IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WALGREEN CO.,	)	
Plaintiff,	)	Civil Action No.
v.	)	JURY TRIAL DEMANDED
THERANOS, INC.,	)	**PUBLIC VERSION**
Defendant.	)	

COMPLAINT

INTRODUCTION

1. This case arises from a breach by Defendant Theranos, Inc. ("Theranos") of its contract with Plaintiff Walgreen Co. ("Walgreens"). Theranos failed to meet the most basic quality standards and legal requirements of the contract. Pursuant to the terms of the contract, Theranos now must refund the money it took from Walgreens, and pay all other damages to be proven.

2. Walgreens provides pharmacy, health, and wellbeing services to the communities served by its more than 8,000 stores in the United States. Its core mission is to help people in those communities lead healthier and happier lives.

3. As part of that mission, Walgreens entered into a contract with Theranos, a company that purported to have developed "disruptive" technology that would make blood testing "less invasive, faster, and far more accessible, effective, and actionable." [redacted]

[redacted]

4. The fundamental premise of the parties' contract—like any endeavor involving human health—was to help people, and not to harm them. In this respect, the quality of Theranos's blood testing was critical. [redacted] Theranos broke each of those promises.

5. As detailed below, the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") determined that Theranos's quality controls were so deficient that they posed an immediate risk to patient health and safety. Based on Theranos's failure to fix these and other deficiencies, CMS issued sanctions against Theranos, including, among others, the revocation of Theranos's license to operate one of its two laboratories and the banning of Theranos's founder and Chief Executive Officer, Elizabeth Holmes, from owning or operating a laboratory for at least two years.

6. In response to CMS's findings, Theranos stated that it would "accept full responsibility" and undertake "comprehensive remedial actions," including "shutting down and subsequently rebuilding the Newark lab from the ground up" and "rebuilding quality systems."

7. Similarly, in April 2016, Ms. Holmes admitted on the *Today Show* that she is "devastated," and that Theranos will need to "rebuild [its] entire laboratory from scratch so that we can ensure it never happens again." In August 2016, Ms. Holmes admitted (this time on CNN) that "[a]t the highest level, we didn't have the right leadership in the laboratory" and "we

didn't have the implementation of the quality system in terms of procedures and the associated documentation to ensure that we were realizing the quality standards that we hold ourselves to."

8. Most troublingly, as a result of Theranos's problems, including pervasive issues in its laboratories, Theranos voided and/or corrected tens of thousands of tests without telling Walgreens it was doing so. Walgreens repeatedly sought detailed information from Theranos about those voided tests. Theranos ultimately admitted to Walgreens on June 11, 2016, that 31,000 test reports offered to Walgreens customers were voided. Theranos also admitted that this number represents more than 10% of the test reports provided to Walgreens' customers that used Theranos's services during the course of the relationship between Walgreens and Theranos.

9. Walgreens terminated the Agreement with Theranos on June 12, 2016.

10. Now, Theranos is not even attempting to rebuild its laboratories. On October 5, 2016, in a letter to stakeholders, Ms. Holmes announced that Theranos would close both of its laboratories and all of its blood-drawing centers. Theranos was unable to provide blood-testing services at the level of quality it promised or in compliance with law, and now will not perform blood-testing services at all.

11. [redacted]

PARTIES

12. Plaintiff Walgreen Co. is an Illinois corporation with its principal place of business at 108 Wilmot Road in Deerfield, Illinois.

13. Defendant Theranos, Inc. is a Delaware corporation headquartered at 1701 Page Mill Road in Palo Alto, California. Theranos was founded in 2003 by Elizabeth Holmes as

a next-generation healthcare system, built on the premise of using proprietary, patented technology to offer nearly the full range of diagnostic tests from only a few drops of blood. Ms. Holmes currently serves as Defendant's CEO and Chairman. For much of the relevant time period, Theranos's President and Chief Operating Officer was Ramesh "Sunny" Balwani.

JURISDICTION AND VENUE

14. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a). Defendant is not a citizen of the same state as Plaintiff and the amount in controversy exceeds $75,000, exclusive of interest and costs.

15. This Court has personal jurisdiction over Defendant because it is a Delaware corporation.

16. Venue rests with this Court pursuant to 28 U.S.C. § 1391(b) because Defendant is a Delaware corporation.

17. The contract between Walgreens and Theranos expressly requires all suits arising from the contract to be brought in the District Court of Delaware. *See* Ex. A, Agreement ¶ 26.

FACTUAL ALLEGATIONS

Theranos's Finger-Stick Blood-Testing Technology

18. Theranos approached Walgreens in early 2010 with the promise of an innovative technology that would revolutionize blood testing.

19. Commercial blood testing traditionally involves the venipuncture methodology of drawing blood using needles and large vials. This process is performed through venous draws.

20. When a Theranos representative contacted Walgreens by e-mail in January 2010, she stated that Theranos had developed "small point-of-care devices that, for the first time,

can run any blood test in real-time for less than half the cost of central lab tests." That e-mail further confirmed that Theranos could offer "in-store blood testing from a single finger-stick." Theranos's device purportedly was capable of detecting "viruses like H1N1 or STDs" or the "earliest appearance of cancers and other diseases," thus "enabling early intervention and initiation of treatment long before complications emerge." Theranos's President and CEO, Ms. Holmes, and President and COO, Mr. Balwani, were interested in introducing their technology to Walgreens and discussing its deployment in Walgreens stores.

21. After some initial conversations, Ms. Holmes and Mr. Balwani made a presentation to Walgreens executive management on March 22, 2010.

22. At the meeting on March 22, using a PowerPoint presentation, Ms. Holmes and Mr. Balwani again told Walgreens' executive management that Theranos had developed a "proprietary, patented technology" capable of running "comprehensive blood tests from a finger-stick in real-time at the point of care, outside of traditional lab settings." Such a setting, of course, would include a retail pharmacy like Walgreens.

23. According to Ms. Holmes and Mr. Balwani, the blood tests would be run on a proprietary device they called "Theranos Systems." On information and belief, this device later was called the "Edison" machine.

24. Ms. Holmes and Mr. Balwani assured Walgreens that the technology was viable and consumer-ready. At the March 22 presentation, Ms. Holmes and Mr. Balwani represented that the proprietary technology had been "comprehensively validated over the course of the last seven years by ten of the fifteen largest pharmaceutical companies." Further, according to Theranos, the technology already had been used by numerous current and past clients, including these same pharmaceutical companies, midsized bio-pharma companies,

prominent research institutions, and U.S. and foreign government health and military organizations.

25. The next step was to launch the finger-stick technology to consumers, which Theranos represented it would be ready to do as early as later that year. At the March 22 presentation, Ms. Holmes and Mr. Balwani specifically highlighted that a number of the "real-time finger-stick-based tests" would be ready for launch in Walgreens by the fourth quarter of 2010. This included general chemistry panels and standard blood tests, influenza tests, and fertility tests. Ms. Holmes and Mr. Balwani emphasized the health benefits of Theranos's finger-stick testing, such as reduced hospital visits, more effective treatment options, and earlier detection of pregnancy.

