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14  
15 **UNITED STATES DISTRICT COURT**  
16 **NORTHERN DISTRICT OF CALIFORNIA**  
17

18 C.M. and S.G., on behalf of themselves and  
19 all others similarly situated,

20 Plaintiffs,

21 v.

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

24 Defendants.

Case No. \_\_\_\_\_

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

**INTRODUCTION**

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

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

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

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

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

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

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

28

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

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

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

28



**THE PARTIES**

**I. Plaintiffs**

17. Plaintiffs are identified herein using their initials to preserve the confidentiality of their personal medical information.

18. Plaintiff C.M. is a resident of Maricopa County, Arizona. She purchased blood testing services from Theranos at a Walgreens wellness center located in Goodyear, Arizona in 2015.

19. Plaintiff S.G. is a resident of Maricopa County, Arizona. She purchased blood testing services from Theranos at a Walgreens wellness center located in Glendale, Arizona in 2015.

**II. Defendants**

20. 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.

21. 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.**

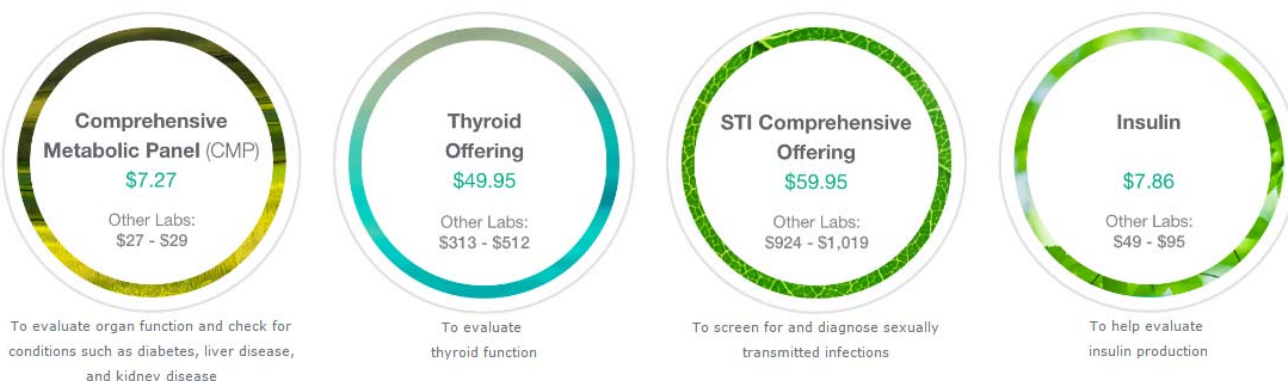
22. Elizabeth Holmes was 19 years old and a sophomore at Stanford when, in 2003, she saw an opening into the United States’ multibillion-dollar lab testing market. Driven, she has said, by her phobia of needles, Holmes dropped out of Stanford and founded Theranos, a company that has sought to “disrupt”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

23. 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.<sup>1</sup>

The same low prices for everyone.

Whether you have good insurance, bad insurance or no insurance at all, at Theranos we believe you should be able to afford lab testing. Which is why Theranos charges everyone the same low prices. Period. Theranos prices are clear, up-front, published online, and always a fraction of other labs. Meaning there are no surprises, and you know exactly what you’re paying before you get tested.

[View test menu >](#)



<sup>1</sup> Theranos.com, “Test Menu,” <https://www.theranos.com/test-menu> (last visited June 8, 2016).

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

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

13           26.     Theranos, however, sought to sidestep doctors and their traditional gatekeeping function  
14 by marketing, selling, and delivering its services directly to patients. Theranos even developed  
15 smartphone apps to deliver test results, so that patients would receive (and have to interpret) test results  
16 themselves.

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

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

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

27           29.     At the same time, Walgreens was seeking opportunities to capture new revenue streams  
28 by branching out beyond traditional drugstore offerings. For example, in 2009, following a severe flu



1 season, Walgreens and other pharmacy chains lobbied state legislatures to permit pharmacists to begin  
2 administering injections of flu vaccine. By 2012, Walgreens was giving more than 6 and a half million  
3 flu shots per year and reaping month-after-month revenue increases as a result.

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

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

11 32. By spring of 2011, the parties' talks had become serious. Walgreens started making  
12 plans to vet Theranos. Walgreens, however, never followed through on its plans. Fearful that Theranos  
13 would strike a deal with one of its competitors instead, Walgreens looked past Theranos's failure to  
14 provide access to promised data and information, accepted incomplete information, and failed to  
15 adequately test and inspect Theranos's equipment and capabilities.

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

23 34. Instead of insisting that Theranos keep its promise, Walgreens obtained a prototype of  
24 the Edison device. And rather than providing this device to Johns Hopkins, Walgreens had its  
25 employees set up the prototype in a cubicle and began trying to verify its accuracy themselves. They  
26 discovered, however, that the test results delivered by the prototype could not be compared to those of  
27 conventional labs, as the prototype reported results using values like "high" or "low" instead of the  
28 numeric values that conventional labs use, and only performed unusual tests that conventional labs do

1 not offer. Despite these incomplete and inconclusive efforts, Walgreens did not halt the deal with  
2 Theranos.

