	Case 2:16-cv-02138-HRH Doc	cument 159	Filed 10/20/17	Page 1 of 132			
1	Lynn Lincoln Sarko (<i>pro hac vice</i>) T. David Copley						
2	Gretchen Freeman Cappio (<i>pro hac vice</i>) KELLER ROHRBACK LLP						
3	1201 Third Ave., Ste. 3200						
4	Seattle, WA 98101 Telephone: (206) 623-1900						
5	Facsimile: (206) 623-3384 Email: lsarko@kellerrohrback.com Email: dcopley@kellerrohrback.com Email: gcappio@kellerrohrback.com						
6							
7							
8	Michael W. Sobol (<i>pro hac vice</i>) Roger N. Heller (<i>pro hac vice</i>)						
9	Melissa Gardner (<i>pro hac vice</i>) LIEFF CABRASER HEIMANN						
10	& BERNSTEIN, LLP 275 Battery St., 29th Floor						
11	San Francisco, CA 94111-3339 Telephone: (415) 956-1000 Facsimile: (415) 956-1008 Email: msobol@lchb.com Email: rheller@lchb.com Email: mgardner@lchb.com						
12							
13							
14							
15	Interim Co-Lead Plaintiffs' Counsel						
16	UNITED STATES DISTRICT COURT						
17	DISTRICT OF ARIZONA						
18	In re:		No. 2:16-cv-21				
19	Arizona THERANOS, INC.,		(Consolidate No. 2:16-cv-23	73-HRH			
20	Litigation		No. 2:16-cv-26 No. 2:16-cv-27				
21			-and- No. 2:16-cv-35	99-HRH			
22			SECOND AM				
23			CONSOLIDA' ACTION CON	FED CLASS			
24			JURY TRIAL				
25			JUNI IMILI				
26							
27							
28							

	Case	e 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 2 of 132	
1		TABLE OF CONTENTS	
2		Pag	Je
3	I.	INTRODUCTION	-
4	II.	JURISDICTION AND VENUE	5
5	III.	PARTIES	5
6	IV.	FACTUAL BACKGROUND	7
0 7		A. The Critical Importance of Reliable Blood Tests	7
		B. The Edison Device and Its Premature Rush to Market	8
8		C. Theranos and Walgreens Join Forces	2
9		D. Defendants Intentionally Concealed the Truth From Consumers	6
10 11		E. Defendants Falsely Promoted Theranos Testing as Reliable and Made Other Affirmative Misrepresentations	21
12		F. Theranos Tests Were Unreliable and Dangerous	8
		G. Defendants' Fraudulent Scheme Unravels	-2
13		H. Defendants Continue to Fail to Protect Customers	0
14		I. The Members of the Edison Subclass Were Subjected to Battery	4
15		J. Defendants' Misconduct Has Significantly Harmed Consumers	2
16		K. Factual Allegations Regarding Plaintiffs	3
17	V.	CLASS ACTION ALLEGATIONS	6
18	VI.	CAUSES OF ACTION	
19	VII.	PRAYER FOR RELIEF	
20	VIII.	DEMAND FOR JURY TRIAL	7
20 21			
22			
23			
24			
2 4 25			
26			
27			
28			
		- i - SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT CASE NO. 2:16-CV-2138-HRH	Г

1 2

I. <u>INTRODUCTION</u>

Plaintiffs bring this Second Amended Consolidated Class Action Complaint
 against Defendants Theranos, Inc. ("Theranos"), Walgreens Boots Alliance, Inc. and
 Walgreen Arizona Drug Company (collectively, "Walgreens"), Elizabeth Holmes
 ("Holmes"), and Ramesh Balwani ("Balwani").

- 6 2. This class action lawsuit concerns a massive fraud perpetrated on hundreds
 7 of thousands of consumers of Theranos testing services and the public, and battery
 8 committed by Walgreens and Theranos against tens of thousands of consumers subjected
 9 to so-called "tiny" blood draws under false pretenses.
- 3. For years, Walgreens and Theranos marketed and sold blood testing services
 they knew were unreliable, not ready-for-market, and failed to meet even basic industry
 standards. Walgreens and Theranos sold these services and administered the
 corresponding blood draws primarily at numerous Walgreens pharmacies in Arizona and
 California, and also at a few Theranos-owned Wellness Centers.
- 15 4. With respect to the "tiny" blood draws in particular, the subjects agreed to 16 submit to these blood draws under false pretenses and substantially mistaken belief as to 17 their essential nature and purpose. Defendants Walgreens and Theranos knowingly and 18 intentionally concealed vital information from consumers, their doctors, and the public at 19 large, including that the "Edison" "tiny" blood technology was, throughout the time the 20 "tiny" blood draws were being administered, still in-development, not ready-for-market, 21 and nowhere near in a position to serve the purpose of providing reliable blood test 22 results. Walgreens and Theranos further embarked on a pervasive promotional campaign 23 that misrepresented and clearly portrayed the "tiny" blood tests as being market-ready and 24 serving the purpose of providing reliable blood test results. Simply put, the "tiny" blood 25 draws that Theranos and Walgreens administered to these consumers were not intended by 26 Theranos and Walgreens to provide, and could not serve the purpose of providing, reliable 27 blood test results to the subjects (hereinafter, "legitimate blood testing").
- 28

5. With respect to both the Edison and non-Edison "tests," Defendants
 Walgreens, Theranos, Holmes and Balwani each concealed material information about the
 unreliability of all of the testing services, and about the grossly deficient nature of the
 testing facilities and equipment.

6. Walgreens and Theranos also made pervasive misrepresentations, including
through their broad marketing campaign, falsely touting the services as being market
ready and reliable, meeting the highest standards of reliability, industry-leading in quality,
and developed and validated under, and compliant with, federal guidelines.

9 7. Walgreens and Theranos aggressively promoted and portrayed Theranos
10 tests as being ready-for-market, and encouraged consumers and their doctors to use and
11 rely on them in making important health and treatment decisions, including, but not
12 limited to, regarding such critical health and treatment matters as cancer, HIV, diabetes,
13 kidney disease, and heart disease.

14 8. In reality, as each of the Defendants contemporaneously knew but the
15 consumers could not, Theranos tests were dangerously unreliable, had not been validated
16 as advertised, and did not meet federal guidelines as advertised. Multiple regulatory
17 investigations and many thousands of voided tests now confirm this.

18 9. With respect to the Edison technology in particular, each of the Defendants 19 knew—throughout the time the "tiny" blood draws were being administered—that the 20 Edison technology was still in development, not ready-for-market, and nowhere near in a 21 position to serve, and was not intended by Walgreens and Theranos to serve, the purpose 22 of legitimate blood testing that the subjects believed to be the purpose of their blood 23 draws. Nevertheless, in a hurry to begin marketing and administering these "tiny" blood 24 draws, and thereby assist in researching and developing the still-in-development 25 technology, to advance the narrative that Theranos's "disruptive" technology had 26 "revolutionized" the medical testing industry, and to woo and placate investors, potential 27 investors, and co-investors by giving the false impression that they had a market-ready, 28 breakthrough product, Walgreens and Theranos prematurely marketed, sold, and

administered, the "tiny" blood draws to tens of thousands of unwitting consumers who
 were, in essence, subjected to beta testing and product development research without their
 knowledge or consent—a course of conduct that would be wrong in any context but is
 shockingly improper and dangerous in the context of blood testing.

5 10. Defendants' scheme started to unravel when various governmental agencies 6 and others began investigating Theranos's "tests" and facilities. After the Center for 7 Medicare and Medicaid Services cited Theranos's Newark, California lab for numerous 8 deficiencies in 2016, Theranos informed regulators that it voided "all" blood-testing results from the Edison devices.¹ Other investigations and reports have revealed 9 10 numerous other serious deficiencies and problems regarding Theranos's tests (including 11 beyond Edison), including the manipulation of test results, the dilution of blood samples 12 used in testing, and deficiencies at both of Theranos's testing facilities. Numerous 13 additional test results, in addition to the tens of thousands of voided Edison-device tests, 14 have now been voided or belatedly "corrected" by Theranos, including results that were 15 "corrected" several months (or even years) after the blood draws and tests were conducted 16 and the results relied upon by the consumers. Defendant Holmes, Theranos's founder and 17 CEO, was banned from owning or operating a blood-testing business for at least two 18 years. Defendant Balwani, Theranos's second in command, was banned as well, and 19 Theranos's license to operate a lab was revoked. Continuing the fallout, Walgreens sued 20 Theranos for breach of contract, and Theranos, Holmes, and Balwani were all sued by 21 multiple investors for misrepresenting and concealing the truth about Theranos's 22 technology and testing, and in particular regarding the readiness of the Edison technology.

11. Before Defendants' scheme collapsed, hundreds of thousands of consumers,
including Plaintiffs, were deceived by Defendants' misconduct and paid for and were
subjected to Theranos "tests." Defendants have failed to deliver the products and services

 ²⁷ ¹ John Carreyrou, *Theranos Voids Two Years of Edison Blood-Test Results*, Wall St. J.
 ²⁸ (May 18, 2016) (Ex. 1).

they promised and that their customers reasonably expected, and have endangered their customers' health and well-being, the very thing they promised to promote and protect.

12. None of the consumers who obtained test results from Theranos received
what they paid for and what they reasonably expected. None of them received tests that
they could reasonably rely on given the numerous problems alleged herein that have come
to light.

7 13. Moreover, the tens of thousands of consumers who submitted to the "tiny"
8 blood draws (i.e., involving the finger-stick devices), including Plaintiffs B.P., R.C., and
9 S.J. did so under false pretenses and substantially mistaken about the essential nature and
10 purpose of those blood draws, and were all victims of battery.

- 11 14. Worse yet, as a result of the unreliable and inaccurate Theranos test results,
 12 many consumers have been subjected to unnecessary or potentially harmful treatments,
 13 and/or have been denied the opportunity to seek treatment for treatable conditions.
- 14 15. As described in further detail below, Plaintiffs, for themselves and all others 15 similarly situated, (i.e., the members of the Class and Subclasses described and defined 16 herein), bring this action for, *inter alia*, damages, restitution, punitive damages, statutory 17 damages, and other monetary relief, and requiring Defendants to provide adequate notice to their customers,² pursuant to the Arizona Consumer Fraud Statute A.R.S. §§ 44-1521 et 18 19 seq.; California Business and Professional Code §§ 17200, et seq.; California Business 20 and Professional Code §§ 17500, et seq.; California Civil Code §§ 1750, et seq.; California Civil Code §§ 1709-1710; Civil RICO 18 U.S.C. §§ 1962(c); and common law 21 22 causes of action for fraud, negligent misrepresentation, unjust enrichment, aiding and 23 abetting fraud, battery, and medical battery.
- 24

1

2

²⁴ ² Plaintiffs recognize that the Court dismissed their individual claims for injunctive relief
in the form of notice to the Class, and also recognize the Court's instruction that all claims
dismissed with prejudice do not need to be re-pled to be preserved for appeal (Dkt. 139 at
60; Dkt. 157 at 11). Plaintiffs reserve all appeal rights, but also respectfully request that
the Court consider this particular request for the provision of Class notice in light of the
fact that there are numerous other victims of Defendants' practices who still, as of this
filing, have not received notice and thus may still be relying on the unreliable test results.

1

II. JURISDICTION AND VENUE

2	16. This Court has subject matter jurisdiction over this action pursuant to 28			
3	U.S.C. § 1332(d)(2) because at least one member of the Class is a citizen of a state that is			
4	different from at least one of the Defendants and because the aggregate amount in			
5	controversy exceeds \$5,000,000 exclusive of costs and interest, and there are more than			
6	100 members in each of the proposed Class and Subclasses.			
7	17. This Court has personal jurisdiction over Theranos, Walgreens, Holmes, and			
8	Balwani because each of these Defendants has conducted business in the State of Arizona,			
9	and because each Defendant has committed acts and omissions complained of herein in			
10	the State of Arizona.			
11	18. Venue as to Defendants is proper in this judicial district because a			
12	substantial part of the events and omissions giving rise to the claims alleged herein			
13	occurred in this District. Venue is also proper because Defendants have conducted, and			
14	continue to conduct, business within this District.			
15	III. <u>PARTIES</u>			
16	19. Plaintiff A.R. is a resident and citizen of San Jose, California and is using			
17	his initials to protect his privacy in this litigation.			
18	20. Plaintiff B.B. is a resident and citizen of Chandler, Arizona, and is using her			
19	initials to protect her privacy in this litigation.			
20	21. Plaintiff B.P. is a resident and citizen of Phoenix, Arizona and is using his			
21	initials to protect his privacy in this litigation.			
22	22. Plaintiff D.L. is a resident and citizen of Maricopa, Arizona and is using her			
23	initials to protect her privacy in this litigation.			
24	23. Plaintiff L.M. is a resident and citizen of Chandler, Arizona and is using her			
25	initials to protect her privacy in this litigation.			
26	24. Plaintiff M.P. is a resident and citizen of Scottsdale, Arizona and is using his			
27	initials to protect his privacy in this litigation.			
28				

Plaintiff R.C. is a resident and citizen of Sun City West, Arizona and is
 using his initials to protect his privacy in this litigation.

3 26. Plaintiff R.G. is a resident and citizen of Gilbert, Arizona and is using his
4 initials to protect his privacy in this litigation.

5

6

27. Plaintiff S.J. is a resident and citizen of Mesa, Arizona and is using her initials to protect her privacy in this litigation.

7 28. Plaintiff S.L. is a resident and citizen of Chandler, Arizona and is using his
8 initials to protect his privacy in this litigation.

9 29. Defendant Theranos, Inc. ("Theranos") is based in Palo Alto, California.
10 Theranos operates, or during the relevant time period operated, two laboratories: one in
11 Newark, California, and another in Scottsdale, Arizona. Predominantly in Walgreens
12 pharmacies in Arizona and California, and also in a few Theranos-owned Wellness
13 Centers in Arizona and California, Theranos, along with Walgreens, sold blood and other
14 clinical testing services to individuals.

15 30. According to reports, since 2013, Theranos has conducted 6.1 million
16 diagnostic tests.

17 31. Defendant Walgreens Boots Alliance, Inc., of Deerfield, Illinois, is a global 18 pharmacy-led health and well-being enterprise, which, among other segments, operates 19 the Walgreens retail pharmacy chain in the United States. Defendant Walgreen Arizona 20 Drug Company, an Arizona corporation, is a wholly-owned subsidiary of Walgreens 21 Boots Alliance, Inc. involved in operating Walgreens retail stores in Arizona. Walgreens 22 Boots Alliance, Inc. and Walgreen Arizona Drug Company are referred to collectively 23 herein as "Walgreens." In numerous Walgreens pharmacies in Arizona and California, 24 Walgreens, along with Theranos, sold blood and other clinical testing services to 25 individuals. The vast majority of the services sold by Walgreens and Theranos, including 26 the vast majority of the so-called "tiny" blood draws, occurred at Walgreens pharmacies. 27 32. Defendant Elizabeth Holmes, a citizen and resident of California, is the

28 founder of Theranos and at all relevant times has been Theranos's Chief Executive

Officer. Holmes has had a primary role in, and in significant part has personally directed,
 Theranos's misconduct as alleged herein. Further, Holmes personally made material
 misrepresentations and omissions as alleged herein. On information and belief, Holmes
 has personally received millions, if not billions, of dollars in compensation as a result of
 the business and revenue generated through the misconduct alleged herein.

6 33. Defendant Ramesh "Sunny" Balwani, a resident of California, is the former 7 President and Chief Operating Officer of Theranos, and was Theranos's second in 8 command, behind Defendant Holmes, before he resigned from Theranos in 2016 amid the 9 various investigations. Balwani had a primary role in Theranos's misconduct alleged 10 herein. Mr. Balwani personally directed misconduct alleged herein. Further, Balwani 11 personally made material misrepresentations and omissions as alleged herein. On 12 information and belief, Balwani has personally received millions of dollars in 13 compensation as a result of the business and revenue generated through the misconduct 14 alleged herein.

15 34. Each of the acts and/or omissions of each Defendant alleged herein were
16 made known to, and ratified by, each of the other Defendants.³

- 17
- 18

IV. FACTUAL BACKGROUND

A. <u>The Critical Importance of Reliable Blood Tests</u>

Blood tests and other clinical lab tests ("test results") are an everyday and
 invaluable part of the practice of modern medicine. Test results can offer crucial details
 about an individual's health, and doctors rely on test results to detect everything from
 cholesterol and glucose levels to infections, blood cell counts, and cancer.

36. Test results aid in the process of medical diagnosis and treatment decisions,
and in some cases are a prerequisite for additional medical tests. Because test results are
such a foundational part of medical treatment, test results that are unreliable or inaccurate

 ³ The Court dismissed with prejudice Plaintiffs' claims to the extent they were based on an agency or joint venture theory of liability (Dkt. 139 at 55-56; Dkt. 141). Plaintiffs respectfully preserve any and all rights to pursue such claims and arguments on appeal.

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 10 of 132

1 can be catastrophic: serious conditions may go undetected, patients may not receive the 2 treatments and medications that they need, and patients may be misdiagnosed and receive 3 treatments or medications that they have no need for. It is absolutely critical that 4 consumers be able to rely on test results.

5

As the Theranos "direct testing menu" (Ex. 2 hereto) reflects, the "tests" 37. 6 offered by Theranos and Walgreens at their Wellness Centers, including at Walgreens 7 stores and in the Theranos-owned facilities, included more than 200 different medical 8 tests and combinations of tests (panels). These included tests concerning critical medical 9 and health issues including, but not limited to, cancer, heart disease, diabetes, kidney 10 disease, auto-immune disorders, and viruses. Id.

11

B.

The Edison Device and Its Premature Rush to Market

12 38. Theranos was founded in 2003 by Elizabeth Holmes, then a sophomore at 13 Stanford studying chemical engineering, who dropped out a few months later to focus on 14 Theranos. As CEO, Holmes has maintained that she developed the idea for Theranos as a 15 result of her self-professed phobia of needles.⁴ According to published reports, Theranos 16 initially focused on development of a hand-held device that would use a tiny needle to 17 obtain a small drop of blood for analysis. By 2008, the project had grown into attempting 18 to develop what is now known as the "Edison" device.

- 19 39. In contrast to the standard-sized needle and numerous tubes required in a 20 typical venipuncture blood draw, Theranos claimed that its Edison device could eliminate 21 the need for laboratories altogether. The Edison device (which Theranos never allowed to 22 be photographed) was supposedly able to take a few drops of blood from a patient's finger 23 placed into a "nanotainer" capsule, and reliably conduct hundreds of blood tests, all 24 outside a lab. This concept would have enabled Theranos to conduct all testing outside of
- 25

²⁶ ⁴ Marco della Cava, *Change Agents: Elizabeth Holmes Wants Your Blood*, USA Today (July 26, 2014), available at http://www.usatoday.com/story/tech/2014/07/08/change-27 agents-elizabeth-holmes-theranos-blood-testing-revolution/12183437/ (last visited Oct. 20, 2017). 28

the laboratory in the Wellness Centers and thus—according to statements made by
 Theranos, Walgreens, Holmes, and Balwani—revolutionize testing by significantly
 reducing the time and costs involved.