26. The most important requirement of any new entry in the health care space is, of course, the ability to provide high quality and accurate information. Here, Theranos promised that its tests already had met this requirement. Theranos represented that it had "Wellness, Diagnostic & Predictive Tests," and that "[t]hese tests predict the onset of disease far before clinical symptoms and more accurately than conventional testing methods."

27. Another critical prerequisite to consumer launch was regulatory approval, particularly by the U.S. Food and Drug Administration ("FDA"). At the March 22 presentation, Ms. Holmes and Mr. Balwani told Walgreens' executive management that the Theranos Systems were validated under FDA guidelines, and that Theranos's "systems are classified as non-significant risk devices." Further, regulatory filings were already ongoing in preparation for the launch to consumers.

28. Based on Theranos's representations, Walgreens continued to perform additional due diligence.[1] This included engaging consultants and other third-parties.

29. In late April 2010, a team at Johns Hopkins University commented on the validity of Theranos's products and technology, and the potential for use within Walgreens stores. Theranos provided the Johns Hopkins review team with proprietary testing data, and gave a demonstration of how its proprietary technology purportedly worked. Based on its review of the data provided by Theranos, the Johns Hopkins team concluded that Theranos's technology was "novel and sound" and could "accurately run a wide range of routine and special assays." Based on what Theranos provided to it, the Johns Hopkins team also noted that one of the "[s]pecial strengths of the technology" was "[a]ccuracy."

30. Walgreens also followed up with Theranos as to the status of regulatory approval from the FDA.

31. On May 7, 2010, Ms. Holmes sent to Walgreens a "Regulatory Summary" prepared by Theranos. The Regulatory Summary explained that the Theranos Systems were first reviewed by the FDA in 2005 and received approval to be launched in clinical studies. "After receiving endorsement from FDA," the Theranos Systems were "the sole means for collecting all clinical data, including drug concentrations, and CRFs in registrational studies across a broad range of therapeutic areas."

32. The Regulatory Summary further represented that Theranos was positioned to receive approval to introduce its technology outside of the clinical field. In particular, panels of tests that had shown predictive value in pharmaceutical clinical studies were currently

[1] In connection with Walgreens' continued due diligence, Walgreens and Theranos entered into a Mutual Confidentiality and Non-Disclosure Agreement, which restricted the disclosure of certain information exchanged by the parties. *See* Ex. B.

undergoing studies for approval for use outside of clinical studies. Such approvals were to include direct to consumer sales, use in physician's offices for routine care of patients, and use in retail pharmacy settings.

33. Based on Theranos's representations and other information learned during Walgreens' on-going due diligence, on July 30, 2010, Walgreens and Theranos entered into the Theranos Master Purchase Agreement (the "July 2010 Agreement"). *See* Ex. C. The July 2010 Agreement provided an initial framework for the relationship. The launch of Theranos testing services in Walgreens stores, however, remained subject to further negotiations between the parties. This included, in particular, Theranos receiving further regulatory approval.

34. In order for any lab to perform testing, it is required to comply with all requirements under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), and thus be certified by its state as well as by CMS. In October 2010, Ms. Holmes shared with Walgreens a summary of Theranos' Regulatory Strategy, which stated that Theranos would be proceeding with CLIA certification. The document further stated that, "[a]s the CLIA certification requires us to perform proficiency testing three times a year on sets of blinded samples across the entire clinically relevant dynamic range for every test we offer, starting at the time of CLIA certification, we are constantly generating robust data to support the accuracy and performance of our tests." Theranos further assured Walgreens that, under this regulatory approach, it would "be providing even more comprehensive oversight than a traditional central lab" and that it would "have all of the right infrastructure in place."

35. On December 15, 2010, Ms. Holmes sent to Walgreens a "Regulatory and Business Model Strategy" prepared by Theranos. In that document, Theranos explained that it was "undergoing CLIA certification as a high complexity laboratory." In particular, Theranos

stated that its "core functionality is the laboratory oversight and dynamic controls that characterize CLIA certified labs brought through Theranos' lab infrastructure to the same or higher levels of accuracy than required by current Proficiency Testing standards under CMS guidelines for laboratory performance." Theranos also stated that, "because the performance levels and oversight are what differentiates the Theranos lab infrastructure at its core, Theranos and its regulatory advisers clearly agreed that CLIA-certification is the correct regulatory path and body of oversight for the Theranos lab infrastructure."

36. Theranos further stated in its December 2010 Regulatory and Business Model Strategy summary that "CLIA certification will allow Theranos to bear the highest burden of oversight from a regulatory standpoint with respect to laboratory testing and will serve as an important demonstration of quality assurance and ongoing performance." Further, Theranos's lab infrastructure would be tested "at least three times a year with blinded samples … for Proficiency Testing demonstrating the quality and safety of Theranos tests." Theranos further represented that its infrastructure had "been thoroughly validated under FDA … guidelines internally and externally by leading centers of excellence to demonstrate the superior quality, safety, and performance not only of the tests themselves but also of the improvements in patient outcomes associated with faster and more accurate laboratory results being delivered to physicians."

37. In a January 2012 presentation, Ms. Holmes and Mr. Balwani similarly assured Walgreens that Theranos's CLIA-certified labs—which would become the "world's first finger-stick based CLIA-certified lab,"—would offer the "highest quality testing from a finger-stick," and present "[n]o regulatory risk."

38. In the same presentation, Ms. Holmes and Mr. Balwani further highlighted the purported advancements of its revolutionary technology. Compared to other traditional blood-testing services, they explained, Theranos's finger-stick technology would require 99.9% less blood. And it offered a "[s]tate of the art result turnaround" of 4-24 hours. In short, Theranos would be the "[n]ation's lowest cost and highest quality laboratory provider."

The June 2012 Agreement

39. In June 2012, Theranos and Walgreens entered into the Amended and Restated Theranos Master Services Agreement (the "Agreement"). *See* Ex. A. The Agreement provided a framework pursuant to which "Theranos Wellness Centers" could operate inside Walgreens stores, in which technicians would collect blood samples. Consistent with their negotiations and Theranos's representations, it was the parties' intention and expectation that the blood would be collected using Theranos's finger-stick technology. The blood then would be sent to a Theranos CLIA-certified laboratory for testing, and Theranos would send the blood test results to the requesting physician, who would communicate the results directly to the patients. This Agreement remained operative throughout the course of the parties' contractual relationship, from June 5, 2012 until June 12, 2016.

40. During the relevant time period, Theranos owned and operated two offsite CLIA-certified laboratories: a laboratory in Newark, California, and a laboratory in Phoenix, Arizona. After receiving CLIA certification, the laboratories remained subject to periodic recertification surveys by CMS to confirm that they remained in compliance.

