able to run all of the over 200 tests it offers on its Edison machines. Simply put, Theranos and Walgreens misrepresented the nature of the service offered.

49. Walgreens allowed Theranos to control and obscure what went on inside the wellness centers it hosted in its stores. The centers were staffed by Theranos employees. Theranos conducted blood draws on site, but did not place its testing equipment on site; rather, it sent the samples it collected to its Scottsdale or Newark labs. Additionally, Walgreens reportedly had no access to Theranos's clinical data or financial records—a concession that reportedly is unusual for Walgreens to make when investing in another company. Despite having surrendered to Theranos control over the services Theranos offered in its stores, Walgreens promoted those services and helped Theranos draw in patients.

IV. Published Reports Undermine Theranos's Claims of Accurate, Reliable Testing.

50. In October 2015, the *Wall Street Journal* issued the first of a series of articles revealing that Theranos's claims of a revolution in accurate, reliable, speedy blood testing were at best misleading and in many respects false.

51. Despite Theranos's having made Edison the centerpiece of its brand, by December 2014 Theranos reportedly was performing only 15 of the over 200 tests that it offered on Edison devices. Following the October 2015 article, Holmes confirmed that Theranos was using Edison devices for just one test.

52. Theranos changed its website during the period of the *Journal*'s reporting to delete the claim that "[m]any of our tests require only a few drops of blood," as well as the claim that it usually collected [only three tiny micro-vials . . . instead of the usual six or more large ones." Theranos admitted that these changes were made for "marketing accuracy."

53. Moreover, Theranos has since revealed that it stopped using Edison for testing altogether in June 2015, though it continued to advertise its finger stick collection methods and the advantages of its testing solution, which were purportedly obtained through Edison.

54. Theranos employees have leaked to the press that Theranos diluted the "microsamples" of blood that they took so that the samples would meet the minimum volume requirements of the conventional machines Theranos used.

55. Notwithstanding Theranos's claims of enhanced speed, numerous patients have publicly reported delayed test results—one of the outcomes that Edison was supposed to prevent. For example, a journalist reported having had his blood drawn at a wellness center and receiving results back 3 days later, rather than the few hours that Theranos advertised.

V. Published Reports and Government Investigations Undermine Theranos's Claims of Accurate, Reliable Testing.

56. In January 2016, news reports revealed that the Centers for Medicare & Medicaid Services ("CMS"), the federal regulator responsible for the integrity of laboratory testing, had inspected Theranos's Newark lab and found five major infractions, including one "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."

57. The CMS sent a letter and a report to Theranos, dated January 25, 2016, which outlined the five major infractions, along with numerous other infractions. The five major infractions were violations of the following federal regulations:

- 42 C.F.R. § 493.1215: The CMS observed that Theranos failed to conduct adequate quality controls relating to hematology. This was the violation that the CMS identified as likely to cause serious injury, harm, or death at any time. One observation underpinning the CMS's finding of inadequate quality controls related to PT/INR test results. The PT/INR test measures how long blood takes to clot, and it is used to monitor individuals being treated with the blood-thinner warfarin, sold under the trade name Coumadin—a medication prescribed to help prevent heart attack and stroke in especially vulnerable patients.
- 42 C.F.R. § 493.1250: This finding related to numerous failures in Theranos's analytic systems, including failures to perform required weekly maintenance on certain of its testing machines and failures to keep freezers at the proper temperature.

- 42 C.F.R. § 493.1441: The CMS observed numerous failures relating to Theranos's failure to employ a qualified lab director. The CMS found, among other things, that the director failed to ensure that required daily quality controls were performed, failed to ensure that the results of quality control materials met the laboratory's own criteria for acceptability, and failed to ensure that laboratory personnel were properly trained.
- 42 C.F.R. § 493.1447: The CMS made numerous findings related to the inadequacy of Theranos's lab supervisors, for example, finding that two of the three supervisors failed to meet federal minimum standards requiring four years of experience.
- 42 C.F.R. § 493.1487: The CMS found that some of the testing personnel employed in the Newark lab lacked federally required degrees in the hard sciences (one, for example, had a Liberal Studies degree) and had not received required training on the testing machines they operated.