4 40. Neither Holmes nor any of the other Defendants ever explained to the public the science or technology underlying the Edison device, and they, in fact, refused to 5 6 provide any meaningful explanation based on the claimed need to protect Theranos's 7 intellectual property. Despite the industry practice for companies to publish their results 8 and allow for peer review by experts in the field when launching a new medical product, Theranos has still never published its data or allowed for peer review.⁵ One writer 9 10 described Holmes's explanation of what Edison does as "comically vague" after she 11 explained, "[a] chemistry is performed so that a chemical reaction occurs and generates a 12 signal from the chemical interaction with the sample, which is translated into a result, which is then reviewed by certified laboratory personnel."⁶ 13

14 41. Despite the fact that the Edison technology was, to put it generously, still in
15 development and not ready-for-market, and nowhere near in a position to serve the
16 purpose of legitimate blood testing, Theranos and Walgreens prematurely rushed the
17 "tiny" blood "tests" to market.

42. In connection with the launch of Theranos testing to the consumer public,
Theranos and Walgreens embarked on a large-scale media campaign designed to, *inter alia*, let the medical profession and the consuming public know that the Edison
technology was revolutionary and ready for public use for the full range of medical testing
offered. In a September 8, 2013 interview with the *Wall Street Journal*, for example,

- 23
- 24

⁵ John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*,
Wall St. J. (Oct. 16, 2015) (Ex. 3).

⁶ Ken Auletta, *Blood, Simpler, One woman's drive to upend medical testing*, The New Yorker (Dec. 15, 2014), available at http://www.newyorker.com/magazine/2014/12/15/blood-simpler (last visited Oct. 20, 2017).

Holmes boasted that Theranos was able to "run any combination of tests, including sets of
 follow-on tests" quickly from a single tiny blood sample.⁷

,

3 43. Various press releases and other statements to the media during that time 4 period trumpeted the same themes. For example, a September 9, 2013 joint press release 5 by Theranos and Walgreens stated: "For the first time, Theranos is introducing CLIA-6 certified laboratory services with the ability to run its tests on micro-samples. Theranos's 7 proprietary laboratory infrastructure minimizes human error through extensive automation 8 to produce high quality results. Test results are available to physicians in a matter of 9 hours, enabling fast diagnoses to help informed treatment choices. . . . For the past 10 10 years, Theranos has worked relentlessly to reach a point at which we could help make actionable information accessible to physicians and patients at the time it matters most."⁸ 11 12 A second joint press release by Theranos and Walgreens, issued on November 13, 2013 and excerpted below, included many of the same themes.⁹ 13

44. Theranos's website similarly claimed, at around this same time, that its
"laboratory can perform your tests quickly and accurately on samples as small as a single
drop."

45. In a recorded interview with Medscape's Eric J. Topol, M.D., Holmes
reaffirmed her claims that Theranos tests were validated, run on tiny samples, and more
accurate than traditional blood tests: "We spent many years redeveloping every test that is
recognized by Medicare in the form of a CPT (Current Procedural Terminology) code to
be able to run it on a tiny sample"... "we focused a great deal on these tests and
validated and verified them over the years, building an infrastructure that was highly

⁷ Joseph Rago, *Elizabeth Holmes: The Breakthrough of Instant Diagnosis*, Wall St, J.
(Sept. 8, 2013) (Ex. 4).

⁸ Press Release, Theranos, Inc., *Theranos Selects Walgreens as a Long-Term Partner Through Which to Offer Its New Clinical Laboratory Service* (Sept. 9, 2013) (Ex. 5).

 ⁹ Press Release, Theranos, Inc., *Theranos and Walgreens Expand Diagnostic Lab Testing* to the Phoenix Metropolitan Area; New TheranosTM Wellness Centers at Walgreens stores provide consumers with less invasive, fast, affordable testing on samples as small as a few drops of blood (Nov. 13, 2013) (Ex. 6).

automated and standardized such that the quality of the data that we generate could be
 used in an actionable manner."¹⁰

3 46. Balwani also publicly spread the misleading claims that Theranos testing, 4 including Edison, was safe, reliable, and ready for use by the public. In a presentation 5 before the Arizona Senate Health and Human Services Committee on March 12, 2014, 6 Balwani stated that Theranos was "able to provide a majority of the testing from only two 7 or three drops of blood," and although those drops of blood could be taken from a 8 traditional venipuncture, "most likely patients will prefer a simple finger stick, and we are able to do that."¹¹ Later in 2014, Balwani emphasized Theranos's supposedly ready and 9 10 working technological advancement (i.e., Edison) in an interview with the The New 11 *Yorker*, claiming that "[0]ur platform is about automation. . . We have automated the process from start to finish."¹² 12 47. 13 Based on such representations by Holmes, Balwani, Theranos, and 14 Walgreens, and based on a pervasive joint-marketing campaign by Theranos and 15 Walgreens discussed in detail below, people believed that Theranos testing was ready-for-16 market and that the Edison technology was a true disruptive technology breakthrough. 17 Holmes was hailed as the next Steve Jobs, and by 2014, Theranos was valued at \$9 18 billion—approximately the same as each of its two largest and long established 19 competitors in the medical testing industry.¹³ 20 48. In reality, as described in further detail herein, none of the testing services 21 that Theranos and Walgreens offered were reliable or certified, as each of the Defendants 22 ¹⁰ Eric J. Topol, M.D., Creative Disruption? She's 29 and Set to Reboot Lab Medicine, Medscape (Nov. 18, 2013), available at http://www.medscape.com/viewarticle/814233 23 (last visited Oct. 20, 2017). ¹¹ Presentation by Dr. Ramesh Balwani to Arizona Senate Health and Human Services 24 Committee (Mar. 12, 2014), at 3:08-3:22, available at 25 http://azleg.granicus.com/MediaPlayer.php?clip_id=13816 (last visited Oct. 20, 2017). ¹² Ken Auletta, *Blood*, *Simpler*, *supra* n.6. 26 ¹³ Steve Denning, Is Theranos Too Good To Be True?, Forbes (Feb. 13, 2016), available 27 at http://www.forbes.com/sites/stevedenning/2016/02/13/is-theranos-too-good-to-betrue/#47de558857f8 (last visited Oct. 20, 2017). 28

1 had stated and suggested. With respect to the Edison technology in particular, the 2 technology was simply not ready-for-market or anywhere near ready to serve the purpose 3 of legitimate blood testing at any time the "tiny" blood draws were being administered. 4 Walgreens and Theranos knew this, but nevertheless prematurely rushed the "tiny" blood 5 "tests" to market to, *inter alia*: further the research and development of this as-yet 6 undeveloped technology, promote the narrative that Edison was a "disruptive" technology, 7 and to woo and/or satisfy investors, potential investors, and co-investors by making it 8 appear that Edison was a market-ready, breakthrough technology and not, at best, an 9 ambitious idea that was still-in-development.

10

C.

Theranos and Walgreens Join Forces

11 49. By 2011, Theranos was in talks with both Safeway and Walgreens to offer 12 Theranos testing in their stores. In or around 2012, Theranos entered into a partnership 13 agreement with Walgreens, under which Walgreens invested \$140 million in Theranos, 14 \$100 million of which was characterized as an "Innovation Fee," and the two companies 15 agreed to place and operate clinics, which it called "Wellness Centers," at Walgreens 16 Pharmacies in Arizona and California. Following the launch of the partnership in 2013, 17 Theranos and Walgreens planned to build Wellness Centers in Walgreens stores 18 nationwide.¹⁴

19 50. Under their partnership agreement, Theranos and Walgreens opened a total
20 of 40 Wellness Centers within Walgreens pharmacy stores in Arizona, and one in a
21 Walgreens pharmacy in California, to sell the majority of the "tests."¹⁵

51. The agreement between Walgreens and Theranos ("Master Services
Agreement" or "MSA") lists the two companies' respective tasks regarding the services
offered to consumers in the Walgreens store locations. Among other tasks, the MSA

- ²⁵ ¹⁴ *Theranos Selects Walgreens* Press Release (Ex. 5), *supra* n.8.
- ¹⁵ James B. Stewart, *A Marriage Gone Bad: Walgreens Struggles to Shake Off Theranos*, N.Y. Times (Apr. 21, 2016), available at http://www.nytimes.com/2016/04/22/business/aonce-avid-ally-walgreens-is-struggling-to-shake-off-theranos.html (last visited Oct. 20, 2017).

1 provides that Walgreens personnel (called "Walgreen Technicians") were responsible for 2 the following tasks: "handl[ing] the patients"; 3 a. physically administering the "tiny" blood draws (["Walgreen 4 b. 5 Technicians will draw blood using the finger stick technique"]); 6 "collecting the proper other specimens according to directions" c. 7 provided by Theranos"; 8 collecting demographic and insurance information, and co-pays; and d. 9 "properly stor[ing] and prepar[ing] the specimen for pick-up".¹⁶ e. 10 52. Pursuant to the MSA, Theranos's tasks included providing training and other assistance to the Walgreens personnel performing the "laboratory patient services," 11 as well as testing the samples collected.¹⁷ 12 13 53. Jay Rosan, Senior Vice President of Health Innovation at Walgreens, 14 explained that with respect to arrangements like the one with Theranos: 15 We're focused on pharmacy innovation and health, healthcare services and e-commerce and it's led, we do the thing called 16 co-production... We're co-producing things together.¹⁸ 17 54. At all times that Theranos testing services were being sold in Walgreens 18 stores, Walgreens knew and/or should have known that the tests could not reasonably be 19 relied on by consumers and their doctors in making health and treatment decisions. 20 Walgreens was aware of numerous serious red flags about the tests that put it on notice 21 about the unreliability of the tests, and deliberately chose to ignore, not follow up on, and 22 conceal that information. With respect to the Edison technology, Walgreens knew that 23 Edison was still in development, not ready-for-market, and not ready to serve the purpose 24 25 ¹⁶ Dkt. 123-1, Ex. A (MSA) at 9, ¶ 15. ¹⁷ *Id.* at 8-9. 26 ¹⁸ Int'l Bus. Forum, Walgreens Venture Capital Success (Jay Rosen, presenting) (Feb. 7, 27 2014), available at https://www.youtube.com/watch?v=ZFjgqapXFQc&t=4s (last visited Oct. 20, 2017) (emphasis added). 28

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 16 of 132

1 of legitimate blood testing. To the extent Walgreens lacked any more detailed knowledge, 2 it was by virtue of its own deliberate decision to ignore and/or avoid such details.

3 55. Walgreens' knowledge regarding these problems and regarding the unready 4 state of Edison, was reinforced by complaints it received from customers who had blood 5 draws at Walgreens stores and received "test results" that were significantly out-of-whack.

6

56. Before entering into the partnership with Theranos, Walgreens' Chief 7 Medical Officer neither reviewed Theranos's technology nor independently validated or verified the accuracy, reliability, or results of the tests.¹⁹ Nevertheless, and despite the 8 9 fact that Walgreens executives had expressed doubts about the reliability of Theranos tests 10 and the quality of its equipment and/or facilities, Walgreens reportedly said it was "confident in the quality of Theranos's services," in 2015.²⁰ 11

12 57. In fact, although a Johns Hopkins University scientist had requested, on 13 Walgreens' behalf, that Theranos provide his researchers with an Edison device so that they could verify the technology for Walgreens, and Holmes initially agreed to provide 14 one, the device was never provided.²¹ Instead, Walgreens got a prototype which the Johns 15 16 Hopkins team tried to evaluate, but the prototype was useless when evaluating the 17 accuracy and reliability of the tests because it produced results such as "low" or "high" 18 rather than numeric values that could be compared to other labs' tests. As a result, there 19 was no way to compare results from the prototype Edison device to the results of other commercially-available tests.²² 20

- 21 58. In the summer of 2011, just after Theranos and Walgreens signed an initial letter of agreement, Walgreens sent a delegation, including its finance chief, internal 22
- 23 ¹⁹ Blood Sports, Pressure is Mounting on a Startup That Has Tried to Shake Up the Lab-Test Market, The Economist (Apr. 23, 2016), available at 24

https://www.economist.com/news/business/21697273-pressure-mounting-startup-has-25 tried-shake-up-lab-test-market-blood-sports (last visited Oct. 20, 2017).

26

²⁰ *Id*.

²¹ Christopher Weaver and John Carreyrou, Craving Growth, Walgreens Dismissed Its 27 Doubts About Theranos, Wall St. J. (May 25, 2016) (Ex. 7).

²² *Id*. 28

auditor, and lab experts from a consulting firm called Colaborate, LLC, to a meeting at
 Theranos headquarters in Palo Alto, the purpose of which was to gain a firsthand view of
 the Theranos business and its capabilities.²³

4

5

6

7

8

59. At that meeting, however, the consulting lab experts were chaperoned during the entire visit, including during visits to the restroom, and were not allowed access to Theranos's lab area or Edison technology. Despite the lack of access, Walgreens did discover problems with Theranos's information management systems meant to keep track of patients.²⁴

60. According to published reports, throughout the process, despite their
concerns and the numerous red flags they identified, Walgreens executives nevertheless
looked the other way. They deliberately did not press for further verification, and instead
went ahead with the Theranos partnership, despite their concerns and known problems
about the reliability of Theranos's facilities and tests. Walgreens apparently was afraid
that Theranos would respond to its questions by choosing another retail chain to work
with as a partner.²⁵

16 61. Later in 2011, Colaborate, LLC, issued a report concluding that Walgreens
 17 needed more information to assess the proposed partnership with Theranos.²⁶

62. Similarly, in October 2012, Walgreens sent two executives and a retired
Quest Diagnostics Corp. executive to Theranos to review quality-control data. According
to reports, the retired Quest executive stated that they were not allowed inside Theranos's
lab, and while they were led to believe the data they reviewed was from an Edison device,
Theranos did not confirm that it was.²⁷ Walgreens continued to work on the partnership

- 23
- 24
- 25
- $\begin{array}{c|c} 24 & Id. \\ 25 & Id. \\ 25 & Id. \\ \end{array}$

²³ *Id*.

- 20 25 *Id.*
- 27 26 *Id.*
- 28 27 Id.

agreement despite the lack of access to the technology and despite its concerns about the
 reliability of Theranos's facilities and tests.

3 63. According to published reports, Walgreens executives were privy to 4 information that Safeway, Inc. had also agreed to host Theranos testing sites at some of its 5 stores. According to reports, Safeway dissolved its partnership with Theranos before it 6 began hosting Theranos testing sites in Safeway stores due, in part, to its due diligence 7 that raised questions about the accuracy of Theranos's testing. For example, the 8 unreliability of Theranos tests became apparent after Safeway employees in Pleasanton, 9 California had their blood tested by both Theranos and another conventional lab, and the test results differed significantly.²⁸ 10

64. In response to pressure from Theranos, despite its concerns and knowledge
about problems, Walgreens ceded even more control to Theranos in the final agreement
reached between Walgreens and Theranos, and Walgreens gave up the right to review
Theranos's clinical data or financial records.

15

D.

Defendants Intentionally Concealed the Truth From Consumers

16 65. Theranos, Walgreens, Balwani, and Holmes each intentionally concealed
17 known problems regarding Theranos testing equipment and facilities, and regarding the
18 unreliability and un-readiness of Theranos testing. The information that each of the
19 Defendants concealed was highly material information, and included information
20 pertinent to both the Edison technology and non-Edison tests.

66. For example, each of the Defendants knew, but concealed, that:
(a) Theranos's laboratories were not in compliance with federal guidelines; (b) Theranos's
Edison device lacked regulatory approval; (c) with the exception of a single approved test,
Theranos tests had not been approved by the FDA despite attempts to get such approval
for more than 100 tests; (d) internal testing and data showed that Theranos's technology,
including but not limited to Edison, was unreliable; (e) Theranos's testing equipment,

²⁷ ²⁸ John Carreyrou, *Safeway, Theranos Split After \$350 Million Deal Fizzles*, Wall St. J.
²⁸ (Nov. 10, 2015) (Ex. 8).

1 including Edison, had failed proficiency testing and Theranos manipulated the testing 2 process in an attempt to cover that up; (f) for some tests that were to be conducted on 3 "tiny" blood samples, Theranos even went so far as to *dilute* the samples prior to 4 conducting the "tests"; (g) Theranos testing was not ready-for-market; (h) the Edison 5 technology was still in development and not nearly in a position to serve the purpose, and 6 not intended by Theranos and Walgreens to serve the purpose, of legitimate blood testing; 7 (i) the consumers subjected to the "tiny" blood draws were being used, in essence, to 8 experimentally beta test Edison and for other research and product development purposes; 9 (j) inspections by regulators had revealed a wide range of serious deficiencies at 10 Theranos; and (k) Walgreens had identified numerous red flags regarding the reliability of 11 Theranos testing, but had nevertheless gone ahead with offering the tests in its stores 12 while deliberately failing to conduct any meaningful investigation or to follow up 13 regarding the problems and concerns identified.

67. With respect to the undisclosed material information, all such information
was known by Theranos. Theranos knowingly engaged in and assisted the concealment of
material information as alleged herein.

17 68. With respect to the undisclosed material information, all such information
18 was known by Walgreens and/or would have been known but for Walgreens' deliberate
19 choice to ignore and/or not obtain such information or conduct a reasonable investigation.
20 Walgreens knowingly engaged in and assisted the concealment of material information as
21 alleged herein.

69. Holmes and Balwani were personally privy to the material undisclosed
information by virtue of their extensive, hands-on involvement in these matters and their
respective roles as leader and second in command, at Theranos. Holmes and Balwani
knowingly engaged in and assisted the concealment of material information as alleged
herein.

27 70. All of the Defendants went to great lengths to conceal the truth about
28 Theranos testing. For example, Theranos refused to allow its Edison device to be

1 photographed; would not permit peer review of its testing or technology, even though that 2 is customary in the medical testing and health care industry; and refused to even provide 3 meaningful explanations when asked about how its technology worked. All of the 4 Defendants affirmatively covered up reliability problems when they were identified 5 internally, and concealed and downplayed the fact that Theranos and Walgreens had 6 phased out, and then ultimately discontinued entirely in or around the summer of 2015, 7 use of the "tiny" blood draws and Edison, a decision, on information and belief, that was 8 related to increased regulatory scrutiny of the Edison technology.