41. [redacted]

[redacted]

42. [redacted]

43. [redacted]

44. [redacted]

45. [redacted]

[redacted]

46. [redacted]

47. [redacted]

Theranos Wellness Centers Open at 41 Walgreens Stores

48. On March 20, 2013, the parties began the pilot with a controlled soft launch at a single store in Phoenix, Arizona.

49. On September 9, 2013, the parties publicly announced the opening of the first Theranos Wellness Center in Palo Alto, California. Later that year, additional Theranos Wellness Centers opened in Walgreens stores in Phoenix. By the fall of 2015, Theranos Wellness Centers were located in 41 Walgreens locations: one in Palo Alto, and the remaining 40 in Arizona.

50. [redacted] This was the last agreement entered into between the parties, and no agreement on the expansion of Theranos Wellness Centers beyond the pilot stores ever was finalized. Nor were any additional locations opened.

News Reports Raise Concerns Regarding the Accuracy and Viability of Theranos's Blood-Testing Technology, and Theranos Finally Admits it Has Stopped Using its Own Technology

51. On October 15, 2015, *The Wall Street Journal* published an article raising questions concerning the accuracy of some of Theranos's blood tests. The *Journal* reported that some Theranos employees "were leery about the [Edison] machine's accuracy," and that "one Theranos employee accused the company of failing to report test results that raised questions about the precision of the Edison system." In addition, some doctors stated to the *Journal* that "they stopped steering patients to Theranos because of results they didn't trust." As one internist from Phoenix told the *Journal*, he didn't "'want [his] patients going there until more information and a better protocol are in place.'"

52. The article reported that Theranos was not using its own proprietary technology for a majority of its blood tests. The *Journal* also reported that multiple former Theranos employees shared concerns about Theranos's use of a "special dilution method" for a large number of tests run on traditional testing machines. Because Theranos originally had collected only a small amount of blood using a finger-prick, it had to increase those samples' volume through dilution in order to run the tests on the traditional machines. "For tests done with dilution, the process caused the concentration of substances in the blood being measured to fall below the machines' approved range," the former employees said.

53. The *Journal* continued: "Lab experts say the practice could increase the chance of erroneous results. … 'Anytime you dilute a sample, you're adulterating the sample and changing it in some fashion, and that introduces more potential for error,' says Timothy R. Hamill, vice chairman of the University of California, San Francisco's department of laboratory medicine. Using dilution frequently is 'poor laboratory practice.'"

54. Finally, the *Journal* noted that former employees "say diluting blood drawn from fingers contributed to accuracy problems [in early 2014] with a test to measure potassium. Lab experts say finger-pricked blood … often mixes with fluids from tissue and cells that can interfere with tests. Some of the potassium results at Theranos were so high that patients would have to be dead for the results to be correct."

55. In an interview with CNBC after the *Journal* published its story, Ms. Holmes said, "This is what happens when you work to change things, and first they think you're crazy, then they fight you and then all of a sudden you change the world." Ms. Holmes further said, "we are doing things differently and we are working to make a difference and that means people raise questions, and that's okay."

56. In a press release that same day, Theranos stated: "Theranos' products and services have proven accurate and reliable. … Our focus remains on ensuring high quality, real –time, actionable information to improve diagnosis and treatment decisions." Further, "Theranos is working to reinvent the lab experience by providing high quality tests faster, cheaper, and more conveniently, requiring less blood, and causing less patient discomfort than ever before. We lead the industry in transparency and quality."

57. In another statement issued the next day, Theranos stated: "Actionable health information means testing done in accordance with the highest quality standards – those standards are FDA quality standards and our standards. … [W]e've always been committed to quality, to the best science, and to ensuring that innovation comes to health care."

58. Walgreens promptly sought answers from Theranos. Theranos explained that it had decided to transition from finger-stick blood draws to the traditional venous draws while its blood-collection device was being reviewed for FDA approval. This was the first time

Walgreens learned of this information. Theranos further assured Walgreens that Theranos's "commitment to FDA and quality systems should give you and ... WBA, along with the clinicians and patients we serve[,] confidence in the quality of products and services we provide."

59. Walgreens also learned that Theranos's Newark laboratory recently had been subject to an inspection by CMS. The inspection was a CLIA recertification and complaint survey of Theranos's Newark laboratory, and was ongoing at the time.

60. Walgreens continued to ask Theranos for additional information. Specifically, Walgreens requested additional information regarding the CMS audit of the Newark laboratory.

61. Theranos did not cooperate with Walgreens' requests for information. Theranos only responded to some of Walgreens' requests, missed multiple deadlines and delayed for several weeks for others, and failed to provide any information in response to others.

62. In particular, Theranos resisted Walgreens' requests for information relating to Theranos's lab leadership. Eventually, Walgreens was allowed to speak with the director of Theranos's Newark lab, Dr. Sunil Dhawan, on November 14. Walgreens learned that Dr. Dhawan was a full-time dermatologist, had no experience prior to Theranos with any lab outside of dermatopathology, and spent only one day a week at the Newark lab.

63. Further, as Walgreens noted in a November 30 letter to Ms. Holmes, it recently had learned through a press report that the Arizona Department of Health Services had conducted an audit of the Arizona laboratory in April 2015, and that audit had identified a number of quality assurance issues. Theranos had failed to disclose this information to Walgreens. Walgreens again requested all results or feedback, either interim or final, from the CMS audit currently underway at the Newark laboratory.

64. On December 8, Theranos, through its then-General Counsel, Heather King, responded in writing to Walgreens' November 30 letter. In the letter, Theranos downplayed the recent news reports as "inaccurate" and "unfair" and presenting a "misleading portrayal of Theranos." The information Theranos had provided Walgreens thus far purportedly "directly contradict[ed] those articles, demonstrat[ing] the integrity of [Theranos's] lab services, and the safety of [Theranos's] patients." Theranos also resisted Walgreens' requests for information as seeking "information and actions well beyond the scope of what Walgreens is entitled to."

65. In the letter, Theranos did admit that the Arizona lab had undergone an inspection by CMS in April 2015. Theranos assured Walgreens, however, that the issues identified by CMS already had been addressed, and offered to take Walgreens on a tour of the Arizona lab. With respect to the Newark lab, Theranos stated that the review was "ongoing," and that Theranos was "committed to working with CMS to ensure that all of [its] tests and testing processes meet the highest standards."

66. Theranos also stated that it was in the process of "updating our quality assurance/control processes to a more automated system." Theranos further assured Walgreens that Theranos's "experienced lab personnel working hand-in-hand with [its] automated system will lead to the best quality assurance outcomes, which in turn will continue to allow [Theranos] to provide the most accurate and reliable results for [its] patients."

CMS's Investigation and Other News Reports Raise Concerns Regarding Patient Health and Safety, Which Theranos Attempts to Minimize and Conceal from Walgreens

67. Although Walgreens did not know it (because Theranos did not tell Walgreens), on November 20, 2015, CMS had completed the on-site portion of its CLIA recertification and complaint survey of Theranos's Newark laboratory. CMS concluded the survey on December 23, 2015.