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

7 36. For example, in summer 2011, when Walgreens and Theranos had already signed an  
8 initial letter of agreement, Walgreens sent consultants from a firm called Colaborate LLC, a laboratory  
9 testing and evaluation firm, to Theranos's headquarters in Palo Alto. Accompanying the consultants  
10 were Dr. Rosan, Wade Miquelon (Walgreens' former chief financial officer), and other Walgreens  
11 employees. Throughout the visit, Theranos kept Colaborate and the Walgreens representatives in a  
12 conference room. Theranos declined to show them the laboratory and even escorted them when they  
13 visited the restroom. Neither did Theranos provide Colaborate with access to an Edison machine.  
14 Colaborate eventually issued a report telling Walgreens that it lacked sufficient information to  
15 consummate the Theranos deal, but Walgreens pushed ahead with it regardless.

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

23 38. Publicly available information alone should have led Walgreens to conclude that it  
24 needed further confirmation of Theranos's reliability and accuracy entering into any deal that would  
25 expose patients to Theranos's testing methods. For example, Walgreens should have known and  
26 appreciated the importance of Theranos's improper staffing of its laboratories. The director of  
27 Theranos's Scottsdale lab is Daniel Young, a mechanical engineer with no medical degree. The  
28 director of Theranos's Newark lab was, until recently, Sunil Dhawan, a dermatologist with no degrees

1 or certification in pathology or laboratory science who worked for Theranos only part-time. It was  
2 Dhawan's directorship of the Newark lab that constituted one of the five major violations at the Newark  
3 lab identified by federal regulators and led to the threatened sanctions Theranos now faces. According  
4 to public reports, Dhawan's name was listed on the Newark lab's license.

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

10 40. According to public reports, however, Safeway pulled out of its deal with Theranos after  
11 its due diligence raised questions about the accuracy of the testing Theranos sought to offer. For  
12 example, Safeway executives had their own blood tested by both Theranos and another, conventional  
13 lab. The test results differed significantly. One executive's results from Theranos showed such highly  
14 elevated quantities of prostate-specific antigen (PSA) as to suggest he had prostate cancer.  
15 Conventional lab testing, however, confirmed that his PSA levels were normal. Easily discovered  
16 discrepancies like these contributed to Safeway's reluctance to move forward with offering Theranos  
17 testing to the public.

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

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

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

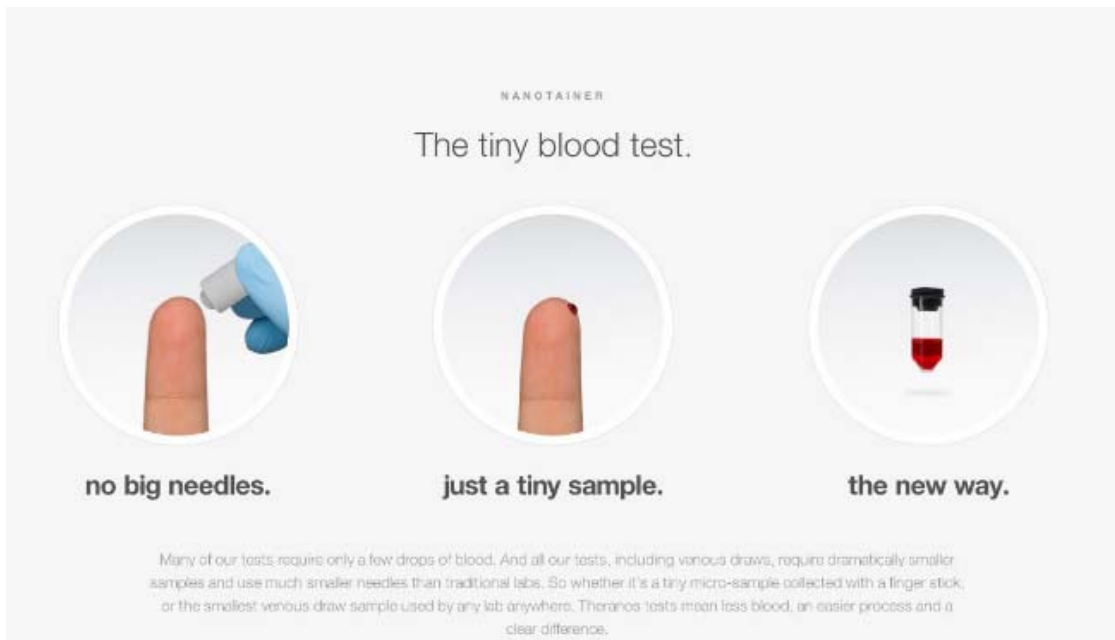
1 **III. Theranos and Walgreens Open Their Wellness Centers**

2 44. Theranos and Walgreens took the first major step of their long-range plan in September  
3 2013, when they announced their partnership and opened the first of more than 40 wellness centers,  
4 mostly clustered in the Phoenix metropolitan area and nearly all of which were inside Walgreens stores.



