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19 ***Attorneys for Plaintiffs***

20 UNITED STATES DISTRICT COURT
21 DISTRICT OF ARIZONA

22 R.C., individually and on behalf of all others
23 similarly situated,

24 Plaintiff,

25 v.

26 THERANOS, INC., a California
27 Corporation, and WALGREENS BOOTS
28 ALLIANCE, INC., a Delaware Corporation,

Defendants.

No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

I. INTRODUCTION

1
2 1. Blood tests are a critical component of a patient’s healthcare. Patients, as well as
3 their doctors, rely on blood tests to detect conditions and use those results to help determine which
4 course of treatment is or isn’t needed. Inaccurate blood test results can contribute to serious
5 conditions going undetected, to treatable conditions growing worse unnoticed, to patients forgoing
6 medications they should take or taking medications they shouldn’t. Inaccurate tests can cost
7 patients time and money, change their lives, cause them emotional distress, lead to unnecessary
8 and improper medical care, and endanger their health and even their lives.
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11 2. Traditionally, blood collection and analysis is straightforward and reliably accurate.
12 Standard blood draw techniques involve venipuncture (drawing blood from a vein, typically in
13 the arm), the collection of a sample using vials of 5 to 10 milliliters, labeling and recording the
14 sample, analyzing it in a lab, and then reporting the results to doctors trained to interpret them.
15 Federal agencies regulate laboratories and lab devices so that patients and doctors can count on
16 accurate testing.
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18 3. Founded in 2003 by Elizabeth Holmes, Defendant Theranos, Inc. (“Theranos”) is a
19 Silicon Valley startup that claims to be a “consumer health technology company” and introduced
20 what it said was a revolutionary new way of drawing and testing blood. Instead of the large
21 needles, tubes, and vials that phlebotomists conventionally use, Theranos claimed to have
22 invented a system that drew blood with a mere pinprick to the fingertip, captured only a few drops
23 in a tiny, proprietary vial or Capillary Tube Nanotainer (“Nanotainer”), and analyzed the sample
24 on a secret device it code-named “Edison.” Edison was supposed to be able to run dozens of tests
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1 using a single miniscule sample, generate results within minutes instead of days or weeks, and
2 deliver results right to a patient's smartphone using a Theranos-developed app.

3
4 4. In the fall of 2013, Theranos announced a long-term partnership with Defendant
5 Walgreens Boots Alliance, Inc. ("Walgreens"), operator of a nationwide drugstore chain.
6 Walgreens and Theranos opened "wellness centers" that conducted blood testing inside
7 Walgreens pharmacies using Theranos's "tiny blood test." Both Theranos and Walgreens assured
8 customers that these tests were highly accurate, industry leading in quality, and developed and
9 validated under—and compliant with—federal guidelines.
10

11 5. Theranos and Walgreens launched their first wellness centers in the Phoenix,
12 Arizona area, along with two wellness centers in northern California near Theranos's Palo Alto
13 headquarters. These wellness centers collected samples that were sent to Theranos-run labs in
14 Scottsdale, Arizona, and Newark, California. Within months of announcing their partnership,
15 Theranos and Walgreens were delivering blood tests to the public through more than 40 wellness
16 centers. Bolstered by the enhanced retail presence and credibility provided through its partnership
17 with Walgreens, Theranos had performed roughly 1.8 million lab tests by the end of 2015.
18

19 6. However, despite the hype, Theranos's Edison system did not work, and the tests
20 were inaccurate.
21

22 7. The Wall Street Journal reported in October 2015 that by the end of 2014, Theranos
23 was actually performing just a handful of tests using the proprietary system on which it had built
24 its brand—less than 10% (or about 15 tests), according to a former senior employee. Theranos
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1 stopped using Edison altogether by June 2015. In place of its highly touted revolutionary
2 proprietary testing system, Theranos secretly used conventional lab machines it purchased from
3 third parties and even outsourced tests to university-affiliated, third-party labs. Even in the face
4 of the public questioning regarding the Edison system, Theranos and Walgreens continued to
5 promote Theranos and its blood tests as less-invasive, quick, and accurate.
6

7 8. But the undisclosed use of conventional systems and outsourcing of tests in place
8 of the Edison system was just the tip of the iceberg. On September 16, 2015, the Food and Drug
9 Administration (“FDA”) issued a two reports raising concerns, *inter alia*, with Theranos’s design
10 validation and that Theranos’s Nanotainer was an uncleared medical device. In January 2016, the
11 Centers for Medicaid and Medicare Services (“CMS”) released a 121-page report detailing
12 violations of federal regulations in Theranos’s Newark lab, the most serious of which posed an
13 “immediate” risk of serious injury or death to patients. The report included findings of five major
14 violations pertaining to hematology, analytics, and staffing. The violations ranged from Theranos
15 staffing its lab with unqualified and inadequately trained personnel to keeping freezers at incorrect
16 temperatures to the failure to calibrate machines properly – or sometimes at all. Theranos even
17 failed its own internal quality-control checks, but would then simply change its quality-control
18 standards so that they matched the data. Independent experts in laboratory science conducted tests
19 that have also confirmed consistent flaws in Theranos’s results.
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23 9. Ms. Holmes told a Fortune reporter that her company was “about being able to do
24 good,” and that she was “building an early-detection system” so that “everybody [could] have
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1 access to the kind of testing infrastructure that can tell you about these conditions in time for you
2 to do something about it.” To the contrary, Theranos’s and Walgreens’ false and misleading
3 marketing around the Theranos tests and the accuracy of their test results prevented consumers
4 from doing the right thing for themselves. As a result, tens of thousands of patients may have been
5 given incorrect blood-test results which, in turn, could result in serious health consequences due
6 to: incorrect diagnoses; the initiation of unnecessary or inappropriate treatments; a delay in or
7 failure to seek treatment for a treatable health condition; the implementation of an ineffective or
8 inappropriate plan of treatment; and/or exposure to unnecessary, inappropriate or potentially
9 harmful treatments.

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12 10. Plaintiff, R.C., went to his local Walgreens store to obtain a Theranos-branded blood
13 test, knowing of Walgreens’ reputation as a longstanding provider of safe and reliable pharmacy
14 care. He received test results that were later invalidated. Plaintiff, for himself, and all others
15 similarly situated, brings this action for damages and injunctive relief.

16 17 **II. JURISDICTION AND VENUE**

18 11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.
19 § 1332(d)(2) because Plaintiff and Defendant are citizens of different states and because, upon
20 information and belief, the aggregate amount in controversy exceeds \$5,000,000 exclusive of
21 costs and interest, there are more than 100 members in the proposed Class, and at least one
22 member of the Class of Plaintiffs is a citizen of a state different from a Defendant.