58. In addition to the major infractions above, the CMS report observed numerous other problems at the Newark lab.

59. Notably, the CMS found that Theranos failed to meet even its own, internal quality controls. While the publicly available version of the CMS report is redacted, published reports from those who have seen an unredacted version of the report state, consistent with the redacted version, that Edison failed 29 percent of quality-control checks in October 2014. Specific tests had similar or even higher failure rates:

- Tests of a hormone that affects testosterone levels failed at an 87 percent rate;
- Tests of the hormone prolactin, which promotes lactation in women after childbirth, failed at a 47 percent rate;
- Tests to measure PSA, the prostate-specific antigen used to help detect prostate cancer, failed at a 22 percent rate.

60. According to the CMS, Theranos's own data showed unacceptable discrepancies between the measurements produced by Edison and conventional testing machines. For example, Vitamin D measurements differed between 21 and 130 percent, thyroid function tests differed by 21 to

39 percent, and testosterone tests differed by 22 to 146 percent. But Theranos's own internal guidelines specified that they should differ no more than 20 percent.

61. The CMS report reflects that, rather than reveal these deficiencies or take steps to inform the public, Theranos instead changed its standards to match its data. The CMS report faulted Theranos for "chang[ing] the criteria for acceptability" for numerous tests but "maintain[ing] no mechanism to assess the effectiveness of this corrective action."

62. The CMS report also faulted Theranos for failing to promptly notify people who ordered tests when it detected errors in the tests.

63. Finally, the CMS stated that its inspection of Theranos's lab took "an overview of the laboratory through random sampling" and observed that, due to its random nature, the inspection might "not find every violation that the laboratory may have committed."

64. The release of Theranos quality control data prompted one professor of pathology to say: "This is the first time that we've actually seen data from the Theranos instrument, and it's as bad as one would have worried it would be." He continued: "Based on this data, it's hard for me to believe that they went live with this instrument and tested patient specimens on it."

65. Independent researchers have confirmed the infirmity of Theranos's results. In March 2016, the Journal of Clinical Investigation published the results of a study of 60 healthy adults that compared test results they received from Theranos with those they received from Quest and LabCorp using samples taken the same day. The study found Theranos was 60 percent more likely to report results outside of normal ranges. For example, Theranos's cholesterol tests were an average of 9.3 percent lower than those of the other labs—a fact which, the report said, could lead health care providers to "either inappropriately initiate or fail to appropriately initiate statin therapy."

66. Had Theranos or Walgreens divulged data reflecting the nature and quality of the tests they offered, patients who relied on their assurances of high-quality, accurate testing would have had the opportunity to make an informed decision about whether to use their services.

VI. Walgreens Takes Pains to Protect Itself, Rather than Its Patients, After Theranos's Problems Become Public.

67. The CMS report became a matter of public knowledge on January 27, 2016 when the *Wall Street Journal* divulged its existence and summarized its major findings. Walgreens executives reportedly held a conference call with Theranos founder Holmes the following day. At that meeting, Walgreens reportedly told Holmes that it would only continue to work with Theranos if it suspended all testing until the issues identified by the CMS report were resolved.

68. Holmes reportedly refused that condition, and threatened to sue Walgreens for even suggesting a suspension.

69. Walgreens then, instead of insisting on a suspension of testing to protect patient health, opted to give Theranos 30 more days to resolve the problems identified at the Newark lab and closed only a single wellness center, the one in Palo Alto, California. It continued to permit the remaining forty wellness centers in Arizona to stay open.

70. Plaintiff's investigation has uncovered no indication that Walgreens required Theranos to verify the reliability and accuracy of results issuing from its Scottsdale lab.

71. Neither has Plaintiff's investigation uncovered any indication that Walgreens has sent direct notification to patients who received test results from its wellness centers, posted a general notification in its stores, or made any oral or written disclosure to prospective patients concerning the problems with Theranos's testing.

72. As a result of Walgreens' refusal to suspend operations at its wellness centers or even to notify patients of the risks of relying on a Theranos-administered lab test, Walgreens continued to profit from exposing the public to Theranos's unsafe and unreliable blood tests.