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

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



47. 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.



Home > Pharmacy & Health

**theranos**

**the lab test, reinvented.**

**Walgreens Partners with Theranos to Provide Lab Services.**

Theranos is working to shape the future of lab testing. Now, for the first time, their high-complexity CLIA-certified laboratory can perform your tests quickly and accurately on samples as small as a single drop.<sup>1</sup>

[Learn more at Theranos.com](#)



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

6           49.     Theranos’s website continues to claim “the highest levels of accuracy,” explaining that  
7 “[a]ll our tests are developed and validated under and to the CLSI, FDA, Centers for Disease Control[,]  
8 and World Health Organization guidelines.”

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

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

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

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

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

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

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

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

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

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

27

28

1           58.     Theranos employees have leaked to the press that Theranos diluted the “microsamples”  
2 of blood that they took so that the samples would meet the minimum volume requirements of the  
3 conventional machines Theranos used.

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

8 **V.     Published Reports and Government Investigations Undermine Theranos’s Claims of**  
9 **Accurate, Reliable Testing.**

10           60.     In January 2016, news reports revealed that the Centers for Medicare & Medicaid  
11 Services (“CMS”), the federal regulator responsible for the integrity of laboratory testing, had inspected  
12 Theranos’s Newark lab and found five major infractions, including one “likely to cause, at any time,  
13 serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of  
14 the general public.”

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

- 18           • 42 C.F.R. § 493.1215: The CMS observed that Theranos failed to conduct adequate  
19 quality controls relating to hematology. This was the violation that the CMS identified  
20 as likely to cause serious injury, harm, or death at any time. One observation  
21 underpinning the CMS’s finding of inadequate quality controls related to PT/INR test  
22 results. The PT/INR test measures how long blood takes to clot, and it is used to  
23 monitor individuals being treated with the blood-thinner warfarin, sold under the trade  
24 name Coumadin—a medication prescribed to help prevent heart attack and stroke in  
25 especially vulnerable patients.
- 26           • 42 C.F.R. § 493.1250: This finding related to numerous failures in Theranos’s analytic  
27 systems, including failures to perform required weekly maintenance on certain of its  
28 testing machines and failures to keep freezers at the proper temperature.



- 1 • 42 C.F.R. § 493.1441: The CMS observed numerous failures relating to Theranos's  
2 failure to employ a qualified lab director. The CMS found, among other things, that the  
3 director failed to ensure that required daily quality controls were performed, failed to  
4 ensure that the results of quality control materials met the laboratory's own criteria for  
5 acceptability, and failed to ensure that laboratory personnel were properly trained.
- 6 • 42 C.F.R. § 493.1447: The CMS made numerous findings related to the inadequacy of  
7 Theranos's lab supervisors, for example, finding that two of the three supervisors failed  
8 to meet federal minimum standards requiring four years of experience.
- 9 • 42 C.F.R. § 493.1487: The CMS found that some of the testing personnel employed in  
10 the Newark lab lacked federally required degrees in the hard sciences (one, for example,  
11 had a Liberal Studies degree) and had not received required training on the testing  
12 machines they operated.

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

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

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

25 64. According to the CMS, Theranos's own data showed unacceptable discrepancies  
26 between the measurements produced by Edison and conventional testing machines. For example,  
27 Vitamin D measurements differed between 21 and 130 percent, thyroid function tests differed by 21 to  
28

1 39 percent, and testosterone tests differed by 22 to 146 percent. But Theranos’s own internal guidelines  
2 specified that they should differ no more than 20 percent.

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

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

9 67. Finally, the CMS stated that its inspection of Theranos’s lab took “an overview of the  
10 laboratory through random sampling” and observed that, due to its random nature, the inspection might  
11 “not find every violation that the laboratory may have committed.”

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

16 69. Independent researchers have confirmed the infirmity of Theranos’s results. In March  
17 2016, the Journal of Clinical Investigation published the results of a study of 60 healthy adults that  
18 compared test results they received from Theranos with those they received from Quest and LabCorp  
19 using samples taken the same day. The study found Theranos was 60 percent more likely to report  
20 results outside of normal ranges. For example, Theranos’s cholesterol tests were an average of 9.3  
21 percent lower than those of the other labs—a fact which, the report said, could lead health care  
22 providers to “either inappropriately initiate or fail to appropriately initiate statin therapy.”

23 70. Had Theranos or Walgreens divulged data reflecting the nature and quality of the tests  
24 they offered, patients who relied on their assurances of high-quality, accurate testing would have had  
25 the opportunity to make an informed decision about whether to use their services.  
26  
27  
28

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

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

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

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

14 74. Plaintiffs' investigation has uncovered no indication that Walgreens required Theranos  
15 to verify the reliability and accuracy of results issuing from its Scottsdale lab.