23
24 12. This Court has personal jurisdiction over Defendant Theranos, Inc., because it
25 conducts business in the state of Arizona.
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1 13. This Court has personal jurisdiction over Defendant Walgreens Boots Alliance, Inc.
2 because it conducts business in the state of Arizona.

3 14. Venue as to Defendants is proper in this judicial district pursuant to 28 U.S.C.
4 §1391(b) because a substantial part of the events or omissions giving rise to the claims occurred
5 in this District. Venue is also proper because Defendants transacted business within the District,
6 and a substantial part of the events establishing the claims arose in this District.
7

8 **III. PARTIES**

9 15. Plaintiff R.C. is a resident of Maricopa County, Arizona and is using his initials to
10 protect his privacy in this litigation. R.C. obtained a blood test at the Theranos Wellness Center
11 located in Walgreen’s pharmacy in Sun City West, Arizona in approximately February 2015.
12

13 16. Defendant Theranos is a Delaware corporation with its principal place of business
14 in Palo Alto, California. Theranos operates two laboratories, one in Newark, California and
15 another in Scottsdale, Arizona. In addition, Theranos operated Theranos Wellness Centers inside
16 Walgreens stores in Arizona and California. Theranos also has its own Wellness Centers in
17 Chandler, Scottsdale, Sun City West, and Tempe, Arizona.
18

19 17. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its
20 principal place of business in Deerfield, Illinois. It is a global pharmacy-led health and well-being
21 enterprise, which, among other segments operates the Walgreens retail pharmacy chain in the
22 United States. Walgreens (along with Theranos) operated Theranos Wellness Centers inside its
23 stores in Arizona and California.
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1 **IV. SUBSTANTIVE ALLEGATIONS**

2 **A. Getting Started**

3 18. Driven by a desire to “revolutionize how effective health care is delivered,”
4 Elizabeth Holmes dropped out of Stanford University in 2003 at the age of nineteen to launch
5 Theranos, despite the fact that she had only rudimentary engineering training and no medical
6 training.
7

8 19. The goal of Theranos was to revolutionize blood testing with tests that could be run
9 with just a few drops of finger-pricked blood—the idea for her company springing forth from her
10 self-professed fear of needles. The company had five objectives: extract blood without syringes,
11 make a diagnosis from a few drops of blood, automate the tests to minimize human error, do the
12 test and get the results more quickly, and do this more economically.
13

14 20. By 2004, Theranos had raised \$6.9 million in funding and gained a valuation of \$30
15 million.
16

17 21. For the next decade, Holmes built the company and sought partners for her concept
18 of the Theranos Wellness Centers. As Theranos described the vision for their Wellness Centers:
19 “Anyone can walk into these Wellness Centers at convenient hours and get accurate, rapid lab
20 testing with transparent prices that are always at least 50-80% below Medicare reimbursement
21 rates.”
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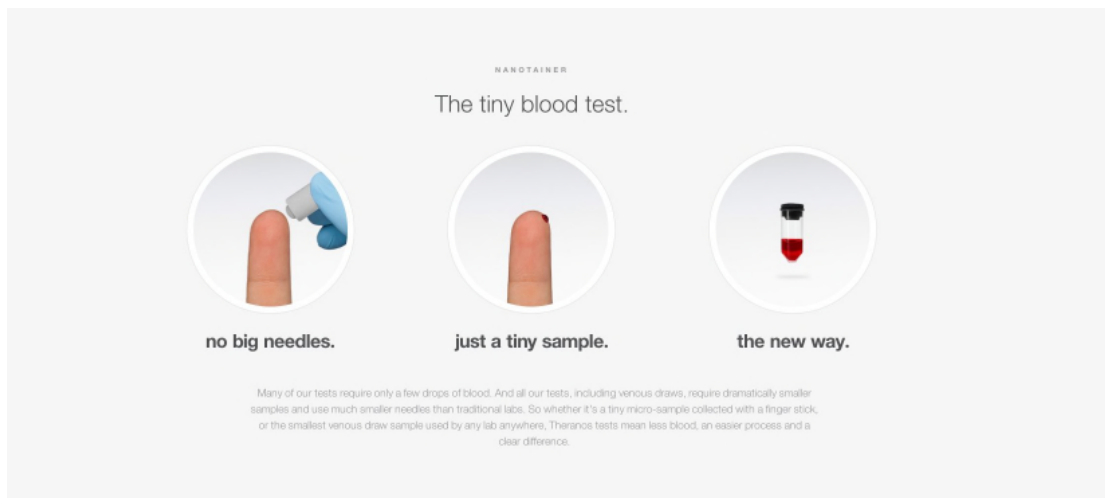
23 22. One of the early partners Theranos found was Walgreens. Walgreens made a deal
24 with Theranos to put its blood-testing centers in thousands of its drugstores nationwide, starting
25 with Arizona and California.
26

1 23. Theranos exploded onto the diagnostic lab testing scene in 2013 with the Theranos
2 Wellness Centers located inside Walgreens stores. Walgreens not only hosted the Theranos
3 Wellness Centers but also provided Theranos with \$50 million in financing and assisted Theranos
4 with scheduling patients and collecting payments.
5

6 24. Theranos eventually opened 56 Theranos Wellness Centers in California and
7 Arizona, the vast majority of which were located in Walgreens stores, even though they were
8 staffed by Theranos employees.
9

10 **B. Theranos’s Tiny Blood Test and Big Claims**

11 25. The main product Theranos offered to consumers was “[t]he tiny blood test.”