68. On January 25, 2016, CMS issued a letter to Theranos, setting forth its findings. As detailed in the letter, CMS concluded "that [the Newark] facility is not in compliance with all of the Conditions required for certification in the CLIA program." Specifically, CMS identified Condition-level deficiencies in the following areas: (1) inadequate operating procedures and Quality Control in the Hematology area; (2) inadequate operating procedures, corrective actions, and equipment preventative maintenance across the lab's analytic systems; (3) inadequate Laboratory Director qualifications and management protocols, including failure to ensure Quality Control and Quality Assurance programs were established and maintained; (4) inadequate Laboratory Technical Supervisor qualifications for high complexity testing; and (5) insufficient number of personnel qualified to perform testing functions of the volume and complexity performed in the laboratory.

69. With respect to the Condition-level deficiency in the Hematology area, CMS found "that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety," with "immediate jeopardy" defined "as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public." A complete listing of all of the deficiencies found during CMS's survey was submitted as an enclosure to the letter (the "CMS Report").

70. Theranos was required promptly to submit to CMS a proposed plan of correction documenting that the immediate jeopardy had been removed and that action had been taken to correct all of the deficiencies identified by CMS (a "Plan of Correction").

71. Theranos concealed the CMS Report from Walgreens. On January 27, 2016, *The Wall Street Journal* revealed the existence of the CMS letter and the CMS Report.

72. The *Journal* quoted Dr. Robert Fitzgerald, professor of pathology and director of toxicology at the University of California, San Diego, who noted that Condition-level deficiencies, like the ones CMS found at Theranos's lab, are "'the most serious level. … It doesn't get worse than that from my perspective.'" Further, Dr. Timothy R. Hamill, vice chairman of the University of California, San Francisco's department of laboratory medicine, told the *Journal* that "[i]t means [Theranos has] a major issue in that lab." As to the personnel issues noted in the CMS report—that the laboratory director was not qualified and other personnel were inadequately trained—Dr. Hamill told the *Journal* that "[e]ither [Theranos doesn't] have enough personnel, or they don't have qualified personnel or the personnel are not performing their duties properly."

73. Although Walgreens was not provided with the CMS Report at that time and thus was not privy to its details, it appeared to demonstrate that Theranos was in breach of the warranties it made in the Agreement. It also ran counter to Theranos's repeated assurances of its commitment to quality. As early as December 2010, Theranos had assured Walgreens that CLIA certification would allow Theranos "to bear the highest burden of oversight from a regulatory standpoint with respect to laboratory testing and [would] serve as an important demonstration of quality assurance and ongoing performance." Theranos had repeated these same assurances throughout the course of the parties' relationship.

Walgreens Issues a Notice of Breach

74. The very next day, January 28, 2016, Walgreens sent a letter to Theranos, communicating Walgreens' concerns regarding the CMS letter, none more important than its concerns for its customers' health and safety. Walgreens insisted, and Theranos agreed, that

Theranos immediately cease sending any clinical laboratory tests obtained at any Walgreens stores to Theranos's Newark laboratory. Walgreens suspended all Theranos blood testing services offered at the Palo Alto Walgreens location, effective immediately, and requested that Theranos promptly provide Walgreens with a copy of the CMS Report.

75. [redacted]

76. On February 4, 2016, Theranos (again through Ms. King) responded in a letter to Walgreens. Theranos admitted that there were deficiencies identified in the CMS letter, but attempted to minimize them. Specifically, Theranos represented to Walgreens that many of the issues identified by the CMS letter "have already been corrected, and the CMS Letter is not reflective of the current state of our Newark lab." Theranos asserted that "the CMS Letter identifie[d] curable deficiencies in our Newark lab" and "provide[d] an express mechanism for Theranos to remedy those deficiencies" through the submission of a Plan of Correction.

77. Theranos also refused to provide Walgreens a copy of the CMS Report until after Theranos submitted its Plan of Correction. (Theranos subsequently allowed Walgreens to view briefly a highly redacted version of the CMS Report, but never did provide the promised copy.)

78. Theranos's February 4 letter also accused Walgreens of breaching the Agreement. Notwithstanding CMS's findings with respect to Theranos's Newark lab, Theranos asserted that Walgreens breached the Agreement by suspending services at the Palo Alto store. Theranos insisted that Walgreens continue to offer Theranos services at the store "until the applicable cure period has run." Theranos also asserted that Walgreens was in breach for purportedly disclosing confidential information to the press, but did not identify any specific instance of such disclosure. Lastly, Theranos accused Walgreens of not "building out Theranos Wellness Centers nationally in accordance with the Agreement," but again failed to identify a specific contractual provision obligating Walgreens to do so.

79. Walgreens promptly responded to Theranos's February 4 letter. In a February 7 letter, Walgreens expressed deep concern at Theranos's refusal to provide Walgreens with a copy of the CMS Report. Theranos's decisions effectively "limit[ed] Walgreens' access to the existing facts and evidence" and Walgreens' "ability to understand the deficiencies identified by CMS."

80. The February 7 letter also denied Theranos's claims of Walgreens' purported breach of the Agreement, and noted Walgreens' concern that, "rather than prioritize remedying the significant concerns raised in the CMS Letter and the health and safety of patients, Theranos has elected to use this circumstance as an opportunity to raise Walgreens' purported delay in building out Theranos Wellness Centers nationally and other contractual complaints."

81. On February 25, Theranos (again through Ms. King) responded to Walgreens' February 7 letter, but declined to provide Walgreens with a copy of the CMS Report. Theranos also assured Walgreens that "Theranos has been steadfast in its commitment to patient safety," and "has worked comprehensively over the past months to ensure best-in-class systems are in

place in its Newark lab before resuming those tests, including hiring new leadership." Theranos's proposed Plan of Correction, however, remained pending.

82. In addition, Theranos's letter again accused Walgreens of breaching its confidentiality obligations under the Agreement. Specifically, Theranos cited content in a February 10 article in *The Wall Street Journal* that included "details that Walgreens, uniquely, was privy to" regarding Walgreens' January 28 letter to Theranos, "purported details of discussions between Theranos and Walgreens executives regarding the CMS Letter," and other facts about the two companies' Agreement.

83. On March 29, 2016, Walgreens responded to Theranos's February 25 letter. Walgreens stated that it was not aware of any leaks within the company, and that "none of the information cited in Theranos's [February 25] letter to which Walgreens was 'uniquely' privy is confidential in any event, much less a disclosure that would reflect a material breach of the Agreement." Further, the content of the article "reflects little more than an interpretation of Walgreens' sentiments and concerns for patient health and safety in light of the CMS Report which, of course, are not confidential information, as defined in the Agreement."

Additional Events Confirm Theranos Breached the Agreement

84. Further events, many of which Theranos did not discuss with or disclose to Walgreens at the time, only confirmed Theranos's persistent quality shortfalls, and that Theranos's representations of having achieved the highest levels of accuracy and quality were unfounded.