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

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

23 **VII. The Federal Government Threatens Sanctions Against Theranos.**

24 77. On March 18, 2016, the CMS sent Theranos a letter proposing to sanction it for failing  
25 to adequately address the five major infractions identified in its January 25, 2016 letter and report.  
26 Among the sanctions proposed are:  
27  
28

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

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

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

20 79. In May 2016, Theranos disclosed that it had withdrawn all of the Edison test results it  
21 produced in 2014 and 2015. Theranos ran approximately 890,000 tests per year during that period.  
22 Theranos told CMS that it had reissued “tens of thousands” of blood-test reports, either voiding results  
23 or correcting them. Theranos’s notification efforts, then, reached roughly 1 to 5 percent of patients who  
24 received unreliable blood tests from Theranos and Walgreens.<sup>2</sup>

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25 <sup>2</sup> Assuming Theranos delivered 890,000 tests in 2014 and 2015, it delivered approximately 1.8  
26 million tests. Assuming that Theranos’s notification of “tens of thousands” of patients means it notified  
27 between 20,000 and 90,000, Theranos notified between 1.1 and 5.0 percent of the 1.8 million test  
28 recipients, approximately.

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

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

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

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

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

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

## 24 **IX. Plaintiffs' Experiences**

### 25 **1. C.M.**

26           86.     Plaintiff C.M. suffers from Hashimoto's disease, an autoimmune disorder in which the  
27 immune system attacks the thyroid gland. As part of her treatment, C.M. undergoes regular blood  
28 testing.

1 87. In the summer of 2015, C.M. decided to try Theranos. She had several tests done at a  
2 Theranos-run wellness center located within a Walgreens in Goodyear, Arizona. As a result of her  
3 Theranos test results, her endocrinologist took her off medication used to treat her thyroid condition.

4 88. C.M. has never received notice of the problems with Theranos's labs and tests from  
5 Theranos or from Walgreens.

6 89. Had C.M. known that Theranos's blood tests were inaccurate or that Theranos violated  
7 federal regulations, she would not have purchased a Theranos blood test or would have paid  
8 significantly less for it.

9 **2. S.G.**

10 90. Plaintiff S.G. undergoes thyroid hormone replacement therapy, and must get her blood  
11 tested regularly.

12 91. In April 2015, S.G. decided to try Theranos. She had a blood test done at a Theranos-  
13 run wellness center located within a Walgreens in Glendale, Arizona.

14 92. S.G. has never received notice of the problems with Theranos's labs and tests from  
15 Theranos or from Walgreens.

16 93. Had S.G. known that Theranos's blood tests were inaccurate or that Theranos violated  
17 federal regulations, she would not have purchased a Theranos blood test or would have paid  
18 significantly less for it.

19 **COLLECTIVE AND CLASS ACTION ALLEGATIONS**

20 94. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action  
21 on behalf of themselves and the following proposed classes and sub-classes, defined as follows:

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

24 i. Arizona Walgreens Subclass: *All persons who purchased a Theranos lab test*  
25 *from Walgreens in Arizona between September 1, 2013, and the present.*

26 B. Nationwide Theranos Class: *All persons who purchased a Theranos lab test from*  
27 *Theranos in the United States between September 1, 2013, and the present.*

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

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

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

12           97. **Commonality and Predominance**. Common questions of law and fact exist as to all  
13 proposed class members and predominate over questions affecting only individual class members.

14 These common questions include whether:

- 15           A. A reasonable consumer would consider the flaws in Theranos's lab testing to be  
16           important;
- 17           B. Theranos knew its lab tests were inaccurate, and if so, when it discovered this;
- 18           C. Walgreens knew that Theranos's lab tests were inaccurate, and if so, when it discovered  
19           this;
- 20           D. Theranos and Walgreens misrepresented to potential customers the lab tests' propensity  
21           for inaccuracy;
- 22           E. Theranos and Walgreens are obligated to provide notice of inaccurate test results to the  
23           patient whose blood or other samples was tested;
- 24           F. Theranos and Walgreens' conduct violates the Racketeer Influenced and Corrupt  
25           Organizations Act; and
- 26           G. Theranos and Walgreens' conduct violates various consumer protection statutes.
- 27
- 28

1           98.     **Typicality.** Plaintiffs' claims are typical of the claims of the proposed classes.  
2 Plaintiffs and the members of the proposed classes all purchased blood tests from Theranos and/or  
3 Walgreens during the Class Period, giving rise to substantially the same claims.

4           99.     **Adequacy.** Plaintiffs are adequate representatives of the proposed classes because their  
5 interests do not conflict with the interests of the members of the classes they seek to represent.  
6 Plaintiffs have retained counsel competent and experienced in complex class action litigation, and will  
7 prosecute this action vigorously on class members' behalf.