26. Theranos emphasized this with its tagline: “one tiny drop changes everything.”

theranos



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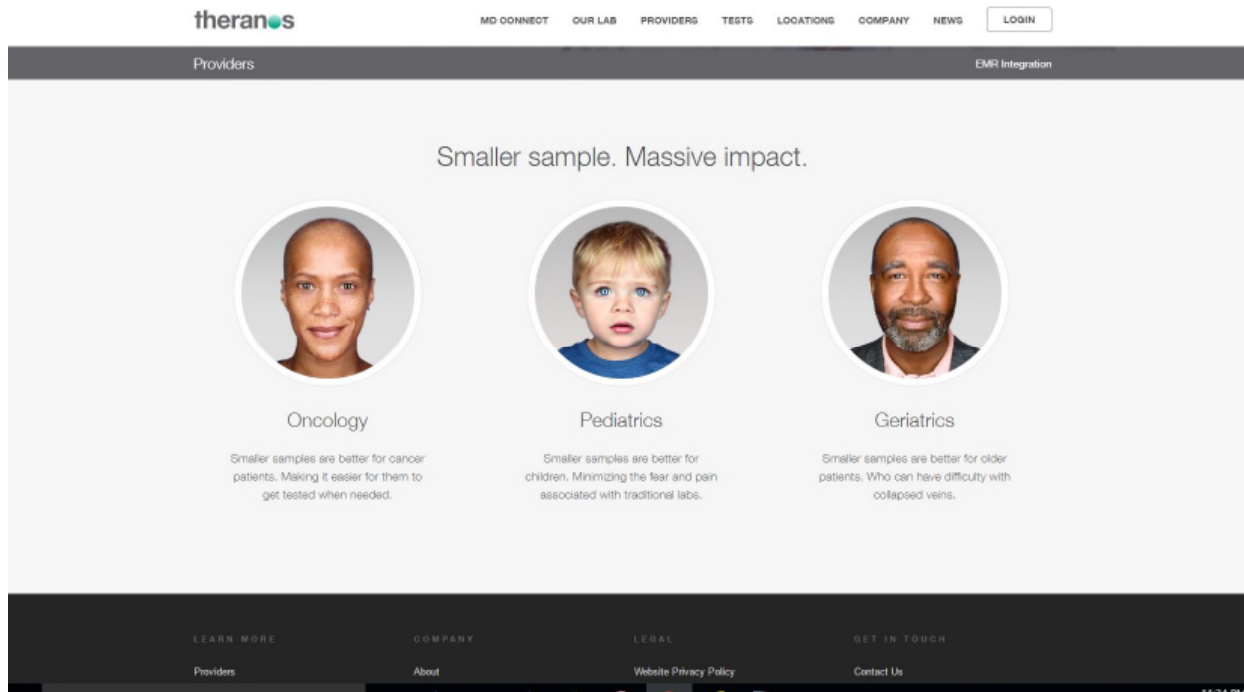
one tiny drop changes everything.

At Theranos, we're working to shape the future of lab testing. Now, for the first time, our high-complexity CLIA-certified laboratory can perform your tests quickly and accurately on samples as small as a single drop.



27. The three pillars of the Theranos blood tests were the small sample needed (“as small as a single drop”), a quick turnaround, and accurate results. Theranos promoted this theme in its advertising materials, on its website, and in numerous public statements.

28. Theranos boasted that it could analyze samples as small as 1/100th to 1/1,000th the size of the ordinary blood draw. Theranos claimed: “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.”



29. Theranos emphasized how it not only used smaller samples but also smaller needles for a less invasive blood-draw experience. They encouraged consumers to “[s]ay goodbye, big bad needle.”



1
2 **goodbye, big bad needle.**

3 Instead of a huge needle, Theranos-trained technicians can use a tiny finger stick² or
4 collect a micro-sample from a venous draw.² It's practically painless and a lot less
5 scary. Now the entire lab testing process is comfortable, accommodating, and less
6 intimidating—for people big and small.



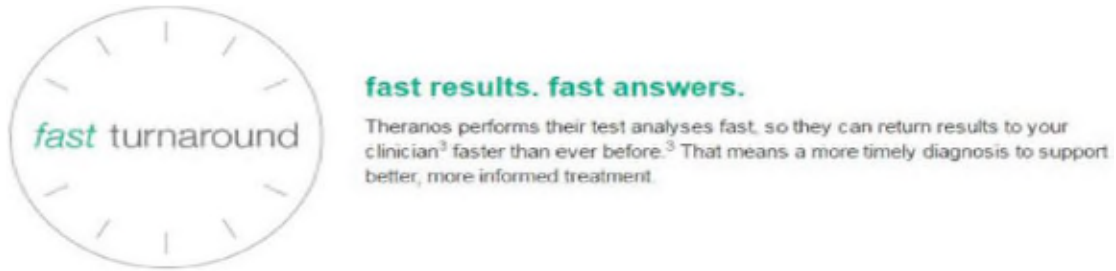
7 30. Theranos assured consumers: “Not a big fan of needles? Neither were we. So we
8 got rid of them.”



22 31. Even though the Theranos tests used very little blood, Theranos claimed their tests
23 were “fast, easy, and the highest level of quality.”

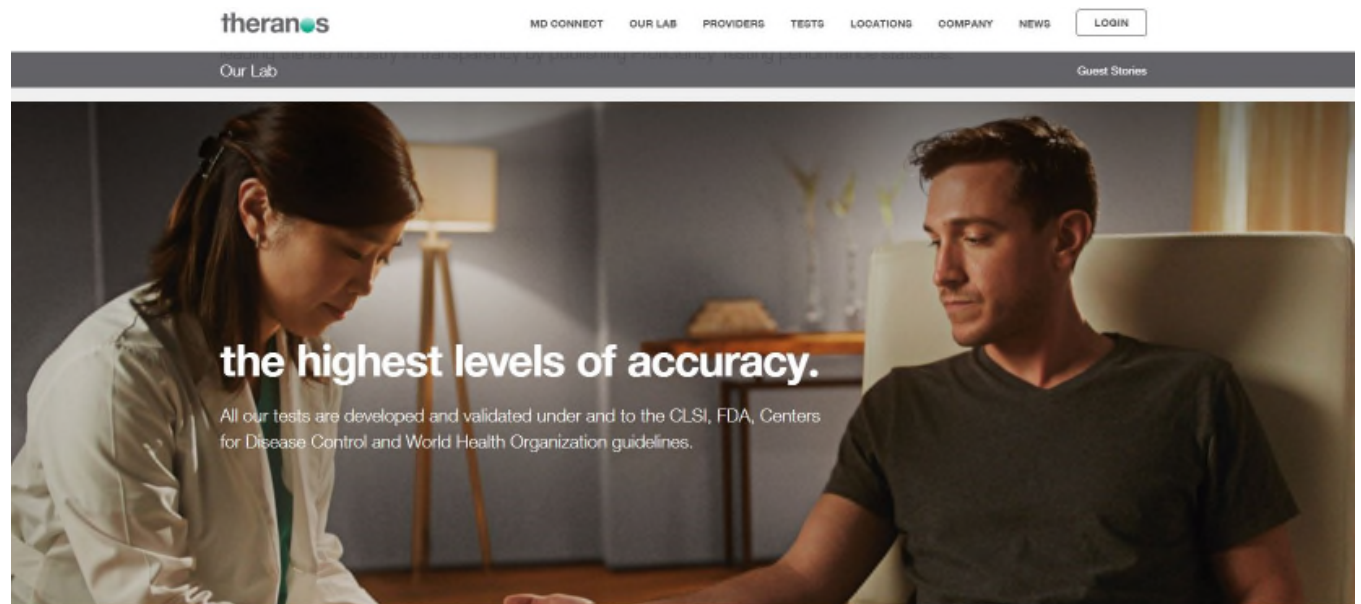
24 32. Theranos also emphasized a benefit of its test being the receipt of accurate results
25 in a timely manner, stating that “what you decide about your health should be informed and timely
26

1 enough to protect or improve it.”