9 71. When the discontinuation of the Edison device occurred, Holmes, for
10 example, misrepresented the reason.²⁹ Walgreens, via its divisional vice-president,
11 Nimesh Jhaveri, told reporters: "TRUST me. If the results are not there we would hear."³⁰

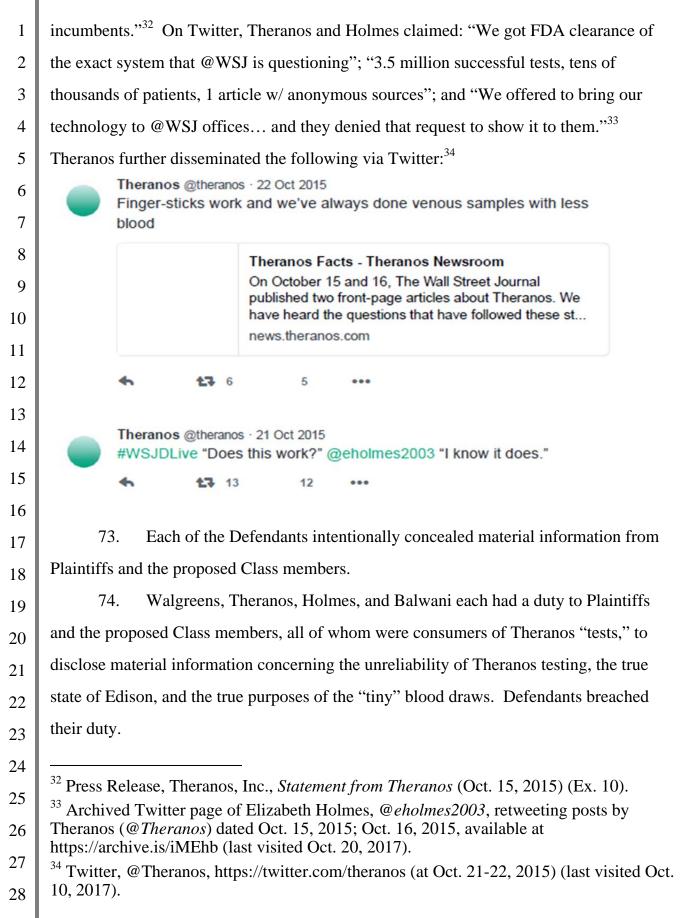
12 72. When concerns were raised internally by Theranos employees, Theranos executives minimized, mocked, and threatened the employees.³¹ And when media outlets 13 14 began questioning things, Theranos and Holmes repeatedly attacked the sources and 15 falsely denied there were any problems. For example, when the *Wall Street Journal* 16 published a story raising alleged issues about Theranos testing in October 2015, Theranos 17 responded by issuing a press release which stated, in part: "Today's Wall Street Journal 18 story about Theranos is factually and scientifically erroneous and grounded in baseless 19 assertions by inexperienced and disgruntled former employees and industry

- 20
- 21

²⁹ In an interview at Fortune's Global Forum on November 2, 2015, Holmes claimed she
"was the person who chose, voluntarily, to stop using our nanotainer tubes" and that it
was the "decision to transition our systems to the FDA framework, which led us right now,
as of this moment, for the last few weeks only, to run just one test" using the finger-stick
and nanotainer collection method. "Temporarily," she emphasized, "as we transition,
which has now been just a few weeks, we would not be using that [nanotainer] tube to
collect our samples." Recorded interview available at
http://fortune.com/2015/11/02/theranos-elizabeth-holmes-fda/ (last visited Oct. 20, 2017).
³⁰ Blood Sports, supra n.19.

²⁷³¹ John Carreyrou, *Theranos Whistleblower Shook the Company—And His Family*, Wall
²⁸ St. J., (Nov. 16, 2016.) (Ex. 9).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 21 of 132



75. The information Walgreens, Theranos, Holmes, and Balwani did not
 disclose was within the exclusive possession of Defendants, who were in a position of
 significantly far superior knowledge, particularly in light of their concealment of
 information.

76. Moreover, the scientific and technical nature of blood and other clinical
testing is such that each of the Defendants knew that consumers depended and relied on
Defendants to provide accurate and complete material information for the consumers' use
in making decisions.

9 77. The Defendants' duties to disclose also arose from the fact that they made 10 numerous misleading and/or partial statements to consumers and the public about and 11 suggesting, *inter alia*, the readiness, quality, reliability, and regulatory approval and 12 compliance of Theranos testing. In promoting Theranos testing, Defendants (including 13 Theranos, Walgreens, and Holmes and Balwani personally) repeatedly made statements, 14 in marketing and elsewhere, suggesting that the testing was accurate, reliable, and of the 15 highest-quality. Each Defendant also expressly stated and implied that Theranos testing 16 was validated by, and compliant with, federal regulations and guidelines. Defendants had 17 a duty to disclose material information regarding the unreliability of Theranos testing and 18 the fact that such testing was not ready-for-market, because Defendants' affirmative 19 representations were misleading and likely to deceive consumers in the absence of full 20 disclosure.

21 78. Defendants' duty to disclose also arose from the very nature of the 22 information in question. Given the critical role that blood testing and other clinical testing 23 plays in monitoring one's health and in making health and treatment decisions, and the 24 corresponding importance of consumers' ability to rely on their test results, Theranos, 25 Walgreens, Holmes and Balwani each knew that the information not disclosed was highly 26 material and that reasonable consumers would not have entered into the transactions in 27 question, and would not have agreed to have their blood drawn and "tested" by Theranos 28 or Walgreens, had the true information about Theranos testing been disclosed, and knew

4

5

that consumers submitting to Theranos blood testing were doing so based on mistaken
 facts, without material information and, in fact, with misleading information disseminated
 by Defendants.

E. <u>Defendants Falsely Promoted Theranos Testing as Reliable and Made Other</u> <u>Affirmative Misrepresentations</u>

79. Not only did Theranos, Walgreens, Holmes, and Balwani all conceal
material information, but each of them made material affirmative misrepresentations as
well.

9 80. Leading up to and throughout the time blood draws were being administered 10 at the Walgreens stores and other Wellness Centers, Theranos and Walgreens engaged in a 11 pervasive marketing campaign promoting the testing services—including specifically 12 promoting the "tiny" blood test technology throughout the time "tiny" blood draws were 13 being administered—to consumers and medical professionals. This broad marketing 14 campaign, including the content thereof, was jointly designed, approved, and implemented 15 by Theranos and Walgreens, such that the representations made pursuant to this broad 16 campaign are appropriately attributable to both companies.

17 81. This marketing was pervasive throughout the geographic areas where the
18 Theranos testing services were offered, and included signs and materials in the Walgreens
19 stores and Theranos Wellness Centers where the services were sold, prominent billboards,
20 electronic advertisements, advertisements on the Theranos and Walgreens websites,
21 television and social media-based commercials, and at the Phoenix Sky Harbor
22 International Airport.³⁵

- 82. As a story in Newsweek summarized it: "In 2015, advertisements for
 Theranos—which promised comprehensive biometric data using only a few drops of
 blood—were everywhere in Arizona. They were on television during commercial breaks
 and on billboards along Interstate 10 through Phoenix. They were above Phoenix Sky
- ³⁵ Seung Lee, *Arizona: Where Theranos Still Has a Friend*, Newsweek (June 14, 2016)
 (Ex. 11).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 24 of 132

Harbor International Airport terminals and pharmacy aisles in Walgreens stores. They
 shared the message that Theranos was here to revolutionize medical lab tests and advocate
 on behalf of Arizonans' right to know their own bodies."³⁶

83. Theranos's and Walgreens' marketing campaign was so pervasive that all
Plaintiffs and members of the proposed Class, and their medical providers, were exposed
to them. Walgreens and Theranos intended for consumers, the public at large, and
medical providers, including in the pertinent geographic areas, to be exposed to this
marketing and to rely on it.

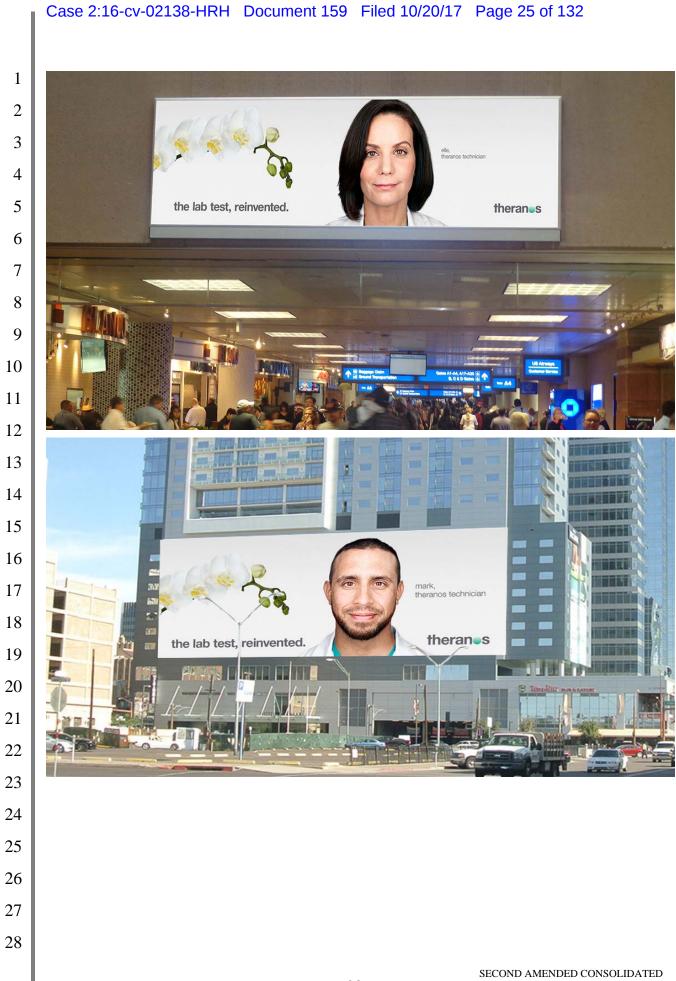
9 84. Plaintiffs and the Class were exposed to this marketing campaign and
10 reasonably relied on it.

11 85. Absolutely fundamental, at the very center of *all* of this broad marketing
12 campaign (indeed, the *entire premise* of the marketing), was the portrayal—both
13 explicitly and implicitly—of the "tiny" blood draws, and of the services generally, as
14 being market-ready and for legitimate testing purposes. Through this marketing,
15 Theranos and Walgreens promoted the services as providing reliable test results, and
16 encouraged consumers to have their blood drawn for that purpose.

17 86. At the very least, with respect to the "tiny" blood draws and Edison, these
18 representations and portrayals were untrue, and Theranos and Walgreens knew it, since
19 Edison was still in-development and nowhere near ready to serve the purpose of
20 legitimate blood testing.

87. For example, during the time the "tiny" blood draws were being offered and
administered, Theranos and Walgreens caused the following prominent billboards to be
erected in high-visibility areas in Arizona:

- 24 25
- 26
- 0
- 27
- $28 \int {}^{36} Id.$





88. During the time the "tiny" blood draws were being offered and administered, Theranos and Walgreens also disseminated mass advertising in the relevant geographic area, promoting the "tiny" blood "tests" through targeted online and mobile advertisements, including ads that provided consumers with the location of nearby Walgreens stores where they could get these blood "tests." For example:

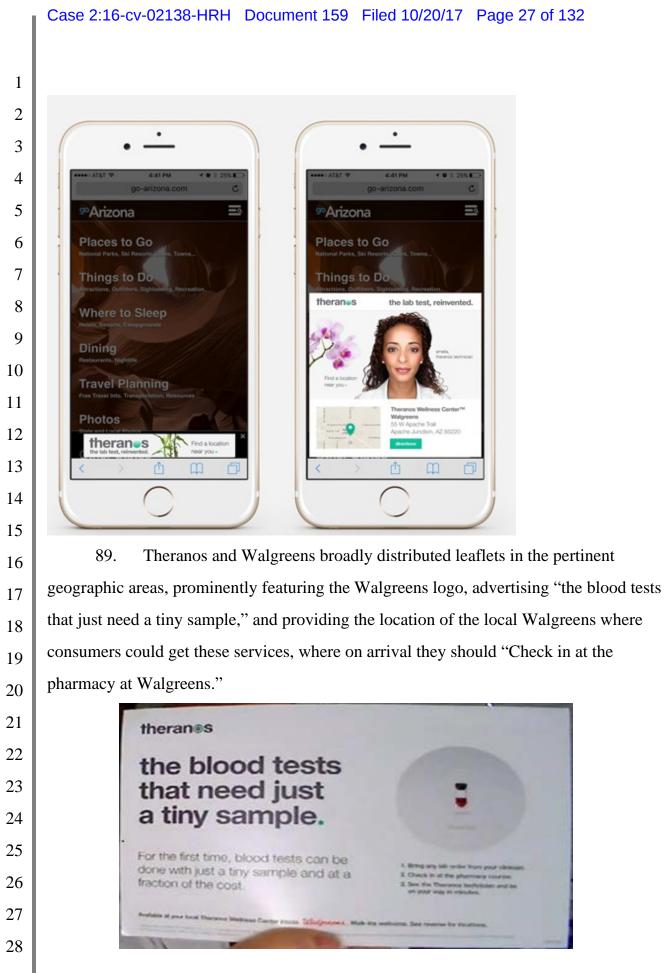
SIZE

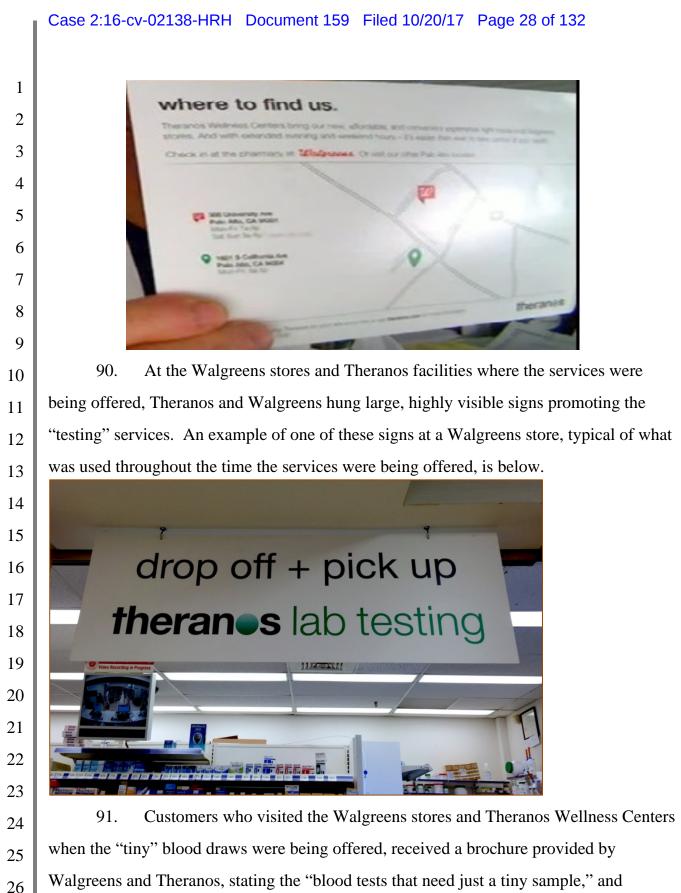


16

17

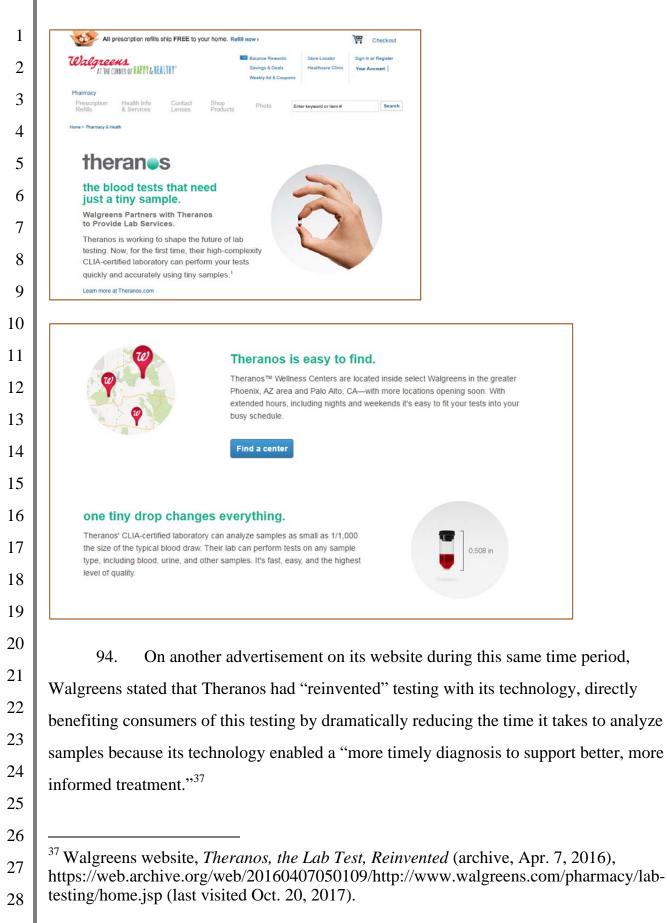
18



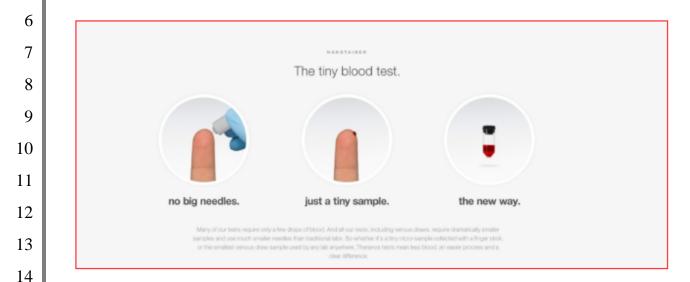


showing a picture of the nanotainer device:



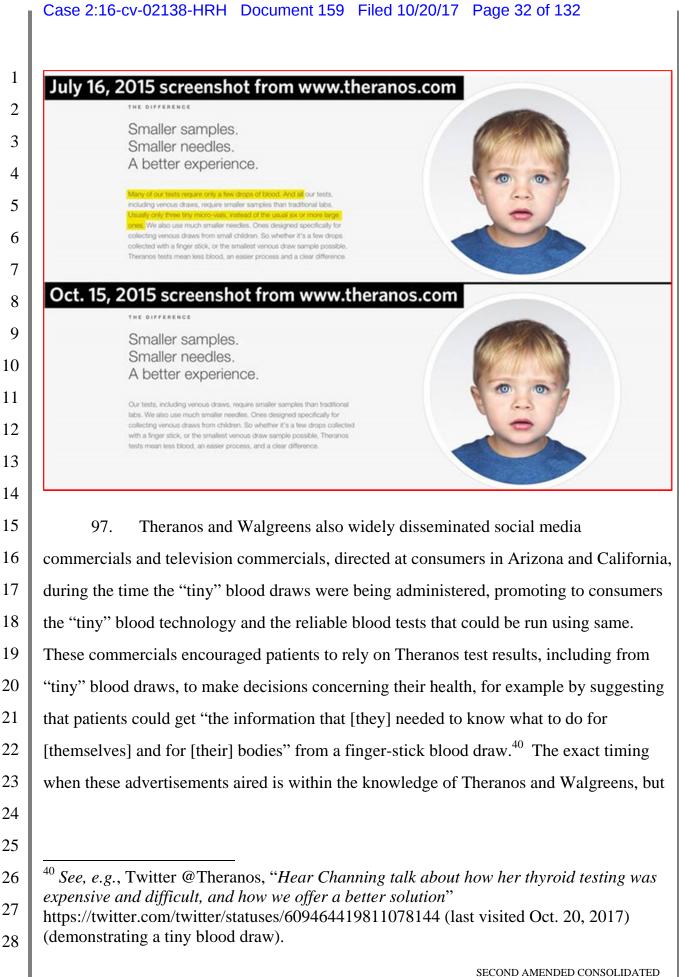


1 95. Other marketing materials by Theranos and Walgreens that appeared on the 2 Theranos website, in the Walgreens stores and Theranos Wellness Centers, and elsewhere 3 throughout the time the "tiny" blood draws were being administered, specifically 4 highlighted the "tiny blood test" technology and described Theranos and Walgreens' 5 offerings as "revolutionary" and a "new way" of testing. For example:



15 96. Similarly, according to reports, until at least October 2015, promotional 16 materials from Theranos promised that "usually only three tiny micro vials" of blood 17 would be collected "instead of the six or more large ones," because "many" of Theranos's tests required no more than "a few drops of blood."³⁸ Theranos reportedly deleted the 18 19 highlighted portions of the materials below in mid-2015 to supposedly improve its 20 "marketing accuracy," after it moved away from Edison testing following a surprise inspection by the FDA:³⁹ 21 22

- 23 24
- 25
- 26 ³⁸ John Carreyrou, Hot Startup Theranos Dials Back Lab Tests at FDA's Behest, Wall St. 27 J. (Oct. 16, 2015) (Ex. 16). ³⁹ *Id*.



on information and belief they aired for at least a substantial portion of the time the "tiny"
 blood draws were being administered.