8           100.    **Superiority.** A class action is superior to other available means for the fair and efficient  
9 adjudication of this dispute. The injury suffered by each class member, while meaningful on an  
10 individual basis, is not of such magnitude as to make the prosecution of individual actions against  
11 Theranos and Walgreens economically feasible. Even if class members themselves could afford such  
12 individualized litigation, the court system could not. In addition to the burden and expense of  
13 managing many actions arising from the faulty blood tests at issue here, individualized litigation  
14 presents a potential for inconsistent or contradictory judgments. Individualized litigation increases the  
15 delay and expense to all parties and the court system presented by the legal and factual issues of the  
16 case. By contrast, a class action presents far fewer management difficulties and provides the benefits of  
17 single adjudication, economy of scale, and comprehensive supervision by a single court.

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

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

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

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

28



**COUNT I**

**California’s Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 *et seq.***

**(on behalf of Plaintiff S.G., the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

105. Plaintiffs incorporate the above allegations by reference.

106. Theranos and Walgreens have violated and continue to violate California’s Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.*, which prohibits unlawful, unfair, or fraudulent business acts or practices.

107. Theranos and Walgreens’ acts and practices, as alleged in this complaint, constitute unlawful, unfair, and fraudulent business practices, in violation of the Unfair Competition Law. In connection with the sale of lab tests to Plaintiff S.G. and class members, Theranos and Walgreens misrepresented the nature of the testing provided, claiming it was a revolutionary new method when in fact it was not materially different than conventional testing. Theranos and Walgreens also misrepresented the reliability and accuracy of the testing. These misrepresentations were important to Plaintiff S.G. and would be important to a reasonable consumer. Theranos and, until days ago, Walgreens sold the lab tests while claiming they are highly accurate and reliable.

108. Theranos and Walgreens’ business acts and practices are unlawful in that they violate the federal Racketeer Influenced and Corrupt Organization Act and California’s Consumers Legal Remedies Act, as discussed in the causes of action that follow

109. Theranos and Walgreens’ business acts and practices are also unlawful in that they violate federal regulations implementing the Clinical Laboratory Improvements Amendments of 1988, including 42 C.F.R. §§ 493.1215, 493.1250, 493.1441, 493.1447, and 493.1487 and other regulations identified in the CMS’s report of January 25, 2016, by, for example, failing to implement compliant quality-control procedures, failing to maintain and calibrate equipment properly, and failing to staff testing laboratories with qualified directors, supervisors, and personnel.

110. Theranos and Walgreens’ acts and practices also constitute fraudulent practices in that they are likely to deceive a reasonable consumer. As described above, Theranos and Walgreens misrepresented the nature of the testing provided, claiming it was a revolutionary new method when in fact it was not materially different than conventional testing. Theranos and Walgreens also

1 misrepresented the reliability and accuracy of the testing. Had Theranos or Walgreens accurately  
2 represented these facts, Plaintiffs and the proposed class members would not have purchased these  
3 blood tests or would have paid significantly less for them.

4 111. Theranos and Walgreens' conduct also constitutes unfair business practices in that:

- 5 A. The gravity of harm to Plaintiff S.G. and the proposed class members from Theranos  
6 and Walgreens' acts and practices far outweighs any legitimate utility of that conduct;  
7 B. Theranos and Walgreens' conduct is immoral, unethical, oppressive, unscrupulous, or  
8 substantially injurious to Plaintiffs and the proposed class members; and  
9 C. Theranos and Walgreens' conduct undermines or violates the stated policies underlying  
10 California's Consumers Legal Remedies Act, which seeks to protect consumers against  
11 unfair and sharp business practices and to promote a basic level of honesty and  
12 reliability in the marketplace, as well as federal regulations implementing the Clinical  
13 Laboratory Improvements Amendments of 1988, which seek to ensure valid and reliable  
14 laboratory examinations.

15 112. As a direct and proximate result of Theranos and Walgreens' business practices,  
16 Plaintiff S.G. and the proposed class members suffered injury in fact and lost money or property,  
17 because they purchased blood tests that they otherwise would not have, or in the alternative, would  
18 have paid less for. Meanwhile, Theranos and Walgreens have sold more blood tests than they  
19 otherwise could have and charged inflated prices for the blood tests, unjustly enriching itself thereby.

20 113. Plaintiff S.G. and the proposed class members are entitled to equitable relief including  
21 an order requiring Theranos and Walgreens to adequately disclose the inaccuracy of the blood tests and  
22 to report all incorrect results to persons whose blood was tested, as well as restitution of the sums paid  
23 to Theranos or Walgreens as a result of their unfair, deceptive, and fraudulent practices.

24 **COUNT II**

25 **California's Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.**

26 **(on behalf of Plaintiff S.G., the Nationwide Walgreens Class, and the Nationwide Theranos Class)**

27 114. Plaintiffs incorporate the above allegations by reference.  
28

1 115. Theranos and Walgreens are, each of them, a “person” within the meaning of Civil Code  
2 §§ 1761(c) and 1770, and have provided “services” within the meaning of Civil Code §§ 1761(b) and  
3 1770.