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7 33. Theranos boasted on its website, “We deliver your results fast and right to your
8 phone – often within a matter of hours.”

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10 34. Theranos’s claims went beyond just being accurate to representing that its test
11 results had “the highest levels of accuracy.”



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22 35. Theranos assured consumers that “[w]e realize our mission only when our tests are
23 performed to the highest standards of quality” and that “[w]e continuously conduct proficiency
24 testing and participate in multiple proficiency testing programs.”
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1 36. At the Wellness Centers, Theranos offered a comprehensive slate of some 200 lab
2 tests. Theranos declared: “Every test that we offer in our lab can be run on our proprietary
3 devices.”
4

5 **C. Walgreens Blindly Jumps**

6 37. Theranos’s partnership with Walgreens, a national drug store chain with thousands
7 of stores, greatly bolstered the validity of Theranos.

8 38. On September 9, 2013, Walgreens issued a joint press release with Theranos,
9 affirming the promises made by Theranos, in which they pronounced that:
10

11 Theranos, Inc. and Walgreens...today announced a long-term partnership to bring
12 access to Theranos’s new lab testing service through Walgreens pharmacies
13 nationwide. As the service becomes available through Theranos Wellness Centers
14 inside Walgreens stores, consumers will be able to access less invasive and more
15 affordable clinician-directed lab testing, from a blood sample as small as a few
16 drops, or 1/1,000 the size of a typical blood draw. The samples are either taken from
17 a tiny finger stick or a micro-sample taken from traditional methods, eliminating the
18 need for larger needles and numerous vials of blood required for most diagnostic
19 lab testing ... Theranos’s proprietary laboratory infrastructure minimizes human
20 error through extensive automation to produce high quality results. Test results are
21 available to physicians in a matter of hours, enabling fast diagnoses to help informed
22 treatment choices...

23 “Theranos’ service offers affordable certified lab testing with quicker response
24 times, and furthers our mission to provide a differentiated patient experience,” said
25 Kermit Crawford, Walgreens president of pharmacy, health and wellness. “This is
26 the next step in Walgreens’ efforts to transform community pharmacy, giving our
27 patients and customers convenient access to the comprehensive care they need, right
28 in their communities.”

29 39. What Walgreens failed to disclose was that it in its desire to expand by
30 “transform[ing] community pharmacy” through a venture into the blood-testing business with
31 Theranos’s technology, it had not fully validated Theranos’s technology. Indeed, Walgreens

1 entered into its partnership with Theranos and began promoting the Theranos blood tests and all
2 their big claims without ever even seeing the magical testing device.

3
4 40. The Wall Street Journal reported that before announcing the deal with Theranos in
5 September 2013, some of Walgreens executives and outside advisers had their doubts about
6 Theranos. Many of the concerns centered on the ability to vet the new technology from a startup
7 company with a scant record, as well as Theranos's fierce secretive streak.

8
9 41. In the spring of 2011, Johns Hopkins University scientists wanted to put Theranos's
10 device in their laboratory to verify the technology on Walgreen's behalf as Walgreens was
11 exploring a potential partnership with Theranos. Holmes brought with her to a meeting with
12 Hopkins scientists a machine she claimed could test tiny samples of blood for dozens of
13 conditions, and she as well as Theranos President Sunny Balwani agreed to provide the Hopkins
14 researchers with the device. However, they never did so.

15
16 42. In the summer of 2011, Walgreens sent representatives to Theranos headquarters
17 with lab experts to review Theranos's business operations and lab capabilities. According to the
18 Wall Street Journal, the Walgreens team was ushered into a conference room and "chaperoned
19 throughout the visit," even when the Walgreens team used the restroom. Access was not given to
20 the lab area at Theranos or the Edison devices.

21
22 43. Rather, Theranos provided a prototype. However, the prototype "came with kits to
23 perform esoteric tests that other labs and test makers apparently didn't offer" so that Walgreens
24 could not compare the results from the Theranos prototype to any commercially available tests.
25

1 44. Then, in October 2012, Paul Rust, a retired executive from Quest Diagnostics
 2 Corporation, a clinical-lab company, and two Walgreens executives went on a trip to review
 3 quality-control data at Theranos. According to Rust, neither he nor the other Walgreens executives
 4 were allowed to go into the lab housing the Edison devices. As a result, he had no idea if the
 5 results they were given were run on the Edison devices or not.
 6

7 45. As Walgreens neared a final agreement with Theranos, Theranos asked for more
 8 control, and Walgreens agreed to highly limit its access to data from the blood testing sites that
 9 would be housed in its stores.
 10

11 46. Despite all the red flags, Walgreens moved forward with its partnership with
 12 Theranos, provided Theranos with \$50 million in financing and opening numerous Theranos
 13 Wellness Centers inside of Walgreens stores.
 14

15 **It's easy to get started**



20 **1.** Get a lab order from
your clinician.



21 **2.** Visit your nearest
Theranos™ Wellness
Center inside
Walgreens.



22 **3.** Bring your lab order
to the pharmacy.



23 **4.** Our friendly
technician will take
your sample.

24 47. Walgreens did not close any of the Theranos Wellness Centers located inside its
 25 stores until January 2016, and then it only closed a single center in its Palo Alto, California store.
 26
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1 48. Walgreens did not terminate its relationship with Theranos or announce that it
2 would be closing operations at all Theranos Wellness Centers located within its Arizona stores
3 until June 12, 2016.
4

5 **D. Things Fall Apart**

6 49. While Holmes had dreams of how she could “revolutionize how effective health
7 care is delivered” with Theranos’s “revolutionary lab services,” Theranos’s claims regarding its
8 tests and services were false, deceptive, and misleading.
9

10 50. A recurring theme in public articles about the company was how “Holmes has kept
11 her company, Theranos--which seeks to radically disrupt the lab test industry--shrouded in
12 secrecy.”