98. In addition to the signs at the Walgreens stores and Theranos Wellness
Centers, Walgreens and Theranos provided materials in the stores regarding the services
that likewise clearly portrayed the services as being for legitimate and reliable testing
purposes. These materials are described in more detail below.

99. In close proximity to their introduction of the "tiny" blood "testing" at the
Walgreens stores, Theranos and Walgreens also issued joint press releases that were
intended for mass distribution, and which received considerable general media coverage
in the pertinent geographic areas and in the medical press.

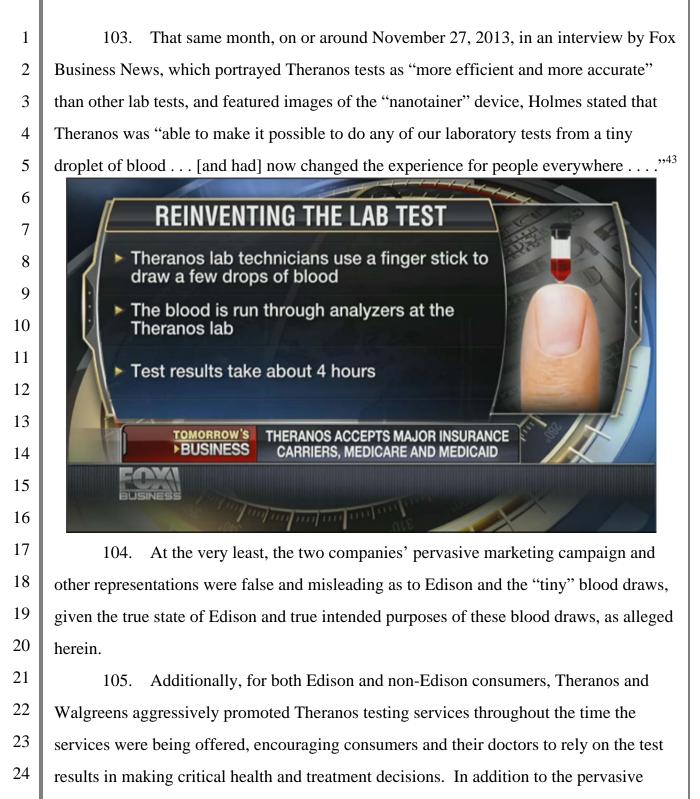
100. When the Theranos-Walgreens partnership was publicly announced in
September 2013, a joint press release from Theranos and Walgreens stated that the deal
would offer consumers access to "less invasive and more affordable clinician-directed labtesting, from blood samples as small as a few drops, or 1/1000 the size of a typical blood
draw." The joint press release touted Theranos's "CLIA-certified laboratory services,"
and promised that its "proprietary laboratory infrastructure minimizes human error
through extensive automation to produce high quality results."

18 101. It further stated, "[t]his is the next step in Walgreens' efforts to transform
19 community pharmacy, giving our patients and customers convenient access to the
20 comprehensive care they need, right in their communities."⁴¹

102. In November 2013, Theranos and Walgreens issued another joint press
release, announcing the opening of Theranos Wellness Centers in Walgreens stores in
Arizona, which repeated the claims about "micro-samples, collected by certified
phlebotomists or trained Walgreens technicians" would "enable[e] fast diagnoses to help
make informed treatment choices."⁴²

- 26
- 27 ⁴¹ *Id.*

28 ⁴² *Theranos and Walgreens Expand Diagnostic Lab Testing* (Ex. 6), *supra*, n.8.



- ²⁵ marketing and joint press releases and statements described in the above paragraphs, the
- 26

 ⁴³ Fox Business News, *Betting Big on Lab Tests* (Nov. 27, 2013), available at
 http://video.foxbusiness.com/v/2874150095001/betting-big-on-lab-tests/ (last visited Oct.
 20, 2017).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 35 of 132

two companies made other pervasive representations designed to give the false impression 1 2 to consumers and medical providers that Theranos testing was reliable and accurate, 3 compliant with and certified by government guidelines, of the highest quality, and could 4 and should be used in making health and treatment decisions. 5 These or similar representations were prominent and persisted throughout 106. 6 the time the testing services were offered by Theranos and Walgreens. 7 For example, in the following marketing that appeared on Theranos's 107. 8 website and in the Wellness Centers, Theranos and Walgreens touted that their testing 9 services would help patients "evaluate" health issues and to screen for diseases: 10 The same low prices for everyone. 11 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. 12 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. 13 View test menus 14 15 Comprehensive Thyroid STI Comprehensive Insulin 16 Metabolic Panel (CMP) Offering Offering \$7.27 \$49.95 \$59.95 \$7.86 17 Other Labs: Other Labs: Other Labs: Other Labs \$27 - \$29 \$313 - \$512 \$924 - \$1.019 \$49 - \$95 18 To evaluate To help evaluate To evaluate organ function and check To screen for and diagnose sexually 19 for conditions such as diabetes, liver thyroid function transmitted infections insulin production disease, and kidney disease 20

108. Theranos's marketing further stated that "[w]e continuously conduct
proficiency testing and participate in multiple proficiency testing programs," and that all
"tests are developed and validated under and to the CLSI, FDA Centers for Disease
Control, and World Health Organization guidelines."

109. On its website, Theranos advertised that Theranos testing was of "the
highest levels of accuracy," and that the tests were "validated" under and in compliance
with federal regulations and guidelines:

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 36 of 132

PROVIDERS

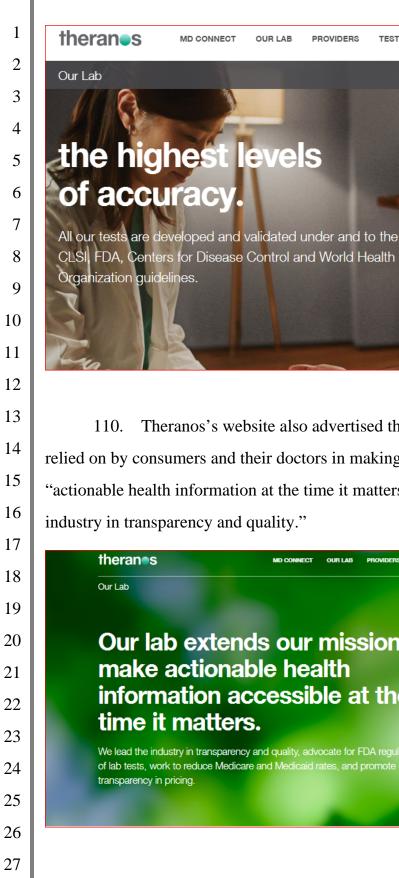
TESTS

CENTERS

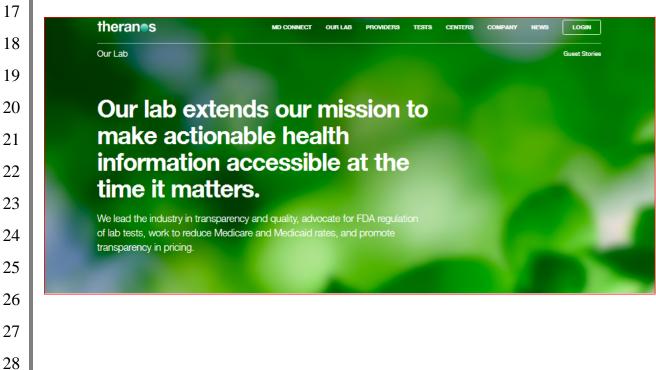
COMPANY

NEWS

OUR LAB



Theranos's website also advertised that Theranos's test results could be relied on by consumers and their doctors in making health decisions, that they provided "actionable health information at the time it matters" to consumers, and that they "lead the



LOGIN

Guest Stories

111. Walgreens' website stated that the Theranos technology supported "better,
 more informed treatment."⁴⁴ The Theranos website similarly claimed that Theranos's
 "laboratory can perform your tests quickly and accurately on samples as small as a single
 drop."

5 112. Throughout its partnership with Theranos, Walgreens endorsed the
6 information on Theranos's website, directing its customers to visit www.theranos.com for
7 more information.⁴⁵

8 113. At Wellness Centers where Theranos tests were offered, including in
9 Walgreens stores, Theranos and Walgreens prominently placed disclosures that touted that
10 Theranos's "CLIA-certified laboratory can perform your tests quickly and accurately
11 using tiny samples."

12 Similar, additional representations were made by Theranos and Walgreens 114. 13 at the Wellness Centers to consumers at the point of purchase. To obtain one or more of 14 the testing services offered by Walgreens and Theranos, customers who did not have an 15 order from their healthcare provider for laboratory tests needed to complete a one-page 16 "Theranos direct testing order form." (Ex. 11). The testing services were marketed and 17 sold directly to consumers, as explained in the pamphlet "a guide to direct testing." (Id.). 18 The Theranos testing order form and guide to direct testing pamphlet both of which were 19 approved by both Theranos and Walgreens, contained further representations and 20 promises that Theranos tests were reliable and could and should be used in medical 21 treatment decisions and other health decisions. For example, the testing order form 22 encouraged consumers to consult with their doctors for "interpretation of the test results." 23 The guide to direct testing touted that the Theranos tests would allow consumers to "own 24 ⁴⁴ Walgreens website, *Theranos, the Lab Test, Reinvented* (archive, Mar. 30, 2014; Apr. 6, 2016), available at 25 https://web.archive.org/web/20140330223244/http://www.walgreens.com/pharmacy/labtesting/home.jsp (last visited Oct. 20, 2017); 26 https://web.archive.org/web/20160407050109/http://www.walgreens.com/pharmacy/lab-27 testing/home.jsp (last visited Oct. 20, 2017). ⁴⁵ *Id*. 28

your own health like never before," allow consumers to "get vital information about their
health when it matters most," allow them to "become better informed earlier" and enable
them to "work with their physician to be proactive and address potential problems
sooner." The guide also stated that consumers could use Theranos test results to monitor
their vital health issues such as "monitor[ing their] thyroid, blood glucose, sexual health,
and more," and directed consumers to consult with their physicians using the test results
once they received them.

8 115. These same themes were advanced and highlighted in the joint press
9 releases by Theranos and Walgreens and in other statements to mainstream and industry
10 media by Theranos, Walgreens, Holmes, and Balwani, described above, including the
11 theme that Theranos testing was government approved and reliable. By way of example
12 only:

13	a.	Theranos Files Comment In Support Of Food and Drug
14		Administration Oversight Of Laboratory-Developed Tests (Mar. 6,
15		2015) ("[We] believe that FDA oversight plays a critical role in
16		ensuring that individuals and their physicians get the most accurate
17		test resultsthere are limits on the adequacy of the peer review
18		systemThat is why we will continue to submit our work to the
19		FDA and why we believe the decision to do so is essential in
20		providing accurate results for individuals and patients.") (Ex. 13).
21	b.	Theranos receives FDA clearance and review and validation of
22		revolutionary finger stick technology, test, and associated test system
23		(July 2, 2015) (Ex. 14).
24	с.	Theranos Receives CLIA Waiver, Paving the Way for Greater
25		Accessibility of Health Information at the Time and Place it Matters
26		(July 16, 2015) ("FDA has concluded that the Theranos test and
27		technology is eligible for waiver under CLIA. The waiver means
28		FDA determined the Theranos test and technology is reliable and
		SECOND AMENDED CONSOLIDATED

accurate and can be used in a broader set of locations outside of a 1 2 traditional CLIA certified laboratory, including Theranos Wellness 3 Centers.") (Ex. 15). d. Holmes told *The New Yorker* that Theranos "ha[s] data that show you 4 5 can get a perfect correlation between a finger stick and a venipuncture for every test that we run."⁴⁶ Holmes knew that 6 statement to be false and misleading when she made it. 7 8 Walgreens CFO, Wade Miguelon, told *The Arizona Republic* that e. 9 Theranos could perform tests "more accurately" than traditional blood tests.⁴⁷ 10 11 116. This advertising served another purpose as well: to lobby the State of 12 Arizona to pass a law allowing consumers to purchase a blood test without a healthcare 13 provider's order. Theranos's lobbying and advertising efforts were successful and the bill 14 was signed in April 2015, despite opposition from the Arizona Medical Association. At 15 the bill's signing, Holmes stated that "Theranos is about access—eliminating the need for 16 painful needles and vials of blood, replacing that with tiny samples taken in convenient 17 locations at convenient hours of operation, always for a fraction of the cost charged 18 elsewhere—to build a health care system in which early detection and prevention become 19 reality. That is why we worked to pass this law; it is why we believe Arizona's law can and should serve as a model for the nation for direct access testing."⁴⁸ The law also 20 21 allowed laboratories to provide blood test results directly to patients, bypassing 22 involvement by doctors, who are trained to question unusual results.

- 23
- 24

⁴⁶ Ken Auletta, *Blood, Simpler, supra* n.6.

²⁵⁴⁷ Ken Alltucker, *Get Your Blood Tested at the Store*, The Arizona Republic (Nov. 13,

^{26 2013),} available at http://archive.azcentral.com/business/news/articles/20131113get-yourblood-tested-store.html (last visited Oct. 20, 2017).

⁴⁸ Press Release, Theranos, Inc., *Theranos Founder and CEO Elizabeth Holmes Speaks at Arizona Bill Signing*, (Apr. 6, 2015) (Ex. 17).

- 117. Walgreens and Theranos jointly marketed Theranos testing services to consumers. Decisions about the joint marketing campaign and about the other representations described herein were made by both Theranos and Walgreens.
- 4

5

1

2

3

118. Holmes and Balwani also knowingly engaged in, assisted the dissemination of, and were at all times aware of, false and misleading representations as alleged herein.

6 119. Walgreens and Theranos knew and intended for consumers to rely on their 7 representations, knew that, by the very nature of blood tests and also based on their 8 representations, consumers who purchased and submitted to the blood draws did so under 9 the belief that such blood draws were for legitimate and reliable testing purposes and 10 would reasonably expect the test results they received to be reliable. Further, Walgreens 11 occupies a special position of trust as a well-established pharmacy entity, as CMO and 12 Group VP of Walgreens Dr. Harry Leider observed in November of 2015: "Everybody 13 knows Walgreens . . . We have 8,300 stores, 25,000 pharmacies, and over 1,000 nurse practitioners in our clinics."⁴⁹ Defendants accordingly knew that the Theranos partnership 14 15 with Walgreens, the imprimatur of Walgreens including via the advertisements, and the 16 presence of Wellness Centers in Walgreens stores, would further lead customers to 17 believe that the Theranos tests were reliable and trustworthy.

18

F. <u>Theranos Tests Were Unreliable and Dangerous</u>

19 120. Theranos's and Walgreens' pervasive marketing and other representations
20 described herein, including but not limited to: (a) their fundamental portrayal of the "tiny"
21 blood draws as being for legitimate testing purposes; and (b) their representations and
22 suggestions that Theranos tests were reliable and complaint with CLIA and other federal
23 guidelines, were knowingly false and misleading.

24

25

121. In fact, each of the Defendants knew, at all relevant times, that: (a) the Edison technology was still in development and not ready-for-market, and not nearly in a

26

⁴⁹ Tom Salemi, *Walgreens: Investing in the Power of the Patient*, Healthegy.com (Nov. 11, 2015), available at https://www.healthegy.com/walgreens-investing-in-the-power-of-the-patient/ (last visited Oct. 20, 2017).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 41 of 132

1 position to serve the purpose, and not intended by Walgreens and Theranos to serve the 2 purpose, of providing reliable blood test results (i.e., "legitimate blood testing"); (b) the 3 true essential nature and purpose of the "tiny" blood draws that subjects submitted to was 4 not, and could not have been, legitimate blood testing; and (c) Theranos testing (including 5 Edison and non-Edison) was decidedly unreliable and posed a serious danger to any 6 consumer who might rely on it.

7

8

9

Each of Walgreens, Theranos, Holmes, and Balwani knew this information 122. to be the case at all relevant times, and yet represented otherwise to consumers and/or concealed that material information from consumers for years, as alleged herein.

10 123. Theranos, Holmes, and Balwani also specifically concealed this information 11 from regulatory authorities. For example, in order to maintain CLIA certification, 12 laboratories are required to administer "proficiency testing" of samples provided by CMS 13 in order to prove that they can produce accurate results. According to reports, Theranos 14 split some of the proficiency-testing samples it got into two pieces: One was tested with 15 Edison machines and the other with instruments from other companies. When Theranos 16 lab employees asked Balwani, by email, which results should be reported back to test 17 administrators and the government, he replied, copying Holmes, that "samples should have never run on Edisons to begin with."⁵⁰ Balwani reportedly ordered lab personnel to 18 19 stop using Edison machines on any of the proficiency-testing samples and report only the 20 results from instruments bought from other companies. The former employees say they 21 did what they were told but were concerned that the instructions violated federal rules, 22 which state that a lab must handle "proficiency testing samples...in the same manner as it tests patient specimens" and by "using the laboratory's routine methods."⁵¹ 23

24

Throughout the more than one year that "tiny" blood draws were being 124. 25 administered in the Walgreens stores and Theranos facilities, the Edison technology was

26

28

²⁷ ⁵⁰ *Hot Startup Has Struggled* (Ex. 3), *supra* n.5. ⁵¹ *Id*.