VII. The Federal Government Threatens Sanctions Against Theranos.

73. On March 18, 2016, the CMS sent Theranos a letter proposing to sanction it for failing to adequately address the five major infractions identified in its January 25, 2016 letter and report. Among the sanctions proposed are:

- Revocation of the Newark laboratory's certification under the Clinical Laboratory Improvements Amendment of 1988 ("CLIA"), which is the certification that permits laboratories to accept human samples for diagnostic testing;
- Upon revocation of Theranos's CLIA certification, a two-year ban on Holmes or the laboratory director owning, operating, or directing a laboratory for two years;
- Monetary penalties of $10,000 per day, along with suspension and cancellation of the laboratory's approval to receive Medicare payments; and
- Provision to the CMS of "a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services from January 2014 to the present date." The CMS would use the list to notify doctors and patients of, among other things, the nature of Theranos's non-compliance with federal regulations.

74. On April 18, 2016, public reports revealed that the U.S. Attorney's office in San Francisco, with assistance from the Federal Bureau of Investigation and the U.S Postal Inspection Service, has opened a criminal investigation into Theranos and subpoenaed documents from Walgreens, as well as the New York State Department of Health. The report also indicated that the Securities and Exchange Commission has begun to scrutinize whether Theranos was truthful when soliciting funding from private investors.

VIII. Theranos Retracts Results from Both Its Newark and Its Scottsdale Labs, But Does Not Notify Patients.

75. In May 2016, Theranos disclosed that it had withdrawn all of the Edison test results it produced in 2014 and 2015. Theranos ran approximately 890,000 tests per year during that period. Theranos told CMS that it had reissued "tens of thousands" of blood-test reports, either voiding results or correcting them. Theranos's notification efforts, then, reached roughly 1 to 5 percent of patients who received unreliable blood tests from Theranos and Walgreens.[2]

[2] Assuming Theranos delivered 890,000 tests in 2014 and 2015, it delivered approximately 1.8 million tests. Assuming that Theranos's notification of "tens of thousands" of patients means it notified between 20,000 and 90,000, Theranos notified between 1.1 and 5.0 percent of the 1.8 million test recipients, approximately.

76. Theranos has emphasized in its public statements regarding the CMS report that the problems the CMS identified were inapplicable to its Scottsdale lab. For example, the current director of Theranos's Newark lab told the media that "the CMS report is about people and processes in one Theranos lab in the past . . . ."

77. Plaintiff's investigation, however, has uncovered that Theranos has sent corrected test reports to doctors in the Phoenix area, including reports pertaining to one of the very same tests identified by the CMS report in finding that the Newark lab posed an immediate threat of serious harm or death.

78. Specifically, on April 13, 2016, the director of the Scottsdale lab sent a form letter addressed "Dear Valued Client" to an as-yet-unknown number of doctors in Arizona. Plaintiff's counsel procured a copy of one such letter. The letter states that Theranos is correcting the results of PT/INR tests "performed at Theranos' clinical laboratory in Arizona."

79. As explained above, lack of quality control for PT/INR was one of the observations underpinning the CMS's finding that conditions in the Newark lab posed an immediate danger of serious harm or death. Doctors use PT/INR tests to prescribe blood-thinning medications to patients especially vulnerable to clotting, such as those who have received heart valve replacements or suffered an ischemic event like heart attack or stroke.

80. The April 13, 2016 letter offers the doctor the option of having complimentary retesting performed. The letter does not offer, however, any way of contacting the patients, and it gives no indication that Theranos itself has sought to contact them.

81. Only in June 2016, months after news of Theranos's problems became public, did Walgreens decide to shut down its Theranos centers. Theranos and Walgreens still have not disclosed to patients the health risks of relying on Theranos tests.

IX. Plaintiff's Experience

82. Plaintiff L.T. suffers from kidney disease and must undergo regular blood testing as a result.

83. L.T. had several blood tests performed at a Theranos-run wellness center located within a Walgreens in Sun City West, Arizona. Initially, these blood tests were finger-prick tests, but later tests were performed using traditional venipuncture testing.

84. L.T. has never received notice of the problems with Theranos's labs and tests from Theranos or from Walgreens.

85. Had L.T. known that Theranos's blood tests were inaccurate or that Theranos violated federal regulations, she would not have purchased a Theranos blood test or would have paid significantly less for it.