13 51. As early as 2012, Theranos knew that concerns were being raised about how “the
14 secretive company was violating federal law.” According to the Washington Post, an official
15 evaluating the Theranos test for use by the Department of Defense in a battlefield environment
16 launched a formal inquiry with the FDA about Theranos’s intent to distribute its tests without
17 FDA clearance. Holmes apparently appealed to a four star marine general she had met at a Marine
18 Memorial event to intervene on Theranos’s behalf. Two months after the general retired from the
19 Marine Corps, he asked a defense department ethics official about future employment with
20 Theranos’s board of directors.
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23 52. In February 2015, John Ioannidis, a Stanford researcher, raised concerns in the
24 Journal of the American Medical Association with Theranos’s secretive approach:
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1 Stealth research creates total ambiguity about what evidence can be trusted in a mix
2 of possibly brilliant ideas, aggressive corporate announcements, and mass media
3 hype. The unquestionable success of computer science, engineering, and social
4 media technologies has created reasonable hope that these technologies can also
5 improve health in ways that the biomedical and life sciences have failed to do until
6 now. But then how can the validity of the claims made be assessed, if the evidence
7 is not within reach of other scientists to evaluate and scrutinize?

8 53. Mr. Ioannidis went on to observe, “investors, physicians, patients, and healthy
9 people will not be able to judge whether some proposed innovation is worth \$9 billion, \$900
10 billion, or just \$9 — let alone if the innovation will improve the health and well-being of
11 individuals.”

12 54. In early May 2015, Eleftherios Diamandis, a Toronto pathologist and lab medicine
13 researcher, published an opinion paper in the *Clinical Chemistry and Laboratory Medicine Journal*
14 concluding that Theranos’s “claims of superiority over current systems and practices are
15 speculative, at best.” In particular, he questioned the quality and robustness of Theranos’s
16 technology:

17 The quality of the results are [sic] not known since the Theranos system has not
18 been independently evaluated, nor do any published results exist to compare with
19 conventional technologies. New diagnostic tests must be evaluated for their
20 accuracy, precision, specificity and long-term robustness. Trueness and precision
21 (accuracy) must be maintained over months or years, and monitored by external
22 quality assurance programs, so that patient’s data can be directly compared over
23 long periods of time. Without independent validation, Theranos technology’s
24 quality and robustness will remain in question.

25 55. On September 16, 2015, the FDA issued two Inspectional Observations reports to
26 Theranos noting deficiencies with Theranos’s devices and procedures. Among the deficiencies
27 noted were:
28

- 1 • Theranos’s Nanotainer was an uncleared medical device that was being shipped in
- 2 interstate commerce;
- 3 • Quality audits have not been performed;
- 4 • Design validation did not ensure the device conforms to defined user need and
- 5 intended uses;
- 6 • The design was not validated under actual or simulated use conditions; and
- 7 • Design input requirements were not adequately documented;

8 56. At the same time the FDA reports were being issued, the Wall Street Journal ran
9 two front-page articles exposing issues with Theranos. Theranos struck back, posting a lengthy
10 response on its website in which it continued to insist:
11

12 “We provide blood tests faster, requiring far less blood and patient discomfort, than
13 for any test previously available—or available today from any other
14 laboratory...We are confident in the reliability of our tests, because we
15 comprehensively validate the accuracy of every test we run ... The faster speed and
16 lower cost of our tests mean that consumers, and their doctors, can monitor their
17 health so that problems are identified early enough to be addressed by medical
18 professionals.”

19 57. In addition, Theranos highlighted in bold lettering its claim that “[o]ur proprietary
20 **devices are making it possible to run finger-stick samples for tests that could never be run**
21 **on finger-stick before.**”

22 58. Complaints also surfaced regarding the length of time it took to receive the results
23 of Theranos tests. For example, William Quirk, a research analyst at Piper Jaffray & Co.,
24 compared blood tests that he took through Theranos and two hospitals. While Theranos
25 proclaimed in its marketing materials that it could provide results in hours, Quirk’s Theranos
26 results came back in 70 hours, nearly three times as long as the hospital labs.
27
28

1 59. On January 25, 2016, Centers for Medicare & Medicaid Services (“CMS”) wrote
 2 Theranos that it had determined through a Clinical Laboratory Improvement Amendments
 3 (“CLIA”)¹ recertification and complaint survey that Theranos’s facility was “not in compliance
 4 with all of the Conditions required for certification in the CLIA program.” CMS further concluded
 5 that “it was determined that the deficient practices of the laboratory pose immediate jeopardy to
 6 patient health and safety.”
 7

8 60. Theranos’s response to CMS was unsatisfactory. Indeed, after reviewing Theranos’s
 9 response, CMS informed Theranos in a March 18, 2016 letter that it had concluded that Theranos’s
 10 response constituted neither a “credible allegation of compliance” nor “acceptable evidence of
 11 correction for the deficiencies cited”:
 12

13 After careful review, we have determined that [Theranos’s] submission does not
 14 constitute a credible allegation of compliance and acceptable evidence of correction
 15 for the deficiencies cited during the CLIA recertification and complaint survey
 16 completed on December 23, 201[5], and does not demonstrate that the laboratory
 17 has come into Condition-level compliance and abated immediate jeopardy. In
 18 general, we find that the statements made in the allegation of compliance and
 19 evidence of correction 1) failed to adequately address the deficient practice cited; 2)
 20 are incomplete and failed to meet the criteria of acceptable evidence of correction;
 21 3) do not ensure sustained compliance; and 4) show a lack of understanding of the
 22 CLIA requirements.

23 61. Based on this survey, Theranos was out of compliance with five CLIA Condition-
 24 level requirements:

D5024: 42 C.F.R. § 493.1215	Condition: Hematology
D5400: 42 C.F.R. § 493.1250	Condition: Analytic systems

25 ¹ CLIA is a federal regulatory standards program whose goal is to ensure accuracy, reliability
 26 and timeliness of test results, regardless of where the test was performed, for all clinical
 27 laboratory tests on humans.

D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director
D6108: 42 C.F.R. § 493.1447	Condition: Laboratories performing high complexity testing; technical supervisor
D6168: 42 C.F.R. § 493.1487	Condition: Laboratories performing high complexity testing; testing personnel

62. The report found that not only did Theranos's blood tests often fail to meet the lab's own standards but also that Theranos employed unqualified personnel to perform, review, and oversee patient test results. The report also found long delays in the notification of patients of flawed test result as well as the storage of blood samples at the wrong temperatures.