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 42 of 132

not yet beyond the prototype stage, was not ready-for-market, and was nowhere near in a
 position to serve the purpose of legitimate blood testing.

- 3 125. Moreover, none of the Theranos tests (including non-Edison) were fit for
 4 their ordinary purposes and the purposes for which they were sold.
- 5 126. Theranos tests were neither conducted in conformity with CLIA regulations,
 6 nor "validated" under or compliant with federal guidelines, as represented.

7 127. Any consumer who had a Theranos test (including non-Edison) could not
8 reasonably rely on the results of such test in light of the litany of problems that have now
9 come to light.

- 10 128. As Theranos, Holmes, and Balwani knew, and Walgreens knew and/or
 11 would have known at the time had it not deliberately ignored the details and conducted a
 12 reasonable inquiry, Theranos did not have the necessary FDA approval, known as a CLIA
 13 waiver, to use the Edison device for conducting on-site blood testing at the Wellness
 14 Centers, with the sole exception of a single test (Herpes Simplex HSV-1), for which
 15 Theranos obtained approval in July 2015.⁵² Theranos sought FDA approval for more than
 16 120 of its tests, none of which have been approved at this time.⁵³
- 17 129. By the end of 2014, Theranos employees reported using the Edison device
 18 for only 15 out of 205 tests.⁵⁴ By or around the summer of 2015, Theranos and Walgreens
 19 stopped administering "tiny" blood draws altogether, a decision that, on information and
 20 belief, coincided with increased scrutiny by regulators of the unready Edison
- 21 technology.⁵⁵

a Huge Seal of Approval from the US Government (July 2, 2015), available at

- 27 ⁵⁴ *Hot Startup Has Struggled* (Ex. 3), *supra* n.5.
- 28 ⁵⁵ Beth Mole, *Theranos Throws in the Towel on Clinical Labs, Officially Pivots to*

 ⁵² Press Release, Theranos, Inc., Statement from Theranos (Oct. 28, 2015) (Ex. 18);
 Lauren F. Friedman, Controversial Multibillion-Dollar Health Startup Theranos Just Got

http://www.businessinsider.com/theranos-gets-fda-approval-2015-7 (last visited Oct. 20, 2017).

 ⁵³ Roger Parloff, A Second FDA Approval Frees Theranos to Do a Blood Test Outside
 Lab, Fortune (July 16, 2015), available at http://fortune.com/2015/07/16/fda-clears theranos-to-do-test-outside-lab/ (last visited Oct. 20, 2017).

1 130. In a report detailing objectionable conditions at Theranos dated September
 2 16, 2015, the FDA informed Theranos that, among other things, the agency considered the
 3 Edison devices to be uncleared medical devices being shipped in interstate commerce
 4 between California, Arizona, and Pennsylvania.⁵⁶

5 Because Theranos did not have FDA approval to conduct tests on the Edison 131. 6 device outside of a laboratory setting (with the limited exception for HSV-1 noted above, 7 which approval did not even come until after or around the time Theranos and Walgreens 8 stopped administering the "tiny" blood draws and using Edison), when Walgreens and 9 Theranos drew "tiny" blood samples at the Wellness Centers, the samples obtained then 10 had to be shipped to one of two centralized labs, either in Newark, California, or 11 Scottsdale, Arizona. The proprietary Edison devices were only located in the Newark 12 laboratory. Accordingly, on information and belief, all the finger stick blood samples 13 were analyzed at the Newark facility, with the potential exception of a limited number of samples that Theranos may have, remarkably, *diluted*.⁵⁷ In all, tens of thousands of "tiny" 14 15 blood draws were conducted on consumers in the Walgreens and Theranos Wellness Centers before the "tiny" blood draws were discontinued in 2015. The vast majority of 16 17 these "tiny" blood draws occurred at Walgreens stores. 18 The Scottsdale Lab only performed analyses on venipuncture tests. 132. 19 According to reports, over 90 percent of Theranos's testing was done at its Scottsdale lab.

20 Of the universe of venipuncture tests, Theranos has also disclosed that it outsourced a

- 21 limited number of "highly complex" tests to third-party, university-affiliated labs.
- 22
- 23 *Footnote continued from previous page*

24 *Devices*, Ars Technica (Oct. 5, 2016), available at

- 25 http://arstechnica.com/science/2016/10/theranos-throws-in-the-towel-on-clinical-labsofficially-pivots-to-devices/ (last visited Oct. 20, 2017).
- ⁵⁶ Department of Health and Human Services, Form FDA-483 (Inspection Report) (Sept. 16, 2015), available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm469395.pdf (last visited Oct. 20, 2017).
- 28 ⁵⁷ Hot Startup Has Struggled (Ex. 3), supra n.5.

1 133. In the context of a regulated laboratory, Theranos did not need FDA 2 approval to perform testing using the Edison devices (because they were not selling the 3 Edison devices), so long as Theranos's lab operations were in compliance with federal 4 guidelines and met proficiency testing and other safeguards. However, the labs that 5 Theranos used failed to comply with such testing and guidelines.

6 134. Statements by Walgreens, Theranos, Balwani, and Holmes—that testing 7 was accomplished through proprietary analysis, which was accurate and compliant with 8 federal regulations and guidelines—were false, both as to the Edison-device tests and the 9 other tests. Simply put, the consumers who submitted to "tiny" blood draws did so under 10 entirely false pretenses and mistaken as to the essential nature and purpose of what their 11 blood draws were about, and no consumer who submitted to a Theranos blood draw 12 (Edison or non-Edison) received what they paid for and what they reasonably expected. 13 None of them could reasonably rely on the test results they received, in light of the litany 14 of problems that have come to light.

15

G. **Defendants' Fraudulent Scheme Unravels**

16 135. In March 2014, a former Theranos employee alleged to New York State's 17 public-health lab that Theranos may have manipulated the proficiency testing process, in part by intentionally excluding data that showed Theranos's technology to be unreliable.⁵⁸ 18 19 The New York State lab responded that the practices described would be a "violation of 20 the state and federal requirements," and forwarded the allegations to the Centers for Medicare and Medicaid Services ("CMS").⁵⁹ 21

- 22 In April 2015, Arizona Department of Health Services inspectors identified 136. 23 multiple deficiencies at Theranos's Scottsdale laboratory, including serious issues with
- Theranos's proficiency testing.⁶⁰ For example, in the Scottsdale facility, regulators found 24
- 25 ⁵⁸ Whistleblower Shook the Company (Ex. 9), supra n.31.
- ⁵⁹ Hot Startup Has Struggled (Ex. 3), supra n.5. 26
- ⁶⁰ Ken Alltucker, Arizona Inspectors Find Theranos Lab Issues, The Arizona Republic, 27 (Nov. 30, 2015), available at
- http://www.azcentral.com/story/money/business/consumers/2015/11/27/arizona-28

that Theranos used mis-programmed machines to evaluate blood coagulation tests, failed
 to properly gauge water purity in machines it used, and failed to meet laboratory quality
 standards.

In September 2015, a former Theranos lab employee filed a complaint with
CMS alleging that Theranos instructed lab employees to keep testing patients with the
Edison devices despite indications of "major stability, precision and accuracy" problems
with those devices.⁶¹

8 138. In October 2015 the FDA released inspection reports of Theranos declaring
9 the nanotainer to be an "uncleared medical device." The investigation also found
10 deficiencies in Theranos's processes for handling customer complaints, monitoring quality
11 and vetting suppliers.⁶²

12 139. In January 2016, CMS cited the Theranos Newark, California lab for
13 multiple serious deficiencies. Among other things, the report stated that in October 2014,
14 29 percent of quality control checks performed on the Edison devices produced results
15 outside the acceptable range, and that in February 2015, quality checks on an Edison test
16 measuring a hormone affecting testosterone levels failed 87 percent of the time.

17 140. The letter from CMS, dated January 25, 2016, noted that, based on a
18 December 2015 survey, Theranos was found to be out of compliance with five CLIA
19 Condition-level requirements, at least one of which posed "immediate jeopardy to patient
20 health and safety," meaning the condition had "already caused, is causing, or is likely to
21 cause, at any time, serious injury or harm, or death, to individuals served by the laboratory
22 or the health and safety of the general public."⁶³

23

Footnote continued from previous page

- 24 inspectors-find-theranos-lab-issues/76021416/ (last visited Oct. 20, 2017).
- ⁶¹ John Carreyrou, U.S. Probes Theranos Complaints, Wall St. J. (Dec. 20, 2015) (Ex. 19).
 ⁶² Id.

⁶³ Carolyn Y. Johnson, *Deficiencies at Theranos 'Pose Immediate Jeopardy to Patient Health,*' Washington Post (Jan. 27, 2016), available at
 https://www.available.com/ava

https://www.washingtonpost.com/news/wonk/wp/2016/01/27/regulators-find-deficiencies at-theranos-that-pose-immediate-jeopardy-to-patient-health/ (last visited Oct. 20, 2017).

1 141. Inspection reports found that Edison devices in the lab often failed to meet
 even the Company's own accuracy requirements, including a test to detect prostate cancer.
 In one report, inspectors found that 81 of 81 final patient results of a blood clotting test
 reported to patients on the blood thinner Warfarin were not accurate.⁶⁴

5 142. In addition, the FDA observed that there were no quality audits being
6 performed at Theranos's Newark lab (where the Edison devices were located), in
7 contravention of FDA regulations.⁶⁵

8 At the very time that each of the Defendants were widely touting Theranos's 143. 9 compliance with federal regulations, Theranos had been repeatedly sanctioned by federal 10 authorities for non-compliance, yet Defendants failed to disclose that fact and in fact 11 continued to represent that there were no problems. After CMS issued findings regarding 12 the Newark facility, Theranos made statements to reassure the public that its Scottsdale, 13 Arizona facility was "not impacted" by the CMS findings and Theranos remained "open 14 for business, confident in our technologies, and unwavering in our commitment to provide Arizonans with the care and service they deserve."⁶⁶ 15

16

144. On March 18, 2016, Theranos received another letter from CMS referenced,

17 "RE: PROPOSED SANCTIONS - CONDITIONS NOT MET IMMEDIATE

18 JEOPARDY," which stated that the Company had not remedied the deficiencies identified

19 by CMS in its January letter. Outlining Theranos's failures to meet quality-control

20 standards, such as improper freezer temperatures, lack of proper documentation, improper

- 21 equipment calibration, and unqualified personnel, CMS notified Theranos that it was out
- 22

⁶⁴ Andrew Pollack, *Report Shows Theranos Testing Plagued by Problems*, N.Y. Times (Mar. 31, 2015), available at http://www.nytimes.com/2016/04/01/business/report-shows-theranos-testing-plagued-by-problems.html?_r=0 (last visited Oct. 20, 2017).

⁶⁵ Department of Health and Human Services, Form FDA-483 (Inspection Report) (Sept. 16, 2015), available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-

26 orgs/documents/document/ucm469395.pdf (last visited Oct. 20, 2017).

⁶⁶ Geoff Weiss, Walgreens Pumps the Brakes on Theranos Partnership Amid Problematic Lab Audit, Entrepreneur (Jan. 28, 2016), available at

28 https://www.entrepreneur.com/article/270154 (last visited Jan. Oct. 20, 2017).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 47 of 132

of compliance with accepted clinical laboratory standards, still had not established 2 compliance with the CLIA requirements previously identified, and had not demonstrated 3 that the laboratory had "abated immediate jeopardy." Notice of Sanctions pursuant to the 4 Clinical Laboratory Improvement Amendments of 1988 (CLIA) was provided.⁶⁷

5 As these reports indicate, Theranos's laboratory operations in both 145. 6 Scottsdale and Newark were found to be deeply flawed and deficient by government 7 regulators. According to published reports, at Theranos's Scottsdale lab, the Company 8 performed lab tests with certain Siemens lab equipment programmed to the wrong 9 settings, and failed to adequately gauge the purity of the water input into Siemens lab 10 equipment, which could affect the outcome of the results of testing run on such devices.

11 The personnel in charge of operating Theranos's laboratories were 146. 12 dangerously underqualified. For example, the Director of Theranos's Newark laboratory 13 was Dr. Sunil Dhawan, a dermatologist who had no prior experience running a blood lab.

14 A peer-reviewed study published March 28, 2016 by researchers at the 147. 15 Icahn School of Medicine at Mount Sinai showed that results for cholesterol tests done by 16 Theranos differed enough from the two largest laboratory companies that it could 17 negatively impact patient care.

18 Regardless, Defendants continued to conceal this critical information, to 148. 19 falsely market Theranos testing services as accurate and reliable, and to encourage 20 consumers to use Theranos test results to make decisions about their health and treatment. 21 In April 2016, Theranos revealed that it was under investigation by the U.S. 149.

22 Department of Justice as well as the Securities and Exchange Commission, and that the 23 Department of Justice had requested documents. Walgreens and the New York State

24 25

26

1

⁶⁷ CMS, *Notice of Proposed Sanctions* (Mar. 18, 2016), available at

²⁷ http://www.wsj.com/public/resources/documents/hhslettertheranos.pdf (last visited Oct. 20, 2017). 28

Department of Health also received subpoenas. Investigators are also examining whether
 Theranos misled government officials.⁶⁸

150. On June 30, 2016, members of the House Energy and Commerce
Committee requested briefing from Theranos regarding Theranos's failure to comply with
federal regulatory standards governing clinical laboratory testing, and the resulting impact
on patients nationwide. The Committee expressed concern over "Theranos's disregard for
patient safety and its failure to immediately address concerns by federal regulators," and
requested "information about how company policies permitted systematic violations of
federal law."⁶⁹

10 151. On July 7, 2016, CMS issued a 33-page Notice to Theranos executives
stating that it was revoking the CLIA certificate of Theranos's Newark laboratory and
banning the owners and operator(s) of Theranos, including Holmes and Balwani, from
owning or running a lab for at least two years. Citing deficiencies in Theranos's training
of lab personnel, quality assurance, and procedures for assessing the "patient impact" of
its proficiency testing, among other shortcomings, CMS also threatened to impose a
monetary penalty of \$10,000 per day for each day of non-compliance.⁷⁰

17 152. As a result of revelations regarding problems with Theranos's technology
18 and laboratory standards, Theranos test results have lost all credibility within the medical
19 community. Dr. Geoffrey Baird, a pathology professor at the University of Washington,
20 reportedly said about Theranos: "I'm incredibly confused by what these people [at

21

⁷⁰ CMS, *Notice of Imposition of Sanctions* (July 7, 2016), available at http://online.wsj.com/public/resources/documents/r_Theranos_Inc_CMS_07-07-

28 2016_Letter.pdf (last visited Oct. 20, 2017).

 ⁶⁸ Christopher Weaver, John Carreyrou, and Michael Siconolfi, *Theranos Is Subject of Criminal Probe by U.S.*, Wall St. J. (Apr. 18, 2016) (Ex. 20).

 ⁶⁹ Press Release, Committee on Energy & Commerce Democrats, *Democratic Committee Leaders Request Information from FDA and CMS on Theranos' Inaccurate Blood Tests* (July 26, 2016), available at http://democrats-

 ^{25 (}July 20, 2010), available at http://democratisenergycommerce.house.gov/newsroom/press-releases/democratic-committee-leaders 26 request-information-from-fda-and-cms-on (last visited Oct. 20, 2017).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 49 of 132

Theranos] are doing. No lab is run like this."⁷¹ Tim Hamill, medical director of UC San
Francisco's clinical labs at China Basin and Parnassus reportedly stated: "The fact that
there are so many [deficiencies identified by CMS] gives me the impression that these
guys don't know what they're doing."⁷² Other doctors "stopped steering patients to
Theranos because of results they didn't trust."⁷³ In the words of one Forbes reporter, "If
there is working technology at Theranos . . . you wouldn't be able to tell."⁷⁴

7

8

9

153. In 2016, Theranos whistleblower Tyler Schultz stepped forward to provide a disturbing, detailed account of his experience as a Theranos employee. Mr. Schultz was reportedly the first to report Defendants' fraudulent conduct to state regulators.⁷⁵

10 154. Mr. Schultz was employed by Theranos as an assay validation team member
11 and was responsible for verifying and documenting the accuracy of tests run on Edison
12 devices before they were deployed in the lab for use with patients.

- 13 155. Mr. Schultz stated that he found the results varied widely when tests were
 14 rerun with the same blood samples. In order to reduce this variability, he states that
 15 Theranos routinely discarded outlying values from validation reports it compiled.
- 16 156. For example, one validation report about an Edison test to detect a sexually-

17 transmitted infectious disease said the test was sensitive enough to detect the disease 95%

18 of the time. But when Mr. Shultz looked at the two sets of experiments from which the

- 19 report was compiled, they showed sensitivities of 65% and 80%. Thus, if 100 people
- ⁷¹ Matthew Herper, Something May Be Working At Theranos, But You Don't Know What
 It Is, Forbes (June 17, 2016), available at
- http://www.forbes.com/sites/matthewherper/2016/06/17/something-may-be-working-attheranos-but-you-dont-know-what-it-is/#42ced77176a8 (last visited Oct. 20, 2017).
- ⁷² Nick Stockton, *Theranos's Lab Problems Go Way Deeper Than Its Secret Tech*, Wired (Apr. 27, 2016), available at https://www.wired.com/2016/04/theranos-lab-problems-go-way-deeper-secret-tech/ (last visited Oct. 20, 2017).
- ⁷³ *Hot Startup Has Struggled* (Ex. 3), *supra* n.5.

⁷⁴ Matthew Herper, *Something May Be Working At Theranos, But You Don't Know What It Is*, Forbes (June 17, 2016), available at http://www.forbes.com/sites/matthewherper/2016/06/17/something-may-be-working-at-

- theranos-but-you-dont-know-what-it-is/#42ced77176a8 (last visited Oct. 20, 2017).
- 28 ⁷⁵ Whistleblower Shook the Company (Ex. 9), supra n.31.

1	infected with the disease were tested only with the Edison device, as many as 35 of
2	them would likely incorrectly get a result concluding they were disease-free.
3	157. Mr. Schultz then moved to Theranos's production team, where he was
4	responsible for quantifying how much patient tests should be allowed to vary during daily

quality-control checks. Labs are permitted to set those parameters subject to them beingwithin the bounds of accepted industry guidelines.