CLASS ACTION ALLEGATIONS

86. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiff brings this action on behalf of herself and the following proposed classes, defined as follows:

A. Arizona Walgreens Class: *All persons who purchased a Theranos lab test from Walgreens in Arizona between September 1, 2013, and the present.*

B. Arizona Theranos Class: *All persons who purchased a Theranos lab test from Theranos in Arizona between September 1, 2013, and the present.*

87. Excluded from the proposed classes are Theranos and Walgreens; any affiliate, parent, or subsidiary of Theranos or Walgreens; any entity in which Theranos or Walgreens has a controlling interest; any officer, director, or employee of Theranos or Walgreens; any successor or assign of Theranos or Walgreens; anyone employed by counsel in this action; and any judge to whom this case is assigned, his or her spouse, and members of the judge's staff.

88. **Numerosity**. Theranos, through the wellness centers it operated with Walgreens and on its own, sold well over one million blood tests. Members of the proposed classes are thus too numerous to practically join in a single action. Class members may be notified of the pendency of this action by mail, supplemented by published notice (if deemed necessary or appropriate by the Court).

89. **Commonality and Predominance**. Common questions of law and fact exist as to all proposed class members and predominate over questions affecting only individual class members. These common questions include whether:

A. A reasonable consumer would consider the flaws in Theranos's lab testing to be important;

B. Theranos knew its lab tests were inaccurate, and if so, when it discovered this;

C. Walgreens knew that Theranos's lab tests were inaccurate, and if so, when it discovered this;

D. Theranos and Walgreens misrepresented to potential customers the lab tests' propensity for inaccuracy;

E. Theranos and Walgreens are obligated to provide notice of inaccurate test results to the patient whose blood or other samples was tested;

F. Theranos and Walgreens' conduct violates the Racketeer Influenced and Corrupt Organizations Act; and

G. Theranos and Walgreens' conduct violates various consumer protection statutes.

90. **Typicality**. Plaintiff's claims are typical of the claims of the proposed classes. Plaintiff and the members of the proposed classes all purchased blood tests from Theranos and/or Walgreens during the Class Period, giving rise to substantially the same claims.

91. **Adequacy**. Plaintiff is an adequate representative of the proposed classes because her interests do not conflict with the interests of the members of the classes she seeks to represent. Plaintiff has retained counsel competent and experienced in complex class action litigation, and will prosecute this action vigorously on class members' behalf.

92. **Superiority**. A class action is superior to other available means for the fair and efficient adjudication of this dispute. The injury suffered by each class member, while meaningful on an individual basis, is not of such magnitude as to make the prosecution of individual actions against Theranos and Walgreens economically feasible. Even if class members themselves could afford such individualized litigation, the court system could not. In addition to the burden and expense of managing many actions arising from the faulty blood tests at issue here, individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation increases the delay and expense to all parties and the court system presented by the legal and factual issues of the

case. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

93. In the alternative, the proposed classes may be certified because:

94. The prosecution of separate actions by the individual members of the proposed class would create a risk of inconsistent adjudications, which could establish incompatible standards of conduct for Theranos and Walgreens;

95. The prosecution of individual actions could result in adjudications, which as a practical matter, would be dispositive of the interests of non-party class members or which would substantially impair their ability to protect their interests; and

96. Theranos and Walgreens have acted or refused to act on grounds generally applicable to the proposed classes, thereby making appropriate final and injunctive relief with respect to the members of the proposed classes as a whole.

COUNT I

Arizona's Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*

(on behalf of Plaintiff, the Arizona Theranos Class, and the Arizona Walgreens Class)

97. Plaintiff incorporates the above allegations by reference.

98. Defendants Theranos and Walgreens, operating in Arizona, engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of "merchandise" (as defined in the Arizona Consumer Fraud Act, A.R.S. §44-1521(5)), in violation of A.R.S. §44-1522(A), including but not limited to the following:

99. Defendants Theranos and Walgreens misrepresented material facts to Plaintiff and class members, in connection with the sale of lab tests, by representing that the tests were reliable, accurate, performed on innovative equipment, and complied with all federal and state laws and regulations;

100. Defendants Theranos and Walgreens omitted, suppressed, and concealed the material fact of the inadequacy of the blood tests' reliability, accuracy, and integrity, with the intent that others rely on the omission, suppression, and concealment;

101. Defendants Theranos and Walgreens engaged in unfair acts and practices, in connection with the sale of blood tests, by misrepresenting the accuracy and reliability of the lab tests they sell and by knowingly concealing and failing to disclose that the lab tests they sell are flawed and unreliable. These unfair acts and practices violated duties imposed by laws including the Clinical Laboratory Improvement Amendments of 1988 and related regulations; and

102. Defendants Theranos and Walgreens engaged in unfair acts and practices with respect to the sale of blood tests by failing to take proper action to notify Plaintiff and class members of the potential inaccuracy of their test results.