63. The Wall Street Journal, which viewed an unredacted version of the 121 page report issued by CMS, revealed that CMS conducted 13 tests on the Edison devices, resulting in numerous problematic findings including:

- 29% of the quality control checks performed on the company's inventions in October 2014 fell outside the normal range;
- In February 2015, a hormone test run on Theranos's proprietary Edison machines failed 87% of quality-control checks;
- In April and May 2015, a test used to detect prostate cancer failed quality-control checks 22% of the time;
- Edison-run tests had frequent, erratic quality-control results in July 2014 as well as from February 2015 to June 2015 and that Theranos sometimes released results to patients even when the Edison devices used to run those tests produced erratic results in quality-control checks; and
- Edison machines often could not reproduce their own results on quality-control samples.

64. CMS inspectors also found that the Edison devices produced test results that differed widely from traditional lab machines for the same blood samples. For example, a gap

1 between the Edison results and those from a traditional machine ranged from 21% to 130% when
2 measuring Vitamin D. However, Theranos's written procedures directed that the difference should
3 be "equal to or less than 20%" according to the Wall Street Journal article.
4

5 65. By the end of 2014, Edison actually handled just a small fraction of the Theranos
6 tests sold to consumers, according to the same article.

7 66. Theranos admitted to regulators it used the Edison, its proprietary device, for 12
8 types of tests out of over 200 types offered to consumers and stopped using the devices altogether
9 in late June 2015.
10

11 67. Rather than running its tests on its revolutionary and widely touted Edison device,
12 Theranos tests were often (incorrectly) run on standard testing equipment.
13

14 68. By mid-May 2016, Theranos voided two years of test results—or tens of thousands
15 of tests—from 2014 and 2015. Theranos also corrected some test results but did not revise others,
16 leaving the void results as the only result the consumer received.

17 69. Theranos proclaims its mission is "to make actionable information accessible to
18 everyone at the time it matters." Theranos claimed its "tiny blood test" was "fast, easy, and the
19 highest level of quality." Theranos sold to consumers that their test results had "the highest levels
20 of accuracy."
21

22 70. Contrary to its mission statement and representations, Theranos's tiny blood test did
23 not provide a test that only needed a finger prick, did not provide timely information, and did not
24 provide accurate information to its consumers. In short, the Theranos test failed on all fronts.
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1 71. Theranos's promises were false, deceptive, and misleading.

2 72. Walgreens's representations regarding the Theranos tests were similarly false,
3 deceptive, and misleading.
4

5 73. Consumers did not receive what they paid for when they received blood tests from
6 Theranos or when they purchased Theranos tests through Walgreens.

7 **V. FACTUAL ALLEGATIONS CONCERNING PLAINTIFF**

8 74. In approximately February 2015, Plaintiff R.C. underwent a Theranos blood test at
9 the Theranos Wellness Center in the Walgreen's pharmacy in Sun City West, Arizona.
10

11 75. R.C. had received orders from his physician to have a routine lipid and A1C blood
12 panel to monitor R.C.'s annual heart health. R.C. knew of Walgreens' reputation as a longstanding
13 provider of safe and reliable pharmacy care and knew that Theranos' blood testing facility was
14 located within a local Walgreen's store. He trusted Theranos and Walgreens to provide reliable
15 test results.
16

17 76. Theranos drew blood from R.C. using its "tiny drop" finger prick method. The
18 process was painful and was not quick as advertised. The phlebotomist struggled to secure enough
19 blood from R.C.'s finger and had to repeat the painful process several times before collecting
20 enough to test.
21

22 77. Theranos tested the blood it drew from R.C.'s arm and sent the results to R.C.'s
23 doctor who reported that R.C.'s blood results were normal. Based on the normal blood test results,
24 R.C.'s doctor recommended R.C. maintain his current medication regime and to return in one year
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1 for repeat testing. R.C. and his doctor relied on the accuracy of the Theranos blood test to make
2 decisions concerning R.C.'s medical treatment.

3
4 78. Less than one month later, R.C. suffered a heart attack. As a result, R.C. was
5 admitted to the hospital and had two stents placed. R.C. and his cardiologist were concerned that
6 R.C. had even suffered an attack given that his blood panels came back clear less than a month
7 prior. Additional blood work performed during his hospitalization strongly suggested that the
8 near-contemporaneous Theranos blood test was inaccurate and that R.C. and his cardiologist's
9 reliance on the Theranos' test results was potentially inaccurate or even harmful.

10
11 79. Subsequently, Theranos "voided" R.C.'s "tiny drop" Theranos test results. This
12 strengthened his concern that the Theranos test results were in fact inaccurate.

13
14 80. Since his 2015 heart attack, R.C. has been receiving medical care using traditional
15 blood testing procedures.

16 VI. CLASS ALLEGATIONS

17 81. Under Rule 23(b)(3) of the Federal Rules of Civil Procedure, Plaintiff seeks
18 certification of the following Class: All purchasers of Theranos lab panels and blood testing
19 services.

20
21 82. Excluded from the Classes are Defendant; the officers, directors or employees of
22 Defendant; any entity in which Defendant has a controlling interest; and any affiliate, legal
23 representative, heir or assign of Defendant. Also, excluded from the Class are any federal, state
24 or local governmental entities, any judicial officer presiding over this action and the members of
25 his/her immediate family and judicial staff, and any juror assigned to this action.
26

1 83. Plaintiff does not know the exact number of Class members. But Theranos claims
2 to have conducted millions of tests, meaning there are at least tens of thousands of Class members
3 such that joinder of all Class members is impracticable.
4

5 84. The Class is easily determined by objective criteria using Defendant's own records,
6 which by law must exist. Theranos knows where each test was performed, by whom, for whom,
7 and when.
8

9 85. There are questions of law and fact common to the Class. Defendant's illegal
10 business practices and unlawful omissions similarly impact Class members, all of whom
11 purchased a Theranos blood test. Plaintiff asserts claims that are typical of the Class. Plaintiff and
12 all Class members have been subjected to the same wrongful conduct because they all purchased
13 a Theranos blood test marketed and sold by Theranos using the same marketing or substantively
14 similar marketing materials or received a test conducted or handled in a similar way. And like
15 other members of the Class, Plaintiff purchased and paid for a Theranos blood test which he
16 otherwise would not have paid for had the test been properly marketed based on truthful and
17 accurate information or did not receive the test promised or due as a matter of law.
18

19 86. As a purchaser of Theranos's services, Plaintiff will fairly and adequately represent
20 and protect the interests of the Class. Plaintiff and the Class are represented by counsel competent
21 and experienced in both consumer protection and Class action litigation.
22

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

- 2 a. Whether Theranos's blood tests were suitable or merchantable.
- 3 b. Whether Theranos's methodologies and equipment complied with industry,
- 4 state, and federal standards.
- 5 c. Whether Theranos's blood tests were as represented or promised.
- 6 d. Whether Theranos's blood tests were of the highest accuracy and quality.
- 7 e. Whether Theranos misrepresented that its tests were minimally invasive,
- 8 accurate, and reliable.
- 9 f. Whether Theranos's conduct violated the Consumer Fraud Act.
- 10 g. Whether the "partnership" announced by Walgreen's and Theranos to
- 11 provide Theranos tests inside Walgreen's stores makes Walgreen's and
- 12 Theranos jointly and severally liable for damages suffered by Plaintiff and
- 13 other members of the Class;
- 14 h. Whether the challenged practices harmed Plaintiff and members of the
- 15 Class; and
- 16 i. Whether Plaintiff and members of the Class are entitled to damages,
- 17 restitution, equitable relief, and/or injunctive relief.