7 158. Mr. Schultz observed that the Edison devices often failed Theranos's own
8 quality-control standards. Mr. Schultz further stated that Balwani, the No. 2 executive at
9 Theranos under Holmes, pressured lab employees to ignore the failures and run blood
10 tests on the devices anyway, contrary to accepted lab practices.

11 159. Mr. Schultz also states that he informed Holmes of his concerns in early12 2014.

13 Unsatisfied with the actions that Balwani and Holmes had taken. Mr. 160. 14 Schultz states that he anonymously emailed his complaint to New York officials who 15 administered a proficiency-testing program in which Theranos was enrolled. 16 161. In April 2014, Mr. Schultz again informed Holmes of the quality-control 17 failures. A few days later, Balwani responded to Mr. Schultz with the following email: 18 We saw your email to Elizabeth. Before I get into specifics, let me share with you that had this email come from anyone 19 else in the company, I would have already held them 20 accountable for the arrogant and patronizing tone and reckless comments.⁷⁶ 21 162. Mr. Schultz resigned from his position with Theranos shortly thereafter. 22 In a recent interview with Forbes magazine, Mr. Schultz summarized his 163. 23 experience with Theranos as follows: "everyone kind of knew that this thing didn't 24 actually live up to what we were claiming."⁷⁷ 25 ⁷⁶ Whistleblower Shook the Company (Ex. 9), supra n.31. 26 ⁷⁷ Ellie Kincaid, After Blowing The Whistle On Theranos, Tyler Shultz Is Going Back Into 27 Medical Testing, Forbes (Oct. 3, 2017), available at https://www.forbes.com/sites/elliekincaid/2017/10/03/after-blowing-the-whistle-on-28

1 164. On November 8, 2016, Walgreens filed a lawsuit against Theranos in
 2 federal court the District of Delaware, alleging that Theranos breached its contractual
 3 obligations by, *inter alia*, providing testing services to Walgreens customers that Theranos
 4 knew lacked accuracy or reliability, and by misrepresenting that its testing, including
 5 Edison, was ready-for-market, reliable and accurate and concealing that the opposite was
 6 true.⁷⁸

165. Partner Fund Management, which invested \$96.1 million in Theranos in
early 2014, filed a shareholder suit on October 10, 2016. The lawsuit names Holmes,
Balwani, and Theranos and alleges that the three engaged in securities fraud, negligent
misrepresentation and violations of the Delaware deceptive trade practices act, among
other things, including in particular by hiding, and misleading investors and others
regarding, the true state of the Edison technology.⁷⁹

13 166. On November 28, 2016, a second Theranos investor filed a putative class
14 action against Theranos, Holmes, and Balwani with similar allegations, including *inter*15 *alia*, that they concealed material information about reliability problems and concerns
16 with Theranos tests, and affirmatively misrepresented that the Edison technology was
17 ready-for-market and reliable.⁸⁰

18 167. In January 2017, it was reported that Theranos's Scottsdale, Arizona
19 laboratory, where the majority of (non-Edison) Theranos tests were conducted, had failed
20 a September 2016 inspection by CMS, thus subjecting Theranos to a new round of
21 potential sanctions. According to reports, Theranos responded to the inspection findings

22

Footnote continued from previous page

²⁵⁷⁹ Reed Abelson and Katie Benner, *Theranos Sued by Investor Who Accuses It of*

 ²³ Toomole commercions page
 24 theranos-tyler-shultz-is-going-back-into-diagnostic-testing/#7e33a054575a (last visited
 24 Oct. 20, 2017).

⁷⁸ Case No. 1:16-cv-01040-SLR (D. Del.), Amended Complaint, Dkt. 14.

Securities Fraud, N.Y. Times (Oct. 10, 2016), available at http://www.nytimes.com/2016/10/11/business/theranos-sued-by-investor-who-accuses-itof-securities-fraud.html (last visited Oct. 20, 2017).

^{28 &}lt;sup>80</sup> Case No. 5:16-cv-06822-NC (N.D. Cal.), Complaint, Dkt. 1.

with a plan to correct the deficiencies found, but CMS rejected the plan as deficient.⁸¹ 1 2 Defendants failed to disclose any of these developments.

3 168. In May 2016, as its scheme was collapsing, Theranos announced that it had 4 voided all blood tests conducted on its Edison device in 2014 and 2015 (which consisted 5 of tens of thousands of tests), and had belatedly "corrected" thousands of other test results 6 it had provided to consumers. In December 2016, Theranos further voided and/or 7 belatedly "corrected" numerous additional test results for tests conducted at its Scottsdale, 8 Arizona laboratory. Defendants have failed to provide adequate notice or disclosure 9 regarding the nature and extent of the tests it has already voided or belatedly "corrected," 10 leaving consumers in the dark. Based on the limited information disclosed, however, it is 11 apparent that a very substantial portion of the tests have already been voided or belatedly 12 "corrected." For example, the complaint in Walgreens' action against Theranos indicates 13 that the voided Edison-device "tests" represented some 10% or more of the overall blood 14 draws conducted at Walgreens stores. That does not include the thousands of others that 15 have been, and continue to be, voided and/or belatedly "corrected."

16

H. **Defendants Continue to Fail to Protect Customers**

17 Defendants' misrepresentations, omissions, and fraudulent conduct alleged 169. 18 herein persisted from before the tests were first offered to the public all the way through 19 the present.

20 Even after the highly damning CMS report became public in January 2016, 170. 21 Defendants still did not take immediate steps to protect the consumers who obtained 22 testing services from Theranos. Walgreens, for its part, failed to take immediate action 23 even at this stage and instead gave Theranos 30 days to resolve the critical issues CMS 24 identified at the Newark lab, and closed only a single Wellness Center. Not only did 25 Walgreens permit the remaining 40 Wellness Centers to remain open at that time, it made 26 no effort to notify prospective patients about potential concerns about the reliability of 27 ⁸¹ Christopher Weaver and John Carreyrou, Second Theranos Lab Failed U.S. Inspection, Wall St. J. (Jan. 17, 2017) (Ex. 21). 28

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 53 of 132

Theranos's testing, or that the Edison "tiny" blood "tests" were not truly for testing
 purposes. Nor did Walgreens notify patients who had previously received Theranos's
 tests at the Wellness Centers that their test results may not have been accurate or reliable.

4

5

6

7

171. Because it had no choice due to regulatory action, Theranos has now completely voided and belatedly "corrected" many thousands of its tests results. In many cases, it took months (or even a year or more) to inform customers and their doctors that the test results should not be relied on.

8 172. The belated "correction" of test results, long after Theranos and Walgreens
9 even had access to the blood samples in question, is inconsistent with industry standards.
10 The Wall Street Journal reported on Theranos sending so-called "corrected results" to
11 some patients. Disturbingly, in some instances, the "corrected" results were even more
12 inaccurate than the initial inaccurate and unreliable results Theranos provided.⁸²

13 173. Even beyond the many thousands of tests that have already been completely
14 voided and belatedly "corrected," no consumer who had a Theranos test could reasonably
15 rely on the results they received given the sweeping litany of compliance issues and the
16 extensive list of other accuracy and reliability problems that have come to light, a list that
17 seems to be expanding even after these lawsuits were filed.

18 174. Defendants have failed to keep customers informed and notified, including 19 but not limited to by: failing to inform customers about the numerous problems when 20 Defendants were aware of them; failing to inform "tiny" blood draw subjects that the true 21 purpose of their blood draws was not legitimate blood testing and concealing the true 22 purposes; pervasively misrepresenting that Theranos tests could and should be trusted 23 when they knew that was not the case; and failing to promptly and properly notify 24 customers about voided and belatedly "corrected" tests results. Even after their scheme 25 began collapsing under its own weight, Theranos, Walgreens, Holmes, and Balwani

26

²⁷⁸² Christopher Weaver, *Agony, Alarm and Anger for People Hurt by Theranos's Botched*⁸⁰ Blood Tests, Wall St. J. (Oct. 20, 2016) (Ex. 22).

1 continued to engage in a pattern of denying and downplaying the problems, further 2 leaving customers in the dark.

3 175. It was not until June 14, 2016, almost six months after CMS's report first 4 became public, and years after Walgreens, Theranos, Balwani, and Holmes were aware of 5 reliability problems across the Theranos testing spectrum, that Walgreens announced it was ending its relationship with Theranos.⁸³ Days later, Theranos sent letters to providers 6 7 encouraging them to direct patients to one of the Theranos-operated Wellness Centers. The letters assured providers that Theranos was "open for business, confident in our 8 9 technologies, and steadfast in our commitment to make lab tests fast, convenient, and 10 affordable for everyone." (emphasis in original). The letters did not disclose, among other 11 things, CMS's sanctions, that Edison was not market-ready when the "tiny" blood draws 12 had been conducted and that Theranos and Walgreens had discontinued using the Edison 13 device and finger prick draws due to scrutiny by regulators of the unready technology, the 14 numerous other problems identified with both the Newark and Scottsdale testing facilities, 15 that it had voided all Edison tests performed, as well as other tests, or that the tests were 16 unreliable. To the contrary, Theranos continued to suggest that its tests were accurate and 17 reliable. In the provider letters, Theranos also directed providers and their patients to 18 Theranos's website, which also concealed the material information omitted from the 19 provider letters. 20 On July 19, 2016, Theranos issued a statement on the CMS findings that 176.

21 included further misleading statements and falsehoods:

ensures:

22 Q: What practices do you undertake to ensure that your test results are accurate? 23 What processes do you use to ensure compliance and quality results? 24 A: We undertake quality and compliance measures including the following that

25

26

Our laboratory leadership, including our lab director and testing 0

27 ⁸³ Michael Siconolfi, Christopher Weaver, and John Carreyrou, *Walgreen Terminates* Partnership with Blood-Testing Firm Theranos, Wall St. J. (June 13, 2016) (Ex. 23). 28

personnel, are highly qualified and well trained

- Processes are properly reviewed and maintained
- Quality control and quality assessment programs are followed
- Lab processes, including assay verification, calibration, equipment maintenance and environmental controls, are followed⁸⁴

6 177. Given, *inter alia*, the lack of transparency and outright fraud from the
7 Defendants, the fundamental and sweeping nature of the numerous deficiencies that have
8 been identified regarding Theranos testing, and the fact that both the list of serious
9 deficiencies made public and the list of tests that have been voided and belatedly
10 "corrected" have continued to expand with no apparent end in sight, the only reasonable
11 conclusion for any Plaintiff or Class member here to reach is that they cannot and should
12 not be relying on the results of their Theranos tests.

13 Theranos has apparently not learned its lesson, despite endangering the 178. 14 health and lives of thousands of patients. CMS banned Holmes and Balwani from owning 15 or operating a blood-testing business for at least two years and revoked Theranos's license to operate a lab in California.⁸⁵ Yet Theranos and Holmes, apparently undeterred, are 16 17 now working on developing a "miniLab" to run diagnostic tests on small amounts of 18 blood. One doctor, after watching Holmes's presentation at the annual meeting of the 19 American Association for Clinical Chemistry, noted that it was not clear how the Edison 20 and miniLab differed, and that Holmes had not actually shown that the device could perform a large number of tests on a single drop of blood.⁸⁶ Theranos's deception and 21

22

1

2

3

4

5

⁸⁴ Press Release, Theranos, Inc., *Theranos Statement and Q&A on CMS Findings* (July 19, 2016) (Ex. 24).

⁸⁵ John Carreyrou, Michael Siconolfi, and Christopher Weaver, *Theranos Dealt Sharp Blow as Elizabeth Holmes is Banned From Operating Labs*, Wall St. J. (July 8, 2016) (Ex.
25).

^{27 &}lt;sup>86</sup> Abigail Tracy, *The Medical Community Isn't Letting Theranos Off the Hook*, Vanity Fair (Aug. 4, 2016), available at http://www.vanityfair.com/news/2016/08/theranos-

²⁸ interview-what-went-wrong (last visited Oct. 20, 2017).

secrecy continues; the miniLab has not been evaluated by a third party and lacks FDA
 approval.

3

4

5

6

7

I.

The Members of the Edison Subclass Were Subjected to Battery

179. The tens of thousands of members of the Edison Subclass, as defined herein, including Plaintiffs B.P., R.C., and S.J., were all subject to one or more so-called "tiny" blood draws. For all of these "tiny" blood draws, a needle was stuck into the subject's finger, penetrating their skin and tissue, and blood was drawn from their body.

8 180. The vast majority of these "tiny" blood draws were administered at
9 Walgreens stores, with a small portion administered at Theranos Wellness Centers.

10 181. For the "tiny" blood draws that were conducted at Walgreens stores, 11 Plaintiffs allege—including based on the MSA between Theranos and Walgreens, which 12 expressly provides that Walgreens Technicians would "draw blood using the finger stick 13 technique," the fact that the draws were conducted by personnel working in a Walgreens 14 store, and based on Plaintiffs' experiences—these blood draws were administered by a 15 Walgreens employee or an individual working for both Walgreens and Theranos, often 16 with the assistance and in the presence of a Theranos employee. In all such cases, *both* 17 Walgreens *and* Theranos did acts that resulted in the blood draws and that encouraged the 18 blood draws—including, but not limited to, through their pervasive marketing of same, 19 through their provision of the space, infrastructure, personnel, and equipment used for 20 same, and through their direct assistance and involvement with the blood draws and in-21 store interactions with the subjects. Both Defendants, including through their respective 22 employees, caused these touchings.

182. For the "tiny" blood draws that were conducted at Theranos Wellness
Centers, Plaintiffs allege—including based on the fact that the draws were conducted by
personnel working at a Theranos facility—the blood draws were administered by a
Theranos employee.

- 27
- 28

1 183. The subjects submitted to the "tiny" blood draws under false pretenses, and
 2 the touchings that resulted were physically harmful, an affront to their human dignity, and
 3 would be viewed by a reasonable person as offensive under the true circumstances.

J

4 184. Walgreens and Theranos intentionally misled Plaintiff B.P., R.C., and S.J.,
5 and the Edison Subclass about the essential nature and purpose of the blood draws to
6 which they submitted. In permitting Walgreens and Theranos to engage in the procedure
7 of drawing blood from their bodies, Plaintiffs B.P., R.C., and S.J., and the Edison
8 Subclass were mistaken and misinformed about the essential nature and purpose of such
9 procedure and thus they did not provide, and could not have provided, consent for such
10 procedure and intrusion.

11 While not disclosed to consumers, the medical field, or otherwise, the 185. 12 Edison technology was still in development and not ready-for-market throughout the time 13 the "tiny" blood tests were offered. By testing their services on many thousands of 14 unwitting customers who thought they were purchasing a ready-for-market service, 15 Theranos and Walgreens intended to develop their product so that it might compete with 16 more established laboratories. In essence, though not disclosed to consumers and indeed 17 represented very differently, Defendants' Wellness Centers, at least throughout the time 18 the "tiny" blood draws were being conducted, were used to gather blood samples and 19 other data for use in Defendants' research and product development.

186. Theranos and Walgreens concealed from consumers that Edison was still indevelopment and not ready-for-market, and in fact affirmatively misled them to believe
such services were ready-for-market and that the corresponding "test results" could and
should be relied upon in making health and treatment decisions, as alleged herein.
Theranos and Walgreens misrepresented and falsely portrayed the purpose of these blood
draws and did not disclose to Plaintiffs B.P., R.C., and S.J., and the Edison Subclass that

the purpose of the blood draws to which they were submitting was for Defendants' use in
research and product development.

28

- 1 187. Plaintiffs B.P., R.C., and S.J. and the other members of the Edison Subclass 2 reasonably believed, when they agreed to submit to their "tiny" blood draws, that the 3 essential nature and purpose of such blood draws was legitimate blood testing.
- 4

In fact, the essential nature and purpose of their "tiny" blood draws was not 188. 5 legitimate blood testing and, indeed, could not have been legitimate blood testing given 6 that, as alleged herein and unbeknownst to the subjects at the time they agreed to submit to the draws, the Edison "tiny" technology was still in development, still in prototype, not 7 8 ready-for-market, and nowhere near in a position to serve the purpose of legitimate blood 9 testing. Theranos, Walgreens, Balwani, and Holmes each knew this to be the case 10 throughout the entire time "tiny" blood draws were being administered at Walgreens 11 stores and Theranos Wellness Centers. To the extent Walgreens lacked any more detailed 12 knowledge, it was by virtue of its own deliberate choices to ignore and/or avoid such 13 details.

14 189. Simply put, the "tiny" blood draws were not intended by Walgreens and 15 Theranos to serve the purpose, and could not have served the purpose of, providing 16 reliable blood testing results (i.e., "legitimate blood testing").

17 190. Unbeknownst to the Edison Subclass members, the essential nature and 18 purposes of the "tiny" blood draws were: to help research and development of the as-yet-19 undeveloped Edison technology that both Theranos and Walgreens had an interest in; to 20 expedite and advance the narrative that the "disruptive" Edison technology had 21 "revolutionized" the medical testing industry; and to woo and placate investors, potential 22 investors, and co-investors by giving the (false) impression that they had a market-ready, breakthrough technology and service.⁸⁷ 23

24 Theranos, Walgreens, Balwani, and Holmes each knew contemporaneously 191. 25 that Plaintiffs B.P., R.C., and S.J. and the other members of the Edison Subclass were 26 operating under a substantial mistaken belief regarding the essential nature and purpose of

27

28

⁸⁷ Discovery in this case may reveal other undisclosed purposes of the "tiny" blood draws.

1 the "tiny" blood draws when they agreed to submit to them, and that any consent the 2 subjects provided was made pursuant to that mistaken belief.

3

192. Theranos's and Walgreens' concealments and affirmative 4 misrepresentations substantially contributed to the Edison Subclass members' mistaken 5 belief about the essential nature and purpose of their "tiny" blood draws. As alleged 6 herein, both companies each concealed substantial, material information from the subjects, 7 their medical providers, and the public regarding the true state and readiness of the Edison 8 technology and the "tiny" blood testing, including that Edison was still in development 9 and not ready-for-market. See, e.g., ¶¶ 65-78. Moreover, both Theranos and Walgreens 10 knowingly and pervasively made affirmative misrepresentations—including through a 11 broad marketing campaign—clearly portraying the "tiny" blood technology as market-12 ready and the "tiny" blood draws consumers were encouraged to submit to as being for 13 legitimate and reliable blood testing. Indeed, that was the entire fundamental premise of 14 Defendants' advertising campaign regarding the services. That was the only purpose 15 suggested for these blood draws, and there was no indication at all, in any of this 16 marketing or elsewhere, that the Edison technology was not market-ready and could not 17 actually serve the purpose of legitimate blood testing. See, e.g., ¶¶ 80-119.