103. The above unfair and deceptive practices and acts by Defendants Theranos and Walgreens were immoral, unethical, oppressive, and unscrupulous. These acts caused substantial injury to consumers that the consumers could not reasonably avoid; this substantial injury outweighed any benefits to consumers or to competition.

104. Defendants Theranos and Walgreens knew or should have known that the blood tests they sold were unreliable and prone to inaccuracy, and that risk of a patient or doctor relying on inaccurate test results was highly likely. Defendants' actions in engaging in the above-named unfair practices and deceptive acts were negligent, knowing and willful, and wanton and reckless with respect to the rights of Plaintiff and class members.

105. As a direct and proximate result of Defendants' unlawful practices, Plaintiff and class members suffered injury and damages.

106. Plaintiff seeks relief under A.R.S. § 4421, *et seq.*, including, but not limited to, compensatory damages, punitive damages, injunctive relief, and attorneys' fees and costs.

COUNT II

Breach of the Implied Covenant of Good Faith and Fair Dealing

(on behalf of Plaintiff, the Arizona Theranos Class, and the Arizona Walgreens Class)

107. Plaintiff incorporates the above allegations by reference.

108. Plaintiff entered into an agreement with Theranos or Walgreens to purchase accurate, reliable lab tests using Theranos's secret, proprietary system in exchange for payment, tendered either directly from Plaintiff or through her insurance.

109. Plaintiff did all the things required of her to do, including tendering payment or insurance information and submitting to testing.

110. Plaintiff's acts satisfied all the conditions required for Theranos and Walgreens to perform.

111. Theranos and Walgreens unfairly interfered with Plaintiff's right to receive the benefit of their agreements by (1) failing to timely notify them of the lab tests' unreliability and propensity for inaccuracy, as well as of any actual inaccuracies, and (2) by failing to state clearly that, notwithstanding Theranos and Walgreens' advertisement of revolutionary new testing technology and procedures, the blood tests they provided often were no different than other blood tests on the market.

112. As a direct and proximate cause of Theranos and Walgreens' breaches, Plaintiff and the class were damaged in an amount that will be proven by paying for worthless tests, as well as consequential damages.

COUNT III

Unjust Enrichment

(on behalf of Plaintiff, the Arizona Theranos Class, and the Arizona Walgreens Class)

113. Plaintiff incorporates the above allegations by reference.

114. As described above, Theranos and Walgreens sold lab tests to Plaintiff and the class even though they knew or should have known those tests to be worthless.

115. These sales enriched Theranos and Walgreens at the expense of Plaintiff and the class, who, without knowledge of the unreliability of the lab tests, purchased testing that was, in fact, worthless.

116. It would be inequitable and unjust for Theranos or Walgreens to retain these wrongfully obtained profits.

117. Plaintiff and the class are entitled to restitution of the profits unjustly obtained, plus interest.

COUNT IV

Negligent Misrepresentation

(on behalf of Plaintiff, the Arizona Theranos Class, and the Arizona Walgreens Class)

118. Plaintiff incorporates the above allegations by reference.

119. Theranos and Walgreens provided false information to Plaintiff and the class, for example, that the lab tests they sold were highly accurate and reliable, when in fact the blood tests were not.

120. Theranos and Walgreens intended for Plaintiff and the class to rely on their representations of accuracy and reliability.

121. Theranos and Walgreens failed to exercise reasonable care in obtaining and communicating the information concerning the accuracy of their blood tests.

122. Plaintiff and the class actually and justifiably relied on the representations made to them by Theranos, a corporation in the business of supplying purportedly advanced blood testing services, and Walgreens, a company of long standing and nationwide reach known for providing pharmacy care.