4 116. Plaintiff S.G. and members of the proposed classes are “consumers” within the meaning  
5 of Civil Code §§ 1761(d) and 1770, and have engaged in a “transaction” within the meaning of Civil  
6 Code §§ 1761(e) and 1770.

7 117. Theranos and Walgreens have violated the Consumers Legal Remedies Act (CLRA),  
8 California Civil Code sections 1770(a),(5),(7), and (9) by engaging in unfair methods of competition  
9 and unfair and deceptive acts and practices in connection with transactions—namely, the sale of lab  
10 tests to Plaintiffs and class members—that are intended to result and have resulted in the sale and lease  
11 of goods or services to consumers.

12 118. Theranos and Walgreens misrepresented that the lab tests Plaintiff S.G. and the class  
13 purchased were accurate and reliable, when in fact they were not.

14 119. Theranos and Walgreens misrepresented that the lab tests Plaintiff S.G. and the class  
15 purchased were performed using innovative new techniques and devices, when in fact they were not.

16 120. Theranos and Walgreens advertised to Plaintiff S.G. and the class that the lab tests  
17 offered were accurate, reliable, and performed using innovative new techniques and devices, but  
18 Theranos and Walgreens did not intend to sell tests with those characteristics.

19 121. Further, Theranos did not inform and has never informed Plaintiff S.G. or class members  
20 that the tests provided were conducted in laboratories staffed by unqualified personnel, under  
21 inadequate supervision, on improperly calibrated and quality-controlled machinery, using inadequately  
22 quality-controlled processes.

23 122. Walgreens did not inform and has never informed Plaintiff S.G. and class members that  
24 the tests provided at its stores were not adequately vetted by Walgreens and were conducted in  
25 laboratories staffed by unqualified personnel, under inadequate supervision, on improperly calibrated  
26 and quality-controlled machinery, using inadequately quality-controlled processes.

27 123. The undisclosed information is material to a reasonable consumers’ decision of whether  
28 or not to purchase a lab test from Theranos or Walgreens.

1 124. Theranos and Walgreens had a duty to disclose these facts because they had exclusive  
 2 knowledge of the condition, management, and staffing at Theranos’s laboratories and of Walgreens’  
 3 vetting of Theranos.

4 125. Theranos and Walgreens also had a duty to disclose these facts because they actively  
 5 concealed the condition, management, and staffing at Theranos’s laboratories, as well as Walgreens’  
 6 vetting process, from Plaintiffs and the class.

7 126. As a result of Theranos’s and Walgreens’ violations of the CLRA, Plaintiff S.G. has  
 8 suffered damages. Plaintiff S.G. spent money on at least one blood test that she would not have  
 9 ordered were it not for Theranos and Walgreens’ practices. Plaintiff S.G. incurred out-of-pocket  
 10 damages in the form of a co-pay.

11 127. Plaintiff S.G. and class members are entitled to equitable relief, including an order  
 12 requiring Theranos and Walgreens to provide notice of the unreliability of Theranos-provided test  
 13 results to all persons who received test results at a Walgreens wellness center in the form of written and  
 14 oral disclosures.

15 128. Pursuant to California Civil Code § 1780, Plaintiff S.G. seeks an order enjoining  
 16 Theranos and Walgreens from the unlawful practices described above, a declaration that Theranos and  
 17 Walgreens’ conduct violates the Consumers Legal Remedies Act, restitution, and reasonable attorneys’  
 18 fees and costs of litigation.

19 129. Pursuant to the provisions of Cal. Civ. Code § 1782(a), Plaintiff S.G. will send notice  
 20 letters to Theranos and Walgreens to provide them with the opportunity to correct their business  
 21 practices. If they do not thereafter correct their business practices, Plaintiffs will amend (or seek leave  
 22 to amend) the complaint to add claims for actual damages under the Consumers Legal Remedies Act.

23 **COUNT III**

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

25 **(on behalf of Plaintiffs, the Arizona Walgreens Subclass, and the Arizona Theranos Subclass)**

26 130. Plaintiffs incorporate the above allegations by reference.

27 131. Defendants Theranos and Walgreens, operating in Arizona, engaged in deceptive and  
 28 unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of

1 material facts in connection with the sale and advertisement of “merchandise” (as defined in the  
2 Arizona Consumer Fraud Act, A.R.S. §44-1521(5)), in violation of A.R.S. §44-1522(A), including but  
3 not limited to the following:

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

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

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

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

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

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

27 138. As a direct and proximate result of Defendants’ unlawful practices, Plaintiffs and class  
28 members suffered injury and damages.

1 139. Plaintiffs seek relief under A.R.S. § 4421, *et seq.*, including, but not limited to,  
2 compensatory damages, punitive damages, injunctive relief, and attorneys' fees and costs.

3 **COUNT IV**

4 **Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c)**  
5 **(on behalf of Plaintiff S.G., the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

6 140. Plaintiffs incorporate the above allegations by reference.