85. On March 28, 2016, the peer-reviewed *The Journal of Clinical Investigation* published a study online comparing "the accuracy and equivalency of clinical laboratory test blood collected via finger prick and tested Theranos against traditional venipuncture followed by

laboratory testing offered through Quest Diagnostics and LabCorp." The study was the first peer-reviewed comparison of Theranos test results with those of other labs.

86. The study showed that Theranos produced more irregular blood test results than the conventional tests. For example, Theranos's results for total cholesterol control were lower by an average of 9.3% than those produced by other lab testing services. The authors concluded that such disparities between testing services could "alter clinical interpretation and health care utilization." *The Wall Street Journal* likewise reported that the disparity in test results, specifically with respect to the cholesterol tests, "differed enough ... that they could throw off doctors' medical decisions."

87. The study also found "higher odds for Theranos to report tests outside of the normal range versus the other services." Specifically, the study found that Theranos tests yielded results outside their normal range 1.6 times more frequently than results from Quest and LabCorp. This "increase in abnormal test results can have negative consequences for medicine in the form of extra testing, additional patient visits to clinics/hospitals, and added doctor services, all of which result in additional costs and burdens to patients or to the healthcare system and are potentially harmful, if the abnormal tests were misdiagnoses (i.e., false positives)."

88. On March 31, 2016, CMS publicly released a redacted version of the CMS Report from CMS's inspection of Theranos's Newark lab in the fall of 2015. This report, which Theranos consistently had refused to share with Walgreens, set forth at least some of the significant deficiencies CMS identified during its survey of the Newark lab (others may have been redacted).

89. Numerous press reports that followed detailed Theranos's significant failures to meet its own quality-control standards for its proprietary blood-testing device, the Edison

machine. As reported by *The Wall Street Journal*, "[e]rratic quality-control results for Edison-run tests were frequent in July 2014 and from February 2015 to June 2015." Specifically, the CMS Report "showed that 29% of the quality-control checks performed on the company's proprietary blood-testing devices in October 2014 produced results outside the range considered acceptable by Theranos." "In February 2015, an Edison-run test to measure a hormone that affects testosterone levels failed 87% of quality-control checks." And "[i]n April and May 2015, a test to measure prostate-specific antigen, or PSA, failed quality-control checks 22% of the time. The PSA test is used to help detect prostate cancer."

90. Independent experts in the field expressed shock at the CMS Report, which offered a glimpse for the first time into data on Theranos's Edison machine. As one expert, an associate professor of pathology at the Weill Cornell Medical College in New York, quoted in *The Wall Street Journal* noted, "'This is the first time that we've actually seen data from the Theranos instrument, and it's as bad as one would have worried it would be.' ... 'Based on this data, it's hard for me to believe that they went live with this instrument and tested patient specimens on it.'"

91. The portions of the CMS Report that were not redacted also contained numerous disturbing findings with regard to tests performed on traditional lab machines. One such finding concerned a blood clotting test used on patients who take the blood thinner warfarin, known as a PT/INR test. As reported by *The New York Times*, the CMS Report found that "some equipment for this test was run numerous times without obtaining acceptable quality control. Yet results were provided to patients." In fact, a review of the results from April to September 2015 found that 81 of 81 reported final patient results were inaccurate.

92. The consequences of inaccurate PT/INR test results are extremely serious and potentially life-threatening: too much warfarin can lead to internal bleeding and too little can leave a patient with an increased risk of a stroke. As described by the Cleveland Clinic Journal of Medicine, patients who take warfarin "walk a tightrope between bleeding and clotting." "Therefore, everyone who prescribes warfarin, whether a cardiologist, family physician, or internist, needs to understand . . . [h]ow to use the INR to determine the dose of warfarin and monitor its anticoagulant effect."

93. Bloomberg similarly described the CMS Report as:

> [P]aint[ing] a picture of an understaffed and inexperienced startup struggling to meet basic requirements, let alone deliver on its promise to revolutionize the blood-testing industry. … Several themes arise over and over again: failure to meet quality-control standards, such as not keeping freezers at the temperatures required by manufacturers, lack of proper documentation and missing signatures on paperwork; and unqualified personnel.

94. Moreover, the CMS Report found that Theranos had failed to report errors in patient test results in a timely fashion. In particular, Theranos's Newark lab "failed to notify the authorized person for approximately seven weeks after the surveyer identified a quality control problem."

95. In response to the report, Theranos, through its spokeswoman Brooke Buchanan, admitted that it had "made mistakes in the past in the Newark" lab. Theranos, though, highlighted that the Company had submitted its Plan of Correction and related evidence to CMS that purportedly "addressed how the company has actively ensured that our lab operates at the highest standard."

96. Contrary to Theranos's statements, however, and although Theranos had not informed Walgreens of this fact, CMS *already* had rejected Theranos's proposed Plan of Correction. In a March 18, 2016 letter to Theranos, CMS stated:

> After careful review, we have determined that the laboratory's submission does not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 201[5], and does not demonstrate that the laboratory has come into Condition-level compliance and abated immediate jeopardy.

97. The March 18 letter also set forth a series of proposed sanctions against Theranos for failing to fix these deficiencies, including revoking the Newark lab's CLIA-certification, thus prohibiting the lab from performing any testing. In addition, CMS proposed a sanction that Ms. Holmes and Mr. Balwani would be banned from owning or operating any other lab for at least two years.

98. Theranos hid the CMS letter from Walgreens for almost a month. In fact, it is likely that Theranos would have hidden the CMS letter for longer. Walgreens learned of the letter for the first time on April 13, 2016, when it was reported by the press.

99. CMS's rejection of the Plan of Correction ran counter to numerous of Theranos's prior public statements. For example, in a March 7, 2016 press release, Theranos had stated that it had "actively addressed, and are continuing to address, every issue identified by CMS." It also ran counter to Theranos's repeated assurances to Walgreens that the issues identified by CMS had already been or were in the process of being corrected. As *The New York Times* reported, the "strongly worded letter" from CMS was "the latest blow to the credibility of Theranos and Elizabeth Holmes."

100. On April 18, 2016, on the heels of these revelations, Ms. Holmes appeared on the *Today Show* and admitted the depth of the quality issues at Theranos. Ms. Holmes stated that she was "devastated." She expressed regret that Theranos "did not catch and fix these issues faster." She stated that Theranos would need to "rebuild [its] entire laboratory from scratch so that we can ensure it never happens again."

101. As Fortune noted in an article later that day, "When [Ms. Holmes] was pressed on whether or not the various violations and deficiencies that Theranos must address should have been fixed from the get-go, Holmes responded, 'Absolutely. Probably the most devastating part of this is that I thought we did.'"