123. Plaintiff and the class suffered damages as a result of their exposure to Theranos and Walgreens' false statements by the purchase of worthless lab tests, the purchase of tests they would not have purchased had they known the truth, and the receipt of test results that were unreliable but which formed the basis of their impressions of and decisions concerning their health.

COUNT V

Negligence

(on behalf of Plaintiff, the Arizona Theranos Class, and the Arizona Walgreens Class)

124. Plaintiff incorporates the above allegations by reference.

125. Theranos and Walgreens each had a duty to provide Plaintiff and the class with reliable, accurate laboratory testing.

126. Theranos and Walgreens breached this duty by providing laboratory tests that were unreliable, conducted in a manner that did not satisfy federal standards for quality control, in laboratories that did not meet federal standards for staffing, on inadequately maintained and calibrated equipment.

127. Plaintiff and class members were damaged as a direct and proximate result of these breaches, including by payment for lab testing services that were unreliable, by submitting to lab testing that they would not have if they had known the tests were unreliable and worthless, by suffering physical invasion of their persons under the false pretense that the blood withdrawal they underwent would result in accurate and reliable test results.

128. Plaintiff and the class are entitled to actual and punitive damages.

COUNT VI

Aiding and Abetting

(on behalf of Plaintiff and the Arizona Walgreens Class)

129. Plaintiff incorporates the above allegations by reference.

130. Theranos has committed torts causing injury to Plaintiff.

131. Walgreens knew that Theranos breached its duties to Plaintiff by providing laboratory tests that were unreliable, conducted in a manner that did not satisfy federal standards for quality control, in laboratories that did not meet federal standards for staffing, on inadequately maintained and calibrated equipment.

132. Walgreens substantially assisted and encouraged Theranos in the breach by agreeing with Theranos to open wellness centers within its stores by which Theranos could offer Plaintiff and the class unreliable and inaccurate lab tests.

133. Walgreens' assistance and encouragement caused Theranos's breach by permitting Theranos to reach an expanded market of consumers and by giving Theranos, a relatively unknown company, the implicit approval of Walgreens, a longstanding company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, prays for the following relief against Theranos and Walgreens, jointly and severally, as follows:

A. An order certifying the proposed class(es), and appointing Plaintiff's counsel to represent the class(es);

B. An order awarding Plaintiff and the class members their actual damages, treble damages, punitive damages, and any other form of monetary relief provided by law;

C. An order awarding Plaintiff and the class(es) restitution, disgorgement, and other equitable relief as the Court deems proper;

D. An order requiring Walgreens to adequately disclose to past recipients of Theranos testing that their test results may be inaccurate and the nature of and reasons for the sanctions faced by Theranos;

E. An order awarding Plaintiff and the class(es) pre-judgment and post-judgment interest as allowed under the law;

F. An order awarding Plaintiff and the class(es) reasonable attorneys' fees and costs of suit, including expert witness fees; and

G. An order awarding such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: August 5, 2016

Respectfully submitted,

GRANT WOODS LAW

By: */s/ J. Grant Woods*

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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): **L.T., on behalf of herself and all others similarly situated,**

County of Residence: Maricopa

County Where Claim For Relief Arose: Maricopa

Defendant(s): **Theranos, Inc. ; Walgreens Boots Alliance, Inc.**

County of Residence: Outside the State of Arizona

Plaintiff's Atty(s):

J. Grant Woods
Grant Woods Law
The Atticus Building, 650 North 3rd Avenue
Phoenix, Arizona 85003
(602) 258-2599

Defendant's Atty(s):

II. Basis of Jurisdiction: **4. Diversity (complete item III)**

III. Citizenship of Principal Parties **(Diversity Cases Only)**

Plaintiff:- **1 Citizen of This State**
Defendant:- **5 Non AZ corp and Principal place of Business outside AZ**

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **370 Other Fraud**

VI.Cause of Action: **28 U.S.C. § 1332(d)(2); Arizona Consumer Fraud Act, A.R.S. § 44-1521, et seq.**

VII. Requested in Complaint

Class Action: **Yes**
Dollar Demand:
Jury Demand: **Yes**

VIII. This case **IS RELATED** to Case Number **2:16-cv-02138** assigned to Judge **G. Murray Snow.**

Signature: /s/ J. Grant Woods

Date: 08/05/2016

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014