7 141. At all relevant times, there existed an "enterprise" within the meaning of 18 U.S.C. §§  
8 1961(4) and 1962(c) that consisted of multiple distinct entities associated in fact, including Theranos  
9 and Walgreens. Theranos and Walgreens are "persons" within the meaning of 18 U.S.C. §§ 1961(3)  
10 and 1962(c) and distinct from the "enterprise" they formed and operated to perpetrate the fraud alleged  
11 in this Complaint, namely, the establishment of purported "wellness centers" that sold patients  
12 inaccurate blood tests conducted under false pretenses.

13 142. As more fully alleged elsewhere in this complaint, Theranos and Walgreens have  
14 conducted this enterprise on an ongoing basis since at least 2011. Through the conduct of this  
15 enterprise, Theranos and Walgreens have used the fraudulent means alleged herein to sell at least 1.8  
16 million worthless and unreliable lab tests from their wellness centers.

17 143. Theranos and Walgreens participated in the conduct of this enterprise in furtherance of a  
18 common purpose that they both agreed upon – the sale of blood tests at Theranos- and Walgreens-  
19 branded wellness centers through material misstatements and material omissions.

20 144. Through explicit or tacit agreements, Theranos and Walgreens agreed to function and  
21 did function as a unit and according to specified roles. Specifically, Theranos agreed with Walgreens to  
22 advertise its blood testing as revolutionary and cutting-edge when in fact most tests sold were done on  
23 conventional equipment and to advertise itself as a qualified provider of lab testing when in fact its labs  
24 were run by unqualified and untrained staff. Walgreens agreed with Theranos to assist in advertising  
25 the blood tests and to provide space for Theranos inside its stores to drive retail customers toward its  
26 services.

27 145. The conduct alleged in this complaint was part of a scheme that Theranos and  
28 Walgreens formulated to defraud Plaintiffs and members of the Nationwide Classes. Theranos and

1 Walgreens perpetrated this scheme with the specific intent to deceive and defraud Plaintiffs and  
2 members of the Nationwide Classes, and Theranos and Walgreens did deceive and defraud Plaintiffs  
3 and the members of that class.

4 146. Theranos and Walgreens committed a continuous series of predicate acts of wire fraud  
5 (18 U.S.C. § 1343) in furtherance of this scheme. Among these predicate acts are the advertisements  
6 and statements made on Theranos' and Walgreens' websites.

7 147. The predicate acts alleged in this complaint constitute a pattern of racketeering activity  
8 within the meaning of 18 U.S.C. § 1962(c). Theranos and Walgreens' conduct, including the predicate  
9 acts and pattern of racketeering activity, amount to and pose a threat of continued criminal conduct.

10 148. As a direct and proximate result of Theranos and Walgreens' wrongdoing, they caused  
11 injury to Plaintiff S.G.'s property, in the form of payment for blood tests she would not have bought or  
12 would have paid less for had Defendants been truthful about their accuracy, and to all class members.  
13 Under the provisions of RICO, Plaintiff S.G. and members of the Nationwide Classes are entitled to  
14 recover treble damages, costs of suit, and attorneys' fees.

15 **COUNT V**

16 **Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(d)**

17 **(on behalf of Plaintiff S.G., the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

18 149. Plaintiffs incorporate the above allegations by reference.

19 150. In violation of 18 U.S.C. 1962(d), Theranos and Walgreens objectively manifested an  
20 agreement to participate, directly or indirectly, in the scheme to defraud and the RICO enterprise  
21 alleged in this complaint and thereby conspired with one another to commit the conduct alleged in this  
22 complaint.

23 151. Theranos and Walgreens objectively manifested an agreement on the common purpose  
24 of this enterprise, deliberately selling unreliable and worthless lab tests to consumers through wellness  
25 centers.

26 152. Further, Theranos and Walgreens objectively manifested an agreement to perpetrate this  
27 scheme through predicate acts amounting to a pattern of racketeering activity. Theranos and Walgreens  
28 agreed to commit predicate crimes and to aid and abet the commission of predicate crimes by other

1 members of the enterprise. They further agreed that some members of the enterprise would commit the  
2 predicate acts for the benefit of all members or the enterprise.

3 153. As a direct and proximate result of Defendants’ wrongful conduct, Defendants caused  
4 harm and injury to the individual Plaintiffs and the class in the form of payments tendered for  
5 unreliable and worthless blood tests. Plaintiffs and the class are entitled to recover treble damages,  
6 costs of suit, and attorneys’ fees.

7 **COUNT VI**

8 **Breach of the Implied Covenant of Good Faith and Fair Dealing**

9 **(on behalf of Plaintiffs, the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

10 154. Plaintiffs incorporate the above allegations by reference.

11 155. Plaintiffs entered into agreements with Theranos or Walgreens to purchase accurate,  
12 reliable lab tests using Theranos’s secret, proprietary system in exchange for payment, tendered either  
13 directly from Plaintiffs or through their insurance.

14 156. Plaintiffs did all the things required of them to do, including tendering payment or  
15 insurance information and submitting to testing.

16 157. Plaintiffs’ acts satisfied all the conditions required for Theranos and Walgreens to  
17 perform.