18 193. Moreover, the very context, nature, design, and infrastructure of the 19 Walgreens and Theranos Wellness Centers in which the "tiny" blood draws were 20 conducted, were intended by Theranos and Walgreens—both of which designed and set 21 up the Wellness Centers in the Walgreens facilities—to give the clear impression, and did 22 give the clear impression, to consumers that all of the blood draws being conducted there 23 were for legitimate blood testing purposes. Again, there was no indication anywhere that 24 the Edison technology was not market-ready and was not intended by Theranos and 25 Walgreens to, and could not actually, serve the purpose of providing reliable blood test results, or that there was some different purpose for the "tiny" blood draws besides 26 27 legitimate blood testing. To the contrary, in addition to the media marketing, the testing 28 order forms, signage, and other disclosures and materials in the Wellness Centers all

clearly reinforced to consumers that the blood draws conducted therein, including the
 "tiny" blood draws, were about legitimate blood testing.

194. The very notion of offering the "tiny" blood "tests" in the market created
and reinforced the belief that these tests were market-ready. The fact that the vast
majority of these "tiny" blood draws occurred in a Walgreens pharmacy, further
reinforced to the subjects that the services were market-ready and the purpose was
legitimate blood testing and not product development, "keeping up appearances" for
investors and co-investors, or some other undisclosed purpose, given Walgreens'
prominence and the nature of its business.

10 195. Though Walgreens and Theranos, and their personnel present in the store,
11 knew the "tiny" blood draw subjects reasonably believed the purpose was legitimate blood
12 testing, by design and as a matter of policy and practice they said nothing to correct that
13 mistaken belief and, to the contrary, reinforced that belief as alleged herein.

14 196. Plaintiffs B.P., R.C., and S.J., and the Edison Subclass would not have
15 agreed to submit to the "tiny" blood draws had they known they were not, in fact, for
16 legitimate blood testing purposes.

17 197. In furtherance of this scheme by Defendants, Theranos also provided the
"tiny" blood draw subjects with reports that took the form of test results. However, these
reports were not, in fact, legitimate test results that could be relied upon, but rather were
used to perpetuated the false impression and belief—among the subjects, potential
subjects, investors, and the public—that these "tiny" blood draws were about legitimate
blood testing. Every single one of the Edison test results has been voided.

198. By procuring "tiny" blood samples from thousands of unwitting consumers,
who mistakenly thought they were submitting to the draws for legitimate testing purposes,
Theranos and Walgreens intended to use these samples to help try to develop (or "coproduce" to use Walgreens' term) the Edison technology which had been in development
for years and, to the Defendants' frustration, was still not ready. Both Theranos and

28

1 Walgreens hoped that, someday, the Edison technology might allow them to compete with 2 more established laboratories.

3 199. Offering "tiny" blood tests to the general public enabled Theranos and 4 Walgreens to collect "tiny" blood samples from human subjects without sacrificing the 5 time and money necessary to recruit and pay volunteers for formal clinical trials. Indeed, 6 by procuring thousands of "tiny" blood samples in this manner, they were able to avoid 7 the costs associated with alternative methods for obtaining blood samples for research, 8 such as to purchase the samples (which would be provided without personal identifying 9 information about the subject) from facilities that have obtained research approval from 10 ethical review boards. On information and belief, because most samples available for 11 research are collected through venous draws, samples taken with a finger-stick method 12 (the type most important to the development of Edison) were particularly costly and 13 difficult to obtain. By disguising their product development and research agenda and 14 activity as a legitimate, ready-for-market testing service, Theranos and Walgreens not 15 only were able to avoid these costs, but were actually able to get thousands of unwitting 16 *consumers to pay them* for the "tiny" blood draws.

17

200. The Wellness Center pretense also helped Theranos evade regulatory 18 scrutiny and in particular the additional regulatory scrutiny that accompanies human 19 testing, such as the requirement to obtain approval for such research by an Institutional 20 Review Board (IRB) in order to protect patient safety.

21 22

201. Theranos's disregard for IRB standards and patient safety is wellestablished. For example, in 2016 it was revealed that Theranos had conducted a study on a blood test for the Zika virus using data that was collected from human test subjects without any IRB approval.⁸⁸

25

26

23

24

⁸⁸ Carolyn Y. Johnson, *Theranos withdraws Zika test after regulators flag problems*, L.A. 27 Times (Aug. 31, 2016), available at http://www.latimes.com/business/la-fi-theranos-zika-20160831-snap-story.html (last visited Oct. 20, 2017). 28

1 202. According to reports, Holmes has claimed that Theranos possesses "data 2 that show you can get a perfect correlation between a finger stick and a venipuncture for every test that we run."⁸⁹ Theranos has refused to identify publically how these 3 4 comparison test results were obtained, except to say that "[t]he clinical tests were conducted by a combination of Theranos and external labs."⁹⁰ The fact that Theranos has 5 6 belatedly "corrected" test results several months (and even years) after taking customers' 7 blood samples indicates that customers' blood samples, submitted at Wellness Centers, 8 were likely used in generating that data.

9 There is additional evidence that Theranos and Walgreens were using these 203. 10 blood draws for research and development purposes. For example, in the case of Plaintiff 11 B.P., Walgreens and Theranos sometimes took blood using *both* finger stick and 12 traditional methods, and sometimes used only one method or the other—for the same panel of tests. On information and belief, Walgreens and Theranos took multiple samples 13 14 in different ways to facilitate analysis of the results obtained by Theranos technology 15 using a variety of sample types, to generate more data correlating the results of finger 16 stick tests and venous draws, and thereby further efforts to develop Edison.

17 204. Relatedly, Theranos used these blood draws to collect and analyze highly 18 confidential health data about large numbers of people. Like other Silicon Valley 19 companies that collect and analyze "big data," Theranos recognized that sufficiently 20 numerous blood samples, if combined with biographical and other information, could 21 reveal patterns that could help Theranos to develop lucrative products. On information 22 and belief, data analysis at Theranos was overseen by Balwani who reportedly said about 23 his decision to join the Company: "When I saw what they were doing at Theranos, [] I thought this will be a really good application for machine learning,⁹¹ because we are going 24 25

- ⁵⁸⁹ Ken Auletta, *Blood, Simpler, supra* n.6.
- $26 \int 90 Id.$

⁹¹ Machine learning is a branch of artificial intelligence through which machines, such as laboratory testing equipment, are exposed to enormous data sets and use statistical analysis and predictive analytics to draw inferences, identify patterns, and generate

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 63 of 132

to generate a lot of data, and we'll be able to do some interesting work around that."⁹² On
information and belief, the most direct way for Theranos to obtain a data set sufficiently
large to support a machine learning application was to convince, by deception, many
thousands of people to submit to blood draws and provide blood samples and other
valuable personal information.

205. According to the Wall Street Journal, when a Theranos employee emailed
Holmes in April 2014 to voice his concerns about quality control failures at Theranos, she
forwarded the internal inquiry to Balwani, who—contrary to his representations to
Arizona's Senate Health and Human Services Committee just weeks before—responded
to the employee that the failures were due to the "newness of some of our processes,
which we are improving every day." "This is product development," he continued, "this
is how startups are built."⁹³

13 Theranos and Walgreens also prematurely rushed Edison and the "tiny" 206. 14 blood draws to market in order to create the public misimpression that Edison was a 15 market-ready technology. Frustrated by the slow progress in developing Edison and the corresponding inability to capitalize on the unready technology, Theranos and Walgreens 16 17 prematurely rushed Edison to market in order to expedite the narrative of Edison as 18 "disrupting" the market and to thereby try to improve their chances of capitalizing upon 19 the market for medical laboratory testing, a highly competitive and fast-growing market estimated to be worth \$198.5 billion by 2024.⁹⁴ They also hoped it would woo and 20

21

Footnote continued from previous page

22 predictions.

 ⁹² Roger Parloff, *Theranos Resignation Is a Major Bid for Atonement*, Fortune (May 12, 2016), available at http://fortune.com/2016/05/12/presidents-departure-atonement/ (last visited Oct. 20, 2017).

^{25 &}lt;sup>93</sup> John Carreyrou, *At Theranos, Many Strategies and Snags*, Wall St. J. (Dec. 27, 2015) (Ex. 26).

 ⁹⁴ Press Release, Grand View Research, Inc., *Clinical Laboratory Tests Market Size* Worth USD 198.5 Billion by 2024 (Dec. 2016), available at

worm CSD 190.5 Bittion by 2024 (Dec. 2010), available at
 https://www.grandviewresearch.com/press-release/global-clinical-laboratory-tests-market
 (last visited Oct. 20, 2017).

1 appease investors, potential investors, and co-investors, to whom they urgently wanted to 2 demonstrate they had a working, viable breakthrough technology.

3 207. In summary, any consent provided by Plaintiffs B.P., R.C., and S.J. and the 4 other Edison Subclass members, to have their blood drawn pursuant to the "tiny" blood 5 draws, was obtained under false pretenses. They agreed to submit to these blood draws 6 operating under a substantial mistake (which Theranos and Walgreens had 7 contemporaneous knowledge of) regarding the essential nature and purpose of these blood 8 draws, and their consent was obtained through fraud, concealment, and substantial 9 misrepresentation by Theranos and Walgreens, as alleged herein. Unbeknownst to them, 10 they were essentially used as human guinea pigs for beta testing and Defendants' product 11 development efforts and as pawns to promote the public impression that Defendants had a 12 working, ready technology. None of the Edison Subclass members knew or could have 13 known the truth. Had they known the truth they would not have consented to the "tiny" 14 blood draws. Any consent they provided for the "tiny" blood draws is vitiated and not 15 effective.

16

J.

Defendants' Misconduct Has Significantly Harmed Consumers

17 208. As a direct result of Defendants' misconduct alleged herein, Plaintiffs and 18 the other consumers who comprise the proposed Class and Subclasses in this case have 19 been harmed in numerous respects, including but not limited to: (a) paying—out-of-20 pocket, through health insurance, or through another collateral source—for Theranos tests 21 that they cannot reasonably rely upon, that unknown to them were experimental in nature, 22 and that in some cases have already been voided or belatedly "corrected"; (b) paying for 23 subsequent replacement testing services from other companies; (c) paying additional 24 money to doctors or other health professionals as a result of the inaccurate and unreliable 25 Theranos tests; (d) being subject to unnecessary or potentially harmful treatments, and/or 26 being denied the opportunity to seek treatment for a treatable condition; (e) harm to their 27 health, injury, and/or death, and corresponding monetary and other damages; (f) invasion 28 of privacy and bodily integrity without their consent, and corresponding damages

1 therefrom; (g) violation of their human dignity for the Edison Subclass members and the 2 corresponding damages therefrom; and (h) severe emotional stress and anxiety.

3

209. Defendants have all benefited, financially and otherwise, from their 4 misconduct alleged herein, including but not limited to from revenue that all of the 5 Defendants have received for Plaintiffs' and the Class members' tests, from the 6 development of their products through research Plaintiffs and the Class members were 7 unwittingly being used for, and additional business that Walgreens has generated as a 8 result of having the Wellness Centers in its retail stores. Theranos and Walgreens shared 9 the revenues received associated with the testing services at the Walgreens facilities. On 10 information and belief, Holmes and Balwani, respectively, have each personally received 11 millions of dollars as a direct result of their misconduct alleged herein.

12 13

K. **Factual Allegations Regarding Plaintiffs**

Plaintiff A.R.

14 210. On or around June 19, 2015, Plaintiff A.R. purchased Theranos blood tests 15 at a Walgreens Pharmacy in Palo Alto, California. His blood was drawn at this Walgreens 16 store. The tests that he purchased included tests regarding protein, blood sugar, 17 cholesterol, and vitamin levels. A.R. purchased Theranos tests to get accurate and reliable 18 results about his health. He trusted Theranos and Walgreens to provide accurate and 19 reliable test results.

20 A.R. had received orders from his medical care provider to have blood 211. 21 testing performed. A.R. was referred to Theranos by his medical care provider. In 22 choosing to have his blood tested by Theranos, he relied on marketing by Theranos and 23 Walgreens regarding the reliability of their services, including, he specifically recalls, 24 leaflets that he had seen in the Walgreens store before having his blood drawn. He also 25 expected tests conducted at Walgreens to be trustworthy and reliable.

26

A.R. paid approximately \$41.79 out of pocket for the Theranos tests. 212.

27 When he purchased Theranos tests, one or more vials of blood were drawn 213. 28 from a vein in A.R.'s arm. A.R. did not know that Defendants drew his blood for the

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 66 of 132

purpose of research and product development and he did not consent to such procedure for
 such purpose. He believed that the purpose of the blood draws he submitted to was
 legitimate blood testing.

4 214. A.R. believed that Defendants' services were ready-for-market and reliable.
5 He had no contemporaneous knowledge about the unreliability and litany of problems
6 with Theranos testing, facilities, and equipment, alleged herein. He relied on the
7 Defendants' omissions in this respect. Had he known of this concealed information, he
8 would not have submitted to this testing.

9 215. Having been led to believe the Theranos results were reliable, A.R. relied on
10 them, using the results to make decisions concerning his health.

216. Approximately one year before having his blood tested by Theranos, A.R.
had his blood tested by another company, and the results showed that A.R.'s blood
contained a normal level of Vitamin D. His Theranos tests indicated that his Vitamin D
levels were low, his blood sugar was high, and his LDL (cholesterol) level was high, and
medication was prescribed for him as a result. The medication that A.R.'s doctor
prescribed to supplement his Vitamin D levels caused excess absorption and buildup of
calcium in A.R.'s blood, and caused pain and other adverse effects to A.R.

18

217. The Theranos tests that A.R. purchased were unreliable and/or inaccurate.

19 218. After learning that his Theranos tests were unreliable and/or inaccurate, he
20 revisited his doctor, and had his blood tested by another company. The results reflected
21 that he is healthier than the Theranos tests had indicated.

219. Plaintiff A.R. would not have purchased any Theranos tests if he had known
that the Theranos testing facilities were not as described, and that Theranos's tests were
inaccurate or unreliable. Plaintiff A.R. would not have submitted to Theranos tests if he
had known that Walgreens and Theranos were using his blood tests for research and
product development.

27 220. Plaintiff A.R. was injured, damaged and harmed by Defendants'
28 misconduct.

221. Plaintiff A.R. suffered damages as a result of Defendants' conduct, in an
 amount to be proven at trial.

3 222. In addition to the other harm described herein, Plaintiff A.R. suffered
4 emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he
5 purchased and the invasion of his body under false pretenses and without his consent.

6 223. Any purported consent by A.R. to have his blood drawn by Defendants was
7 induced by fraud, concealment and misrepresentation, and was not effective.

8

Plaintiff B.B.

9 224. On or around October 3, 2014, Plaintiff B.B. purchased eight Theranos
10 blood tests at a Walgreens Pharmacy in Gilbert, Arizona. Her blood was drawn at a
11 Walgreens store. The tests that she purchased included tests regarding her thyroid. B.B.
12 purchased Theranos tests to get accurate and reliable results about her health. She trusted
13 Theranos and Walgreens to provide accurate and reliable test results.

14 B.B. had received orders from her medical care provider to have blood 225. 15 testing performed. B.B. was informed by her medical care provider that Theranos was the 16 least invasive alternative for blood testing, and also that Theranos tests were cheaper and 17 that the Walgreens locations provided extended hours for her to get tested. In choosing to 18 have her blood tested by Theranos, she relied on marketing by Theranos and Walgreens 19 regarding the reliability of their services, including, she specifically recalls, on the 20 Theranos and Walgreens websites and press releases which she read before visiting the 21 Walgreens store. B.B. specifically recalls visiting and viewing Walgreens advertisements 22 and representations on both companies' websites in or around early October 2014. She 23 also expected tests conducted at Walgreens to be trustworthy and reliable.

24

226. B.B. paid approximately \$81.04 out of pocket for the Theranos tests.

25 227. When she purchased Theranos tests, one or more vials of blood were drawn
26 from a vein in B.B.'s arm. B.B did not know that Defendants drew her blood for the
27 purpose of research and product development and she did not consent to such procedure
28 for such purpose.

1	228. B.B. believed that Defendants' services were ready-for-market and reliable.		
2	She had no contemporaneous knowledge about the unreliability and litany of problems		
3	with Theranos testing, facilities, and equipment, alleged herein. She relied on the		
4	Defendants' omissions in this respect. Had she known of this concealed information, she		
5	would not have submitted to this testing.		
6	229. On information and belief, B.B.'s tests were conducted at Theranos's		
7	Newark, California facility.		
8	230. Having been led to believe the results were reliable, B.B. relied on them,		
9	using the results to make decisions concerning her health.		
10	231. The Theranos tests that B.B. purchased were unreliable and/or inaccurate.		
11	232. After learning that her Theranos tests were unreliable and/or inaccurate, she		
12	had her blood retested multiple times by another company.		
13	233. Plaintiff B.B. would not have purchased any Theranos test if she had known		
14	that the Theranos testing facilities were not as described, and that Theranos's tests were		
15	inaccurate or unreliable. Plaintiff B.B. would not have submitted to Theranos tests if she		
16	had known that Walgreens and Theranos were using her blood tests for research and		
17	product development.		
18	234. Plaintiff B.B. was injured, damaged and harmed by Defendants'		
19	misconduct.		
20	235. Plaintiff B.B. suffered damages as a result of Defendants' conduct, in an		
21	amount to be proven at trial.		
22	236. In addition to the other harm described herein, Plaintiff B.B. suffered		
23	emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests she		
24	purchased and the invasion of her body under false pretenses and without her consent.		
25	237. Any purported consent by B.B. to have her blood drawn by Defendants was		
26	induced by fraud, concealment and misrepresentation, and was not effective.		
27			
28			

Plaintiff B.P.

2 238. Beginning approximately in early 2014, Plaintiff B.P. purchased Theranos
3 blood tests several times at a Walgreens Pharmacy in Ahwatukee Village, Phoenix,
4 Arizona. In all of these instances, he had his blood drawn at this Walgreens store. The
5 tests that he purchased included tests regarding diabetes and cholesterol. B.P. purchased
6 Theranos tests to get accurate and reliable results about his health. He trusted Theranos
7 and Walgreens to provide accurate and reliable test results.