102. Also on April 18, *The Wall Street Journal* and other news outlets reported that federal prosecutors had opened a criminal investigation into whether Theranos "misled investors about the state of its technology and operations." In addition to the criminal investigation, the *Journal* reported that the Securities and Exchange Commission was examining whether "Theranos made deceptive statements to investors when it solicited funding." As *The New York Times* noted, the investigations were "adding to a series of questions from officials about [Theranos's] inner workings."

103. In the face of this news, on May 11, 2016, Theranos announced that Mr. Balwani, at the age of 51, was "retiring."

Theranos Voids Tens of Thousands of Blood Tests and Continues to Refuse to Answer Walgreens' Questions

104. On May 18, 2016, *The Wall Street Journal* reported that Theranos had issued "tens of thousands" of corrected blood-test reports to doctors and patients. The corrected reports include the voiding of *all* tests run on Theranos's proprietary blood-testing devices in 2014 and 2015—the same technology that Theranos represented to Walgreens had been thoroughly validated—as well as many tests run on standard laboratory equipment. The article further reported that the corrected tests include results from both the Newark and Phoenix laboratories. As described by Geoffrey Baird, an associate professor in laboratory medicine at the University of Washington in Seattle, a recall of this scale and scope was "unprecedented." A report in *The*

Washington Post described the news as a "Consumer nightmare." *New York* magazine said it "revealed the astounding scale of [Theranos's] shortcomings."

105. Walgreens immediately contacted Dr. Kingshuk Das, Theranos's new Newark lab director, on the morning of May 19, 2016, seeking a better understanding of the scope of the voided reports. Dr. Das responded that evening. Dr. Das stated that Theranos had voided all tests conducted on the Edison machines from 2014 through September 2015. The voided tests also included some tests run in a standard manner on standard laboratory equipment. Dr. Das estimated that the voided reports involved 50,000 test reports.

106. Dr. Das also confirmed that the corrected and/or voided tests were not limited to Theranos's Newark laboratory. Dr. Das told Walgreens that Theranos's Arizona laboratory had to correct approximately 1,000 reports for PT/INR hematology tests, the same tests CMS specifically had identified in its review of the Newark lab as posing immediate jeopardy to patient health and safety.

107. That evening, Christian Holmes stated in an email to Walgreens that "the basis for voiding test results in [its] Newark lab was the Newark laboratory's failure to implement and adhere to sufficient quality assessment procedures during the period of the CMS review." Mr. Holmes also shared that Theranos had decided to "void all results for tests which were run during a period when the quality standards in the lab were not consistent with the standards to which the lab holds itself today."

108. On May 23, 2016, Walgreens sent a letter to Theranos. The letter demanded confirmation of the tens of thousands of voided and corrected test results and further details from Theranos regarding its decision to issue them, including:

- When did Theranos learn that there were quality control issues with the voided tests?

- When did Theranos first start issuing corrected reports?
- When did Theranos report this information to CMS?
- How many corrected test reports have been issued?
- How many individual test results have been voided or revised?
- How many of those tests were conducted on Edison devices versus standard laboratory equipment?

109. Meanwhile, beginning in late May, several consumer class actions lawsuits were filed against Theranos. On May 30, 2016, Walgreens' parent company, Walgreens Boots Alliance, Inc. ("WBA"), was named as a defendant, along with Theranos, in the lawsuit captioned *R.G. v. Theranos, Inc., Walgreens Boots Alliance, Inc., et al.*. Other similar lawsuits followed, some of which also named WBA as a defendant (collectively, the "Consumer Class Action Litigation").

110. On June 6, 2016, Walgreens sent a follow-up letter to Theranos, again demanding answers to the questions in the May 23 letter, as well as additional questions concerning Theranos's decision to issue tens of thousands corrected and/or voided reports.

111. Ms. King, on behalf of Theranos, responded that day with an e-mail that she had been "planning" to respond to Walgreens "this morning," and also would "respond to [the May 23 letter] in writing." Theranos did not send a written response.

112. Ms. King also offered to have an oral discussion, but refused to confirm any facts in writing.

113. On the evening of June 11, 2016, Ms. King spoke with Walgreens and answered the questions set forth in Walgreens' letters of May 23 and June 6 for the first time. Ms. King stated that Theranos had been aware of quality issues since September 2015. Ms. King stated that Theranos began voiding test reports and/or issuing corrected reports in November

2015. Ms. King stated that Theranos voided additional tests between February and April 2016. Ms. King stated that 31,000 Walgreens customers had received voided test reports, which was 11.3% of total Walgreens customers. Ms. King also informed Walgreens that Theranos had issued 93 corrected reports for the PT/INR hematology test.

Walgreens Terminates its Relationship with Theranos

114. On June 12, 2016, Walgreens sent a letter to Theranos terminating the Agreement for cause, effective immediately. [redacted] Accordingly, Walgreens terminated all Theranos services within its stores, as of that date.

115. That evening, the parties discussed and reached agreement on the orderly transition of Theranos's equipment and services out of Walgreens stores.

116. Two weeks later, on June 26, 2016, Theranos (through Ms. King) responded to Walgreens' June 12 termination letter.

117. Theranos acknowledged that it had issued tens of thousands of voided and/or corrected test results. Theranos also acknowledged that it had suspended its operations at its Newark lab. Yet Theranos characterized these events as "evidence of cure, not breach," even though Theranos had voided the test results in secret—without notifying Walgreens.

118. Theranos also stated that it had "addressed the issues with [Theranos's] Newark lab—including suspending testing completely—with new leadership and enhanced quality systems, policies, and procedures. [redacted]

119. Contrary to Theranos's assertions that it had addressed the issues with its Newark lab, however, CMS had rejected Theranos's proposed Plan of Correction on March 18.

120. On July 1, 2016, the Energy and Commerce Committee of the U.S. House of Representatives announced that ranking members of the Committee had sent a letter to Theranos "requesting information on the company's failure to comply with federal regulatory standards governing clinical laboratory testing and its steps to address flawed test results sent to thousands of medical professionals and patients."

121. The letter stated: "Given Theranos' disregard for patient safety and its failure to immediately address concerns by federal regulators, we write to request more information about how company policies permitted systematic violations of federal law and how Theranos is working with regulators to address these failures."

122. In addition, "[g]iven [the members'] ongoing concerns about Theranos's compliance with Federal statutes and regulations and the quality and accuracy of Theranos's testing," the letter requested that Theranos provide a briefing to Committee staff on a number of issues, including "How is Theranos working with regulators to come into compliance with Federal law?"

123. On July 7, 2016, Walgreens responded to Theranos's June 26 letter. In the letter, Walgreens refuted Ms. King's assertion that Theranos was not in breach. The letter further explained that Theranos's quality issues extended beyond its Newark laboratory. In particular, as noted above, Theranos personnel had admitted to Walgreens personnel that the Arizona laboratory issued approximately 1,000 voided and/or corrected reports for the high risk PT/INR hematology test.

124. Walgreens' July 7 letter also contested Theranos's assertion that Theranos had cured its breach of the Agreement. In particular, and contrary to Theranos's claim, Theranos's voiding of tens of thousands of tests results, and doing it secretly no less, only underscored the severity of Theranos's failure to comply with its obligations under the Agreement.