18 88. A Class action is superior to other available methods for the fair and efficient

19 adjudication of this controversy, since joinder of all the individual Class members is

20 impracticable. Because the restitution and/or damages suffered, and continuing to be suffered, by

21 each individual Class member may be relatively small, the expense and burden of individual

22 litigation would make it very difficult, if not impossible, for individual Class members to redress

23 the wrongs done to each individually, and the burden imposed on the judicial system would be

24 enormous.

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1 89. A Class action is manageable, conserves judicial resources and the parties'
2 resources, and protects the rights of each Class member.

3 **VII. CAUSES OF ACTION**

4 **FIRST CAUSE OF ACTION**
5 **(ARIZONA CONSUMER FRAUD)**

6 **Defendant Theranos**

7 90. Plaintiff incorporates by reference the allegations in the above paragraphs as if fully
8 set forth.

9 91. Defendant's advertising and website made use of deception, deceptive acts, unfair
10 acts, fraud, false pretenses, false promises, misrepresentations, concealments, suppression of
11 material facts, and/or omission of material facts in connection with the sale and advertisement of
12 its services in violation of the Arizona Consumer Fraud Act, Arizona Revised Statute § 44-
13 1522(A). These acts include, but are not limited to:

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

1 testing procedures and equipment are flawed and fail to meet its own
2 standards, standards set by the manufacturer, and industry, state, or federal
3 standards.

- 4 • Advertising its goal is to give consumers actionable information but concealing
5 and obfuscating on the methodologies of its tests.
- 6 • Failing to notify consumers in a timely manner that its tests were inaccurate
7 and voidable despite knowing that the tests were not reliable or accurate.

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

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

13 94. Theranos's actions were willful because it knew or should have known that the
14 practices described in this Complaint violated the Consumer Fraud Act.
15

16 **SECOND CAUSE OF ACTION**
17 **NEGLIGENCE**
18 **Defendants Theranos and Walgreens**

19 95. Plaintiff incorporates by reference the allegations in the above paragraphs as if fully
20 set forth

21 96. Theranos and Walgreens each had a duty to provide Plaintiff and the Class with
22 reliable, accurate laboratory testing.

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

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4 98. In particular, Walgreen's acted unreasonably by promoting the Theranos tests to its
5 patrons as less invasive, leading to quicker results than traditional testing methods, and highly
6 accurate, without requiring Theranos to produce objective data that the tests were going to be run
7 on the Edison system rather than existing lab technology, or that they were even as accurate as
8 existing labs, much less more accurate. Walgreen's public announcements of its "partnership"
9 with Theranos and its statement that "This is the next step in Walgreens' efforts to transform
10 community pharmacy, giving our patients and customers convenient access to the comprehensive
11 care they need, right in their communities" shows that Walgreen's knew and expected that its
12 patients and customers would look to it for information concerning "care they need." Having that
13 knowledge, Walgreen's failed to take reasonable steps to prevent their patients and customers
14 from falling prey to Theranos's unfounded claims.
15
16

17 99. By instead promoting the Theranos tests, Walgreens acted unreasonably under the
18 circumstances.
19

20 100. Plaintiff and Class members were damaged as a direct and proximate result of these
21 breaches, including by payment for lab testing services that were unreliable, by submitting to lab
22 testing that they would not have if they had known the tests were unreliable and worthless, and
23 by suffering physical invasion of their persons under the false pretense that the blood withdrawal
24 they underwent would result in accurate and reliable test results.
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1 101. Plaintiff and the Class are entitled to actual and punitive damages.

2 **THIRD CAUSE OF ACTION**
3 **(NEGLIGENT MISREPRESENTATION)**
4 **Defendants Theranos and Walgreens**

5 102. Plaintiff incorporates the above allegations by reference.

6 103. Theranos and Walgreens provided false information to Plaintiff and the Class, for
7 example, that the lab tests they sold were highly accurate and reliable, when in fact the blood tests
8 were not.

9
10 104. Theranos and Walgreens intended for Plaintiff and the Class to rely on their
11 representations of accuracy and reliability.

12 105. Plaintiff and the Class actually and justifiably relied on the representations made to
13 them by Theranos, a corporation in the business of supplying purportedly advanced blood testing
14 services, and Walgreens, a company of long standing and nationwide reach known for providing
15 pharmacy care.
16

17 **FOURTH CAUSE OF ACTION**
18 **(BREACH OF CONTRACT)**
19 **Defendant Theranos**

20 106. Plaintiff incorporates the allegations in the above paragraphs as if fully set forth
21 herein.

22 107. Defendant Theranos entered contracts with Plaintiff and Class members that were
23 identical or substantially identical. Each contract provided that in exchange for monetary
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1 consideration, Theranos would provide reliable blood tests with its proprietary “Edison” blood
2 analysis technology.

3
4 108. Plaintiff and other Class members each paid money directly or indirectly for the
5 blood tests offered by Theranos.