239. B.P. had received orders from his medical care provider to have blood 8 testing performed. B.P. was informed by his physician that Theranos was the cheapest 9 and least invasive alternative for the tests. In choosing to have his blood tested by 10 Theranos, he relied on marketing by Theranos and Walgreens regarding the nature and 11 reliability of their services, including, he specifically recalls, materials that he saw at the 12 Walgreens store before getting his blood drawn which portrayed and gave the clear 13 impression that the services being advertised were ready, reliable, and for legitimate 14 testing purposes. He also expected tests conducted at Walgreens to be trustworthy and 15 reliable. 16

17

1

240. B.P. paid hundreds of dollars out of pocket for the Theranos tests.

241. The first several times that B.P. had his blood drawn at the Walgreens store, 18 it was exclusively via "tiny" blood draws (between one and three "tiny" blood draws were 19 taken per visit). In each case, a needle was stuck into his finger, penetrating his skin and 20 tissue, and blood was drawn from his body. In each case, the blood draws were 21 22 administered by an individual who B.P. understood to be and who B.P. alleges to be a Walgreens employee, who worked at the Walgreens store, approached B.P. from behind 23 the Walgreens pharmacy counter and was wearing a Walgreens smock. In each case, a 24 second individual, who B.P. understood to be and who B.P. alleges to be a Theranos 25 employee, was also present at, and assisted with and observed, the blood draws. 26

27 242. Starting in or around mid-2015 and through around late 2015, each time he
28 visited the Walgreens store for these services, he was subject to both "tiny" blood draws

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 70 of 132

1 and to larger blood draws whereby one or more larger vials of blood were drawn from a 2 vein in B.P.'s arm. For each "tiny" blood draw, a needle was stuck into his finger, 3 penetrating his skin and tissue, and blood was drawn from his body. During this time, 4 except perhaps as noted below, the "tiny" blood draws were again administered by an 5 individual who B.P. understood to be and who B.P. alleges to be a Walgreens employee, 6 and the venous blood draws were administered by an individual who B.P. understood to 7 be a Theranos employee. For the "tiny" blood draws, again an individual who B.P. 8 understood to be and who B.P. alleges to be a Theranos employee was also present at, and 9 assisted with and observed, the blood draws. On one occasion during this period, B.P. 10 recalls that one "tiny" blood draw was administered by an individual who was working at 11 the Walgreens store, and who identified himself as being affiliated with Theranos testing. 12 Plaintiff B.P. alleges that this individual was a Walgreens employee or worked for both 13 Walgreens and Theranos.

14 243. Starting in around early 2016 and through the last time he had his blood
15 drawn at the Walgreens store, B.P.'s blood draws were only via venous blood draws. In
16 each case, these venous blood draws were performed by an individual B.P. understood to
17 be a Theranos employee.

18 244. Throughout his visits to the Walgreens store, and throughout the process of
19 preparing for and having his blood drawn, he was consistently led to believe that the blood
20 draws were for legitimate blood testing purposes. No suggestion was made to the
21 contrary.

22 245. When B.P. agreed to submit to the "tiny" blood draws (and to the venous
23 blood draws), he understood and believed that the purpose of the blood draws was
24 legitimate blood testing. His consent to these draws was based on this belief. This belief
25 was based on, among other things, marketing from Walgreens and Theranos that he saw
26 before getting his blood drawn, including, he specifically recalls, at the Walgreens store,
27 which clearly portrayed and gave the impression that the services were market-ready and
28 reliable, and the blood draws he was submitting to as being for legitimate testing

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 71 of 132

1 purposes. This belief was also based on the design and nature of, and the infrastructure 2 and signage at, the Wellness Centers where his blood draws were conducted, which gave 3 the definitive, if not obvious, impression that the purpose of the blood draws he was 4 submitting to was legitimate blood testing. The fact that these services were being offered 5 at a Walgreens store, given its prominence and the nature of its business as a pharmacy, 6 reinforced his belief that the service was market-ready and for legitimate testing purposes. 7 He was also told by an individual he believed to be a Walgreens or Theranos employee, 8 during one or more of these visits and before his blood was drawn, that they would only 9 take the amount of blood necessary to run the tests necessary, unlike other blood testing 10 laboratories, which the representative said took far more blood than they required for the 11 tests.

246. As alleged herein, the essential nature and purpose of the "tiny" blood draws
B.P. submitted to was not legitimate blood testing, and indeed could not have been given
the decidedly unready state of Edison. B.P. agreed to submit to the "tiny" blood draws
under false pretenses and under a substantial mistaken belief as to the essential nature and
purpose of the draws.

17 247. B.P. had no contemporaneous knowledge that the Edison technology was
18 still in-development, not market-ready, and not in a position to serve the purpose of blood
19 testing, nor did he have contemporaneous knowledge that the "tiny" blood draws he was
20 submitting to had a nature or purpose other than legitimate blood testing. This
21 information was concealed from him and he relied on Defendants' omissions in this
22 respect. Had he known the truth, he would not have consented to "tiny" blood draws.

23 248. B.P. did not know that Defendants drew his blood for the purpose of
24 research and product development and he did not consent to such procedure for such
25 purpose. He believed that the purpose of all of the blood draws he submitted to was
26 legitimate blood testing.

27 249. B.P. believed that all of the Defendants' services he got were ready-for28 market and reliable. He had no contemporaneous knowledge about the unreliability and

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 72 of 132

1	litany of problems with Theranos testing, facilities, and equipment, alleged herein. He		
2	relied on the Defendants' omissions in this respect. Had he known of this concealed		
3	information, he would not have submitted to any of this "testing."		
4	250. On information and belief, B.P.'s "tiny" blood samples were utilized at		
5	Theranos's Newark, California laboratory.		
6	251. Having been led to believe all of the "test" results were reliable, B.P. relied		
7	on them, using the results to make decisions concerning his health.		
8	252. Based on his Theranos test results, his doctor diagnosed him with diabetes		
9	and high cholesterol, and prescribed certain medications.		
10	253. The Theranos tests that B.P. purchased were unreliable and/or inaccurate.		
11	254. Subsequently, as alleged above, Theranos voided the results of all of the		
12	Edison blood tests, including B.P.'s "tiny" blood tests.		
13	255. After learning that his Theranos tests were unreliable and/or inaccurate, he		
14	had his blood tested by another company. The results reflected that he is healthier than		
15	the Theranos tests had indicated.		
16	256. Plaintiff B.P. would not have purchased any Theranos test if he had known		
17	that the Theranos testing facilities were not as described, and that Theranos's tests were		
18	inaccurate or unreliable. Plaintiff B.P. would not have submitted to Theranos tests if he		
19	had known that Walgreens and Theranos were using his blood tests for research and		
20	product development.		
21	257. Plaintiff B.P. was battered, injured, damaged and harmed by Defendants'		
22	misconduct.		
23	258. Plaintiff B.P. suffered damages as a result of Defendants' conduct, in an		
24	amount to be proven at trial.		
25	259. In addition to the other harm described herein, Plaintiff B.P. suffered pain,		
26	emotional distress, stress, anxiety as a result of the unreliable Theranos blood tests he		
27	purchased and the invasion of his body under false pretenses and without his consent, and		
28	harm to his human dignity connected to being subjected to battery.		
I			

1 260. Any purported consent by B.P. to have his blood drawn by Defendants was 2 induced by fraud, concealment and misrepresentation, and was not effective.

3

7

8

Plaintiff D.L.

4 261. On or around June 1, 2015, and December 14, 2015, Plaintiff D.L. 5 purchased Theranos blood tests at a Walgreens Pharmacy in Chandler, Arizona. In both 6 cases, her blood was drawn at this Walgreens store. D.L. purchased Theranos tests to get accurate and reliable results about her health. She trusted Theranos and Walgreens to provide accurate and reliable test results.

9 D.L. had received orders from her medical care provider to have blood 262. 10 testing performed. D.L. was informed by her physician that Theranos was the quickest 11 and cheapest alternative for the tests. In choosing to have her blood tested by Theranos, 12 she relied on marketing by Theranos and Walgreens regarding the reliability of their 13 services, including, she specifically recalls, signage at the Walgreens store that she saw 14 before having her blood drawn and representations on the Theranos website in or around 15 June and December of 2015. D.L. expected tests conducted at Walgreens to be 16 trustworthy and reliable.

17 263. D.L. paid for the Theranos tests out of pocket and/or through her health 18 insurer.

19 264. Each time she purchased a Theranos test, one or more vials of blood were 20 drawn from a vein in D.L.'s arm. D.L. did not know that Walgreens drew her blood for 21 the purpose of research and product development and she did not consent to such 22 procedure for such purpose. She believed that the purpose of the blood draws she 23 submitted to was legitimate blood testing.

24 265. D.L. believed that Defendants' services were ready-for-market and reliable. 25 She had no contemporaneous knowledge about the unreliability and litany of problems 26 with Theranos testing, facilities, and equipment, alleged herein. She relied on the 27 Defendants' omissions in this respect. Had she known of this concealed information, she 28 would not have submitted to this testing.

266. On information and belief, tests of D.L. were conducted at Theranos's Newark, California and Scottsdale, Arizona laboratories.

3 267. Having been led to believe the results were reliable, D.L. relied on them, 4 using the results to make decisions concerning her health.

5 Based on the results of her Theranos tests, D.L. tested positive for Sjogrens 268. 6 syndrome, which required her to seek treatment from her doctor, to be tested for food 7 allergies, and to spend considerable time learning about Sjogrens syndrome and the 8 impact her diagnosis would have on her lifestyle.

9

1

2

269. The Theranos tests that D.L. purchased were unreliable and/or inaccurate.

10 After learning that her Theranos tests were unreliable and/or inaccurate, she 270. 11 had her blood tested by another company and consulted with her doctor, who after 12 reviewing the new test results has now confirmed that she does not have Sjogrens 13 syndrome.

14 271. Plaintiff D.L. would not have purchased any Theranos test if she had known 15 that the Theranos testing facilities were not as described, and that Theranos's tests were 16 inaccurate or unreliable. Plaintiff D.L. would not have submitted to Theranos tests if she 17 had known that Walgreens and Theranos were using her blood tests for research and 18 product development.

19 Plaintiff D.L. was injured, damaged and harmed by Defendants' 272. 20 misconduct.

21 273. Plaintiff D.L. suffered damages as a result of Defendants' conduct, in an 22 amount to be proven at trial.

23

In addition to the other harm described herein, Plaintiff D.L. suffered 274. 24 emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests she 25 purchased and the invasion of her body under false pretenses and without her consent.

26 275. Any purported consent by D.L. to have her blood drawn by Defendants was 27 induced by fraud, concealment and misrepresentation, and was not effective.

1	Plaintiff L.M.
2	276. On or around October 5, 2015, Plaintiff L.M. purchased Theranos blood
3	tests at a Walgreens Pharmacy in Chandler, Arizona. She had her blood drawn at this
4	Walgreens store. The tests that she purchased included tests regarding her thyroid. L.M.
5	purchased Theranos tests to get accurate and reliable results about her health. She trusted
6	Theranos and Walgreens to provide accurate and reliable test results.
7	277. L.M. had received orders from her medical care provider to have blood
8	testing performed. L.M. was informed by her physician that Theranos was the cheapest
9	alternative for the tests. In choosing to have her blood tested by Theranos, she relied on
10	marketing by Theranos and Walgreens regarding the reliability of their services. She also
11	expected tests conducted at Walgreens to be trustworthy and reliable.
12	278. L.M. paid approximately \$59.34 out of pocket for the Theranos tests.
13	279. L.M.'s best recollection is that when she purchased Theranos tests, one or
14	more vials of blood were drawn from a vein in L.M.'s arm. L.M. did not know that
15	Defendants drew her blood for the purpose of research and product development and she
16	did not consent to such procedure for such purpose.
17	280. L.M. believed that Defendants' services were ready-for-market and reliable.
18	She had no contemporaneous knowledge about the unreliability and litany of problems
19	with Theranos testing, facilities, and equipment, alleged herein. She relied on the
20	Defendants' omissions in this respect. Had she known of this concealed information, she
21	would not have submitted to this testing.
22	281. Having been led to believe the results were reliable, L.M. relied on them,
23	using the results to make decisions concerning her health.
24	282. Based on the results of her Theranos tests, L.M. was diagnosed by her
25	physician as having Hashimoto's Disease, which was devastating to her and required
26	lifestyle changes, medical appointments, and taking unnecessary medication.
27	283. The Theranos tests that L.M. purchased were unreliable and/or inaccurate.
28	
	SECOND AMENDED CONSOLIDATED

1 284. In approximately March 2016, at her physician's direction, L.M. had her 2 blood re-tested by a different testing company, repeating the same tests that Theranos had 3 conducted. These results were dramatically different than the Theranos test results, and as 4 per her physician invalidated the diagnosis of Hashimoto's Disease, meaning L.M. had 5 been needlessly pursuing a course of treatment for a condition she did not have. 6 285. Plaintiff L.M. would not have purchased any Theranos test if she had known 7 that the Theranos testing facilities were not as described, and that Theranos's tests were 8 inaccurate or unreliable. Plaintiff L.M. would not have submitted to Theranos tests if she 9 had known that Defendants were using her blood tests for research and product 10 development. 11 286. Plaintiff L.M. was injured, damaged and harmed by Defendants' 12 misconduct. Plaintiff L.M. suffered damages as a result of Defendants' conduct, in an 13 287. 14 amount to be proven at trial. 15 In addition to the other harm described herein, Plaintiff L.M. suffered 288. emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests she 16 17 purchased and the invasion of her body under false pretenses and without her consent. 18 289. Any purported consent by L.M. to have her blood drawn by Defendants was 19 induced by fraud, concealment and misrepresentation, and was not effective. 20 Plaintiff M.P. 21 290. On or around November 2015, Plaintiff M.P. purchased Theranos blood 22 tests at a Walgreens Pharmacy in Tempe, Arizona. He had his blood drawn at this 23 Walgreens store. The tests that he purchased included STI panels. M.P. purchased 24 Theranos tests to get accurate and reliable results about his health. He trusted Theranos 25 and Walgreens to provide reliable test results. 26 291. In choosing to have his blood tested by Theranos, M.P. relied on marketing 27 by Theranos and Walgreens regarding the reliability of their services, including, he 28 specifically recalls, on the Theranos website that he viewed on or around November 2015

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 77 of 132

1	before visiting the Walgreens store, and at the Walgreens store. He also expected tests	
2	conducted at Walgreens to be trustworthy and reliable.	
3	292. M.P.'s best recollection is that when he purchased Theranos tests, he had	
4	one or more vials of blood drawn from a vein in his arm. M.P. did not know that	
5	Defendants drew his blood for the purpose of research and product development and he	
6	did not consent to such procedure for such purpose.	
7	293. M.P. believed that Defendants' services were ready-for-market and reliable.	
8	He had no contemporaneous knowledge about the unreliability and litany of problems	
9	with Theranos testing, facilities, and equipment, alleged herein. He relied on the	
10	Defendants' omissions in this respect. Had he known of this concealed information, he	
11	would not have submitted to this testing.	
12	294. M.P. paid for the Theranos tests out-of-pocket.	
13	295. The tests that M.P. purchased were unreliable and/or inaccurate.	
14	296. M.P. paid out-of-pocket to be retested with STI panels after learning that the	
15	Theranos tests were unreliable and/or inaccurate.	
16	297. Plaintiff M.P. would not have purchased any Theranos test if he had known	
17	that the Theranos testing facilities were not as described, and that Theranos's tests were	
18	inaccurate or unreliable. Plaintiff M.P. would not have submitted to Theranos tests if he	
19	had known that Defendants were using his blood tests for research and product	
20	development.	
21	298. Plaintiff M.P. was injured, damaged and harmed by Defendants'	
22	misconduct.	
23	299. Plaintiff M.P. suffered damages as a result of Defendants' conduct, in an	
24	amount to be proven at trial.	
25	300. In addition to the other harm described herein, Plaintiff M.P. suffered	
26	emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he	
27	purchased and the invasion of his body under false pretenses and without his consent.	
28		
I		

301. Any purported consent by M.P. to have his blood drawn by Defendants was
 induced by fraud, concealment and misrepresentation, and was not effective.

3

Plaintiff R.C.

302. On or around February 2015, Plaintiff R.C. purchased Theranos blood tests
at a Walgreens Pharmacy in Sun City West, Arizona. He had his blood drawn at this
Walgreens store. The tests that he purchased included tests regarding his heart health.
R.C. purchased Theranos tests to get accurate and reliable results about his health. He
trusted Theranos and Walgreens to provide accurate and reliable test results.

9 R.C. had received orders from his medical care provider to have blood 303. 10 testing performed to monitor his heart health. In choosing to have his blood tested by 11 Theranos, he relied on marketing by Theranos and Walgreens regarding the nature and 12 reliability of their services, including, he specifically recalls, a television commercial he 13 saw before visiting the Walgreens store, and at the Walgreens store before having his 14 blood drawn, all of which portrayed and gave the clear impression that the services being 15 advertised were ready, reliable, and for legitimate testing purposes. He also expected tests 16 conducted at Walgreens to be trustworthy and reliable.

17

304. R.C. paid for the Theranos tests through Medicare.

18 305. When R.C. had his blood drawn at the Walgreens store, it was via "tiny" 19 blood draws. Pursuant to this, a first needle was stuck into his finger, penetrating his skin 20 and tissue, and blood was drawn from his body. The process was painful and was not 21 quick as advertised. The individual administering the draw struggled to secure enough 22 blood from R.C.'s finger and had to repeat the painful process several times before 23 collecting enough to test. In each case, a needle was stuck into his finger, penetrating his 24 skin and tissue, and blood was drawn from his body. For each of these "tiny" blood 25 draws, the blood draws were administered by an individual who worked at the Walgreens 26 store, and who identified themselves as being affiliated with Theranos testing. Plaintiff 27 R.C. alleges that this individual was a Walgreens employee or worked for both Walgreens 28 and Theranos.

306. Throughout his visits to the Walgreens store, and throughout the process of
 preparing for and having his blood drawn, he was consistently led to believe that the blood
 draws were for legitimate blood testing purposes. No suggestion was made to the
 contrary.

5 When R.C. agreed to submit to the "tiny" blood draws, he understood and 307. 6 believed that the purpose of the blood draws was legitimate blood testing. His consent to 7 these draws was based on this belief. This belief was based on, among other things, 8 marketing from Walgreens and Theranos that he saw, including a television commercial 9 and at the Walgreens store before having his blood drawn, which clearly portrayed and 10 gave the impression that the services were market-ready and reliable, and the blood draws 11 he was submitting to as being for legitimate testing purposes. This belief was also based 12 on the design and nature of, and the infrastructure and signage at, the Wellness Centers 13 where his blood draws were conducted, which gave the definitive, if not obvious, 14 impression that the purpose of the blood draws he was submitting to was legitimate blood 15 testing. The fact that these services were being offered at a Walgreens store, given its 16 prominence and the nature of its business as a pharmacy, reinforced his belief that the 17 service was market-ready and for legitimate testing purposes.

308. As alleged herein, the essential nature and purpose of the "tiny" blood draws
R.C. submitted to was not legitimate blood testing, and indeed could not have been given
the decidedly unready state of Edison. R.C. agreed to submit to the "tiny" blood draws
under false pretenses and under a substantial mistaken belief as to the essential nature and
purpose of the draws.

309. R.C. had no contemporaneous knowledge that the Edison technology was
still in-development, not market-ready, and not in a position to serve the purpose of blood
testing, nor did he have contemporaneous knowledge that the "tiny" blood draws he was
submitting to had a nature or purpose other than legitimate blood testing. This
information was concealed from him and he relied on Defendants' omissions in this
respect. Had he known the truth, he would not have consented to "tiny" blood