CMS Issues Final Sanctions Against Theranos, Shutting Down its Newark Laboratory and Banning Ms. Holmes and Mr. Balwani from Owning or Operating a Laboratory for Two Years

125. On July 7, 2016, in a letter to Dr. Dhawan, Ms. Holmes, and Mr. Balwani, CMS set forth its final determination with respect to Theranos's Newark laboratory.

126. The letter first explained that, following CMS's March 18 letter rejecting Theranos's proposed Plan of Correction and setting forth proposed sanctions, CMS received a total of five different submissions from Theranos, collectively referred to as Theranos's "second submission." Theranos's second submission attempted to demonstrate "a credible allegation of compliance and acceptable evidence of correction."

127. Following its review of Theranos's collective submissions, CMS stated:

> After careful review, we have determined that the laboratory's second submission again does not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015, and does not demonstrate that the laboratory has come into Condition-level compliance and abated the immediate jeopardy.

128. Based on the finding of immediate jeopardy and Theranos's failure to fix these deficiencies, the July 7 letter also set forth CMS's final sanctions against Theranos. CMS's sanctions included revocation of the Newark laboratory's CLIA certification, effective September 5, 2016. In addition, and among other sanctions, CMS determined that Ms. Holmes and Mr. Balwani "are prohibited from owning or operating (or directing) a laboratory for at least (2) years from the date of the revocation." Other sanctions include:

- Limitation of the laboratory's CLIA certificate for the specialty of hematology
- A Civil Money Penalty
- A Directed Portion of a Plan of Correction
- Suspension of the laboratory's approval to receive Medicare and Medicaid payments for any services performed for the specialty of hematology
- Cancellation of the laboratory's approval to receive Medicare and Medicaid payments for all laboratory services

129. Further, with respect to one of Theranos's allegation of compliance, CMS found "contradictory statements in [Theranos's] submissions call into question the reliability of the information contained in the submissions." Elsewhere, CMS questioned whether Quality Control information "provided by the laboratory in its first or second submission to CMS is reliable."

130. In addition, with respect to Quality Assessment, CMS stated:

> The laboratory again failed to adequately address issues related to quality assessment and provide acceptable evidence of correction … Specifically, the laboratory failed to indicate what measure has been put in place or what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

131. Theranos's own corrective plan, as quoted in the July 7 CMS letter, admitted "that there is a possible patient impact for every test reported from the laboratory's [proprietary] instruments." The corrective plan further acknowledged that the "fraction of patient results truly impacted, and the nature and magnitude of any effect, are unknown."

132. Experts in the field commented on the unprecedented nature of CMS's sanctions. Geoffrey Baird, associate professor in the laboratory medicine department at the University of Washington, stated, "I can't think of anything this severe ever happening to a clinical laboratory of this size and scale."

133. On July 7, 2016, Theranos issued a statement on its website purporting to continue to work closely with CMS to better understand the agency's findings. Theranos also stated that it "will continue to carry out its mission under the leadership of its founder and CEO, Elizabeth Holmes"—notwithstanding the federal government sanctions and ongoing investigations.

134. [redacted] To date, Theranos still has not confirmed whether it will agree to do so.

135. On August 1, 2016, Ms. Holmes spoke at the annual meeting of the American Association for Clinical Chemistry ("AACC"). As described on the AACC's website, Ms. Holmes was expected, for the first time, to "present data at a scientific conference that describes Theranos's technologies, including small sample volume testing and finger-stick collection."

136. Instead of presenting data on its Edison devices, Ms. Holmes announced a new blood-testing device, called a "miniLab." Indeed, Theranos, in a press release issued that day, announced that this represented "the next phase of the company."

137. Later that day, in an interview with CNN, Ms. Holmes was asked about CMS's findings with respect to Theranos's laboratories. Ms. Holmes stated, "At the highest level, we didn't have the right leadership in the laboratory and we didn't have the implementation of the quality system in terms of procedures and the associated documentation to ensure that we were realizing the quality standards that we hold ourselves to."

138. On October 5, 2016, in an Open Letter from Elizabeth Holmes to Theranos stakeholders, Ms. Holmes announced that, "[a]fter many months spent assessing our strengths and addressing our weaknesses," Theranos had "decided to close its clinical labs and Theranos Wellness Centers."

139. Ms. Holmes further announced that approximately 340 employees, or 40% of its workforce, would no longer be employed by Theranos.

140. This announcement reflected a complete abandonment of Theranos's technology and business model that had been the basic premise of its agreements with Walgreens. Theranos was unable to provide blood-testing services at the level of quality it promised or in compliance with law, and now has admitted that it will not perform blood-testing services at all.

Theranos Has Not Cured its Breach

141. Theranos denied its breach, effectively putting Walgreens on notice that Theranos does not intend to provide the payments to Walgreens that would result from a termination for cause.

142. [redacted]

CAUSES OF ACTION

COUNT I – BREACH OF CONTRACT
19(c)(ii)

143. Plaintiff hereby incorporates each and every allegation set forth in the foregoing paragraphs of this Complaint as if fully set forth herein.

144. Defendant Theranos entered into the Amended and Restated Theranos Master Services Agreement, dated June 5, 2012, with Plaintiff Walgreens.

145. [redacted]

146. [redacted]

147. Theranos has materially breached this warranty.

148. CMS imposed on Theranos an unprecedented series of the most serious sanctions in the clinical laboratory industry, including, among others, revocation of the Newark laboratory's CLIA certificate and banning Ms. Holmes and Mr. Balwani from owning or operating a laboratory for at least two years.

149. CMS's findings and issuance of sanctions show that experts at CMS have concluded not only that Theranos's operations were substandard, but also that Theranos's repeated effort to correct the identified deficiencies itself was a failure. Indeed, following CMS's rejection of Theranos's proposed Plan of Correction on March 18, 2016, Theranos made five additional submissions to CMS. Yet CMS still found these collective submissions to not

constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during CMS's survey completed over 6 months earlier.

150. Theranos also effectively admitted that it was not performing its testing service with the requisite care and skill when it voided tens of thousands of its test results, from both of its labs, spanning a two-year time period. As Theranos admitted, approximately 30,000 voided test reports were issued to Walgreens customers.

151. In addition, during an interview on the Today Show, Theranos's CEO Elizabeth Holmes admitted that she was "devastated," expressed regret that Theranos "did not catch and fix these issues faster," and revealed that Theranos would need to "rebuild [its] entire laboratory from scratch so that we can ensure it never happens again." In a July 7, 2016 statement following CMS's July 7 letter, Theranos affirmed that it would "shut[] down and subsequently rebuild[] the Newark lab from the ground." And again, on August 1, 2016, Ms. Holmes admitted in an interview that it "didn't have the right leadership in the laboratory and we didn't have the implementation of the quality system in terms of procedures and the associated documentation to ensure that we were realizing the quality standards that we hold ourselves to." A laboratory that is operated with ordinary care does not leave its CEO feeling devastated, nor does it need to be "shut down" and "rebuil[t] … from scratch."