6 109. Theranos breached its contract with Plaintiff and Class members by (1) providing
7 tests that were not of the promised high level of accuracy and quality; (2) conducting tests using
8 traditional blood testing methodologies and equipment instead of its self-proclaimed minimally
9 invasive state-of-the art proprietary system; (3) failing to draw blood in the minimally invasive
10 way advertised; (4) failing to ensure its equipment met its own quality standards; (5) failing to
11 ensure its services were tendered with reasonable care and workmanlike effort, including failing
12 to ensure its equipment met industry, state, or federal standards and failing to ensure lab staff was
13 properly trained and monitored; and (6) failing to act in good faith and deal fairly with Class
14 members by acting to deprive Class members of the justified expectations they were to receive
15 under the contract, including failing to notify Class members in a timely fashion of the deficiencies
16 and problems with the tests or their results and not clarifying that certain services were
17 conventional and no different than other blood tests on the market.
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21 110. In May 2016, Theranos informed federal health regulators that the company had
22 voided all 2014 and 2015 blood test results from its Edison blood-testing devices. Each Class
23 member who had a test using the Edison technology during those years did not receive the benefit
24 of their bargain – a reliable, accurate blood test.
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1 111. Theranos purports to be issuing corrected results, but upon information and belief it
2 is impossible re-test samples and give accurate and reliable updated results from samples taken in
3 2014 and 2015, especially when the blood draws should have been minimally invasive, small
4 sample sizes according to Defendant's own advertisements.
5

6 112. Even if re-testing the samples were feasible and would yield accurate, reliable
7 results, these re-tests would still not adequately remedy Defendant's breach of contract. Such
8 blood tests, by their nature, are administered to provide time-sensitive information about an
9 individual's health condition. Receiving such information months or even years after the date of
10 testing will in most cases be of little to no value to Class members.
11

12 113. As a result of Defendant's conduct, Plaintiff and Class members have been injured.
13

14 **FIFTH CAUSE OF ACTION**
15 **(UNJUST ENRICHMENT)**
16 **Defendant Theranos**

17 114. Plaintiff incorporates the allegations in the above paragraphs as if fully set forth
18 herein.
19

20 115. In the event that there is no legal contract between Theranos and Class members,
21 Plaintiff alleges the following in the alternative to the breach of contract claim alleged herein, on
22 behalf of himself and the Class.
23

24 116. As the intended and expected result of its conscious wrongdoing as set forth in this
25 Complaint, Theranos has profited and benefited from the unlawful sale of its misleading,
26 unreliable, and inaccurate blood tests.
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1 117. To the detriment of Plaintiff and Class members, Theranos has been and continues
2 to be unjustly enriched as a result of the unlawful and/or wrongful conduct alleged herein.

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

6 119. Plaintiff and Class members paid for minimally invasive, accurate, and reliable
7 blood tests, but received invasive, inaccurate and unreliable tests.
8

9 120. Between Theranos and Plaintiff/Class members, it would be unjust for Theranos to
10 retain the benefits attained by its wrongful actions.
11

12 121. Theranos has been unjustly enriched at the expense of Plaintiff and Class members
13 who are entitled in equity to disgorgement and restitution of Defendant's wrongful profits,
14 revenue, and benefits, to the extent, and in the amount deemed appropriate by the court, and any
15 other relief the court deems just and proper to remedy Defendant's unjust enrichment.
16

17 **SIXTH CAUSE OF ACTION**
18 **(AIDING AND ABETTING TORTIOUS CONDUCT)**
19 **Defendant Walgreens**

20 122. Plaintiff incorporates the allegations in the above paragraphs as if fully set forth
21 herein.

22 123. Theranos has committed torts causing injury to Plaintiff.

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

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4 125. Walgreens substantially assisted and encouraged Theranos in the breach by agreeing
5 with Theranos to open wellness centers within its stores by which Theranos could offer Plaintiff
6 and the Class unreliable and inaccurate lab tests. Walgreens' assistance and encouragement
7 permitted Theranos to reach an expanded market of consumers and gave Theranos, a relatively
8 unknown company, the implicit approval of Walgreens, a longstanding company.

9
10 126. As a result of its substantial assistance and encouragement of Theranos' wrongful
11 conduct, Walgreens is responsible for the consequences of Theranos' conduct.

12
13 **SEVENTH CAUSE OF ACTION**
14 **(CIVIL CONSPIRACY)**
15 **Defendants Theranos and Walgreens**

16 127. Plaintiff incorporates the allegations in the above paragraphs as if fully set forth
17 herein.

18 128. Theranos and Walgreens agreed to work together and undertook overt acts in
19 furtherance of their agreement, the execution of which constituted the torts alleged herein.
20 Defendants' agreements and resulting overt acts resulted in damages to Plaintiff and the Class.

21 129. As a result, Defendants are jointly and severally liable for the damages resulting
22 from their agreements and resulting overt acts.

**EIGHTH CAUSE OF ACTION
(PUNITIVE DAMAGES)
Defendants Theranos and Walgreens**

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

131. The actions set forth above demonstrate that the two Defendants acted to further their own financial interests while knowing or having reason to know, but consciously ignoring, the substantial risk that the purchasers of the inaccurate tests would suffer significant harm by wasting money on tests that had to be repeated, getting incorrect test results or results that couldn't be trusted, and thus requiring additional testing and possible delays in diagnosis of their physical conditions.

132. Such actions warrant punitive damages under Arizona law, a decision left to the jury, which also decides the amount necessary to punish the conduct of these Defendants and to deter similar conduct in the future by others.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and for members of the Class, respectfully requests that the Court enter judgment in their favor and against Defendants, 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 Defendants from continuing the unlawful, deceptive, fraudulent, and unfair business practices alleged in this Complaint;

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

3
4 D. Punitive damages in an amount determined by the jury to be sufficient to punish the
5 Defendants for their conduct and to deter such conduct by others in the future;

6 E. An order requiring Defendants to pay both pre- and post-judgment interest on any
7 amounts awarded;

8
9 F. An award of costs and attorneys' fees under those causes of action arising from
10 contract pursuant to A.R.S. §12-341.01 and any other applicable law; and

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

12 **DEMAND FOR JURY TRIAL**

13 Plaintiff demands a jury trial for all claims so triable.

14
15 DATED this 15th day of July, 2016.

16 KELLER ROHRBACK L.L.P.

17
18 By: /s/ Mark D. Samson
19 Mark D. Samson
20 Ron Kilgard
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Attorneys for Plaintiffs

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.

Plaintiffs R.C., individually and on behalf of all others similiarly situated

County of Residence: **Maricopa**

County Where Claim For Relief Arose: **Maricopa**

Defendants THERANOS, INC., a California Corporation, and WALGREENS BOOTS ALLIANCE, INC., a Delaware Corporation,
County of Residence: Outside the State of Arizona

Plaintiff's Atty(s):

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Gretchen Freeman Cappio

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Defendant's Atty(s):

II. Basis of Jurisdiction: 4. Diversity

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: **Consumer Fraud Class Action - Diversity**

VII. Requested in Complaint

Class Action: **Yes**
Dollar Demand: **\$5,000,000.00**
Jury Demand: **Yes**

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

Signature: /s/ T. David Copley

Date: 07/15/16

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.