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

23 159. As a direct and proximate cause of Theranos and Walgreens’ breaches, Plaintiffs and the  
24 class were damaged in an amount that will be proven by paying for worthless tests, as well as  
25 consequential damages.  
26  
27  
28



**COUNT VII**

**Unjust Enrichment**

**(on behalf of Plaintiffs, the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

160. Plaintiffs incorporate the above allegations by reference.

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

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

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

164. Plaintiffs and the class are entitled to restitution of the profits unjustly obtained, plus interest.

**COUNT VIII**

**Negligent Misrepresentation**

**(on behalf of Plaintiffs, the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

165. Plaintiffs incorporate the above allegations by reference.

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

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

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

169. Plaintiffs 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.

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

5 **COUNT IX**

6 **Negligence**

7 **(on behalf of Plaintiffs, the Nationwide Theranos Class, and the Nationwide Walgreens Class)**

8 171. Plaintiffs incorporate the above allegations by reference.

9 172. Theranos and Walgreens each had a duty to provide Plaintiffs and the class with reliable,  
10 accurate laboratory testing.

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

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

20 175. Plaintiffs and the class are entitled to actual and punitive damages.

21 **COUNT X**

22 **Aiding and Abetting**

23 **(on behalf of Plaintiffs and the Nationwide Walgreens Class)**

24 176. Plaintiffs incorporate the above allegations by reference.

25 177. Theranos has committed torts causing injury to Plaintiffs.

26 178. Walgreens knew that Theranos breached its duties to Plaintiffs by providing laboratory  
27 tests that were unreliable, conducted in a manner that did not satisfy federal standards for quality  
28

1 control, in laboratories that did not meet federal standards for staffing, on inadequately maintained and  
2 calibrated equipment.

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

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

9  
10 **PRAYER FOR RELIEF**

11 WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for the  
12 following relief against Theranos and Walgreens, jointly and severally, as follows:

- 13 A. An order certifying the proposed class(es), and appointing Plaintiffs’ counsel to  
14 represent the class(es);
- 15 B. An order awarding Plaintiffs and the class members, except as to their CLRA claim,  
16 their actual damages, treble damages, punitive damages, and any other form of monetary  
17 relief provided by law;
- 18 C. An order awarding Plaintiffs and the class(es) restitution, disgorgement, and other  
19 equitable relief as the Court deems proper;
- 20 D. An order requiring Walgreens to adequately disclose to past recipients of Theranos  
21 testing that their test results may be inaccurate and the nature of and reasons for the  
22 sanctions faced by Theranos;
- 23 E. An order awarding Plaintiffs and the class(es) pre-judgment and post-judgment interest  
24 as allowed under the law;
- 25 F. An order awarding Plaintiffs and the class(es) reasonable attorneys’ fees and costs of  
26 suit, including expert witness fees; and
- 27 G. An order awarding such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Plaintiffs demand a trial by jury.

DATED: June 15, 2016

Respectfully submitted,

**GIRARD GIBBS LLP**

By: /s/ Eric H. Gibbs

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**STEPHAN ZOURAS, LLP**

/s/ Ryan F. Stephan  
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*Counsel for Plaintiffs*

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

C.M. and S.G., on behalf of themselves and all others similarly situated,

(b) County of Residence of First Listed Plaintiff Maricopa County, AZ (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Eric H. Gibbs, Girard Gibbs LLP One Kaiser Plaza, Suite 1125, Oakland, California 94612 (510) 350-9700

DEFENDANTS

Theranos, Inc. and Walgreens Boots Alliance, Inc.

County of Residence of First Listed Defendant Santa Clara County, CA (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
3 Federal Question (U.S. Government Not a Party)
2 U.S. Government Defendant
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State PTF 1 DEF 1
Citizen of Another State PTF 2 DEF 2
Citizen or Subject of a Foreign Country PTF 3 DEF 3
Incorporated or Principal Place of Business In This State PTF 4 DEF 4
Incorporated and Principal Place of Business In Another State PTF 5 DEF 5
Foreign Nation PTF 6 DEF 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Estate, etc.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District
6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 18 U.S.C. § 1962; Cal. Bus. & Prof. Code § 17200; Cal. Civ. Code § 1750; Ariz. Rev. Stat. § 44-1521
Brief description of cause: Violation of Racketeer Influenced and Corrupt Organizations Act, state consumer protection laws, breach of contra

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE M.J. Corley, M.J. Lloyd, M.J. Cousins DOCKET NUMBER 16-2810, 16-2835, 16-2891

DATE 06/15/2016 SIGNATURE OF ATTORNEY OF RECORD /s/ Eric H. Gibbs

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only) SAN FRANCISCO/OAKLAND SAN JOSE EUREKA

## INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

### Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.  
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.  
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.  
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.  
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.  
 Original Proceedings. (1) Cases which originate in the United States district courts.  
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.  
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.  
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.  
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.  
 Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.  
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.  
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- Date and Attorney Signature.** Date and sign the civil cover sheet.