152. Now, Theranos is not even attempting to rebuild its laboratories. On October 5, 2016, Ms. Holmes announced that Theranos was shutting down both of its laboratories and all of its remaining blood-drawing centers.

153. The study performed by the Icahn School of Medicine at Mount Sinai and published in the peer-reviewed *The Journal of Clinical Investigation* provides further independent evidence of a breach of Theranos's duty to act with ordinary care and skill. The

authors there demonstrated that Theranos produced more irregular blood test results than conventional tests offered by other lab testing services, and Theranos's own statements confirmed those findings.

154. [redacted]

155. [redacted]

156. Plaintiff also has suffered further damages, to be proven.

COUNT II – BREACH OF CONTRACT
19(c)(iii)

157. Plaintiff hereby incorporates each and every allegation set forth in the foregoing paragraphs of this Complaint as if fully set forth herein.

158. Defendant Theranos entered into the Amended and Restated Theranos Master Services Agreement, dated June 5, 2012, with Plaintiff Walgreens.

159. [redacted]

160. [redacted]

161. Theranos has materially breached this warranty.

162. As previously detailed, CMS conducted a CLIA recertification and complaint survey of Theranos's Newark laboratory in fall 2015, which concluded on December 23, 2015. On January 25, 2016, CMS issued a letter to Theranos setting forth the findings from its survey. In the letter, CMS concluded "that [the Newark] facility is not in compliance with all of the Conditions required for certification in the CLIA program."

163. The letter further noted that one Theranos program "pose[d] immediate jeopardy to patient health and safety," with 'immediate jeopardy" defined "as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."

164. In its February 4 letter to Plaintiff, Defendant acknowledged: "To be sure, the CMS Letter identifies curable deficiencies in our Newark lab, but also provides an express mechanism for Theranos to remedy those deficiencies." In other words, Defendant effectively admitted that it was in breach, albeit one it thought curable.

165. No cure of a violation of law is possible.

166. In any event, Theranos's purported cure never came; to the contrary, CMS, in its March 18, 2016 letter, rejected Theranos' Plan of Correction, stating that it did "not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies

cited," and did "not demonstrate that the laboratory has come into Condition-level compliance and abated immediate jeopardy."

167. Then, in its July 7, 2016 letter, CMS determined that Theranos's subsequent submissions "again [did] not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited" and did "not demonstrate that the laboratory has come into Condition-level compliance and abated the immediate jeopardy."

168. CMS thus imposed on Theranos an unprecedented series of the most serious sanctions in the clinical laboratory industry, including, among others, revocation of the Newark laboratory's CLIA certificate and banning Ms. Holmes and Mr. Balwani from owning or operating a laboratory for at least two years.

169. CMS's findings and its issuance of sanctions show that experts at CMS have concluded that Theranos failed to operate in compliance in all material respects with all applicable laws.

170. Indeed, members of the U.S. House of Representatives stated in a letter to Theranos that, "[g]iven Theranos' disregard for patient safety and its failure to immediately address concerns by federal regulators, we write to request more information about how company policies permitted systematic violations of federal law and how Theranos is working with regulators to address these failures."

171. [redacted]

[redacted]

172. [redacted]

173. Plaintiff also has suffered further damages, to be proven.

COUNT III – BREACH OF CONTRACT
Implied covenant of good faith and fair dealing

174. Plaintiff hereby incorporates each and every allegation set forth in the foregoing paragraphs of this Complaint as if fully set forth herein.

175. Defendant Theranos entered into the Amended and Restated Theranos Master Services Agreement, dated June 5, 2012, with Plaintiff Walgreens.

176. Under the Agreement, Theranos agreed to provide blood-testing services at Walgreens stores.

177. Walgreens had a reasonable expectation that Theranos would perform this contractual obligation using its finger-stick technology.

178. Theranos, in its presentations to Walgreens, repeatedly highlighted the viability of its finger-stick technology. From its first presentation to Walgreens in March 2010, Theranos touted its purportedly disruptive technology that offered "comprehensive blood tests from a finger-stick."

179. Similarly, in January 2012, Ms. Holmes and Mr. Balwani again assured Walgreens that its CLIA-certified labs would become the "world's first finger-stick based CLIA-certified lab," and would offer the "highest quality testing from a finger-stick."

180. Walgreens, accordingly, had a reasonable expectation that Theranos would use its finger-stick technology when performing blood-testing services at Walgreens stores.

181. [redacted]

182. Although Theranos consistently continued to promise the widespread use of finger-stick technology, Theranos did not deliver on that expectation. In fact, Theranos abandoned using its finger-stick draws altogether in 2015, after the FDA deemed the blood-collection container a medical device subject to regulation. Defendant failed to inform Plaintiff of this fact until after it was disclosed in the press months later.

183. Moreover, not only did Theranos fail to perform finger-stick blood draws, it now has admitted it will not perform any blood-testing services at all. Ms. Holmes announced on October 5, 2016, that Theranos would be shutting down both of its laboratories and all of its remaining blood-draw centers.

184. Defendant failed to perform in accordance with the parties' expectations that Theranos would perform blood-testing services at Walgreens stores using its finger-stick technology, and therefore breached its implied covenant. [redacted]

185. Plaintiff also has suffered further damages, to be proven.

COUNT IV – DECLARATORY JUDGMENT

186. Plaintiff hereby incorporates each and every allegation set forth in the foregoing paragraphs of this Complaint as if fully set forth herein.

187. Defendant Theranos entered into the Amended and Restated Theranos Master Services Agreement, dated June 5, 2012, with Plaintiff Walgreens.

188. [redacted]

189. Several consumer class action lawsuits have been filed against Theranos, some of which also named WBA as a defendant (the "Consumer Class Action Litigation").

190. The claims involved in the Consumer Class Action Litigation trigger each and every one of the above-cited clauses in paragraph 22.1 of the Agreement.

191. [redacted]

192. Theranos still has not confirmed to Walgreens whether it will agree to do so.

193. [redacted]

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

(a) [redacted]

(b) [redacted]

(c) an order awarding Plaintiff damages it has suffered from being named as a defendant in the Consumer Class Action Litigation, in an amount to be proven;

(d) an order awarding Plaintiff reputational damages, in an amount to be proven;

(e) an order awarding Plaintiff pre- and post-judgment interest to the extent allowed by law;

(f) [redacted]

(g) an order declaring that Theranos must defend, indemnify, and hold harmless Walgreens and its affiliates (including their respective agents, directors, officers, employees, successors and assigns) in the Consumer Class Action Litigation; and

(h) such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Walgreens demands a jury trial on all issues so triable.

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Dated: November 8, 2016
Public Version Dated: November 15, 2016
1237625

Exhibit A

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

Exhibit B

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

Exhibit C

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

Exhibit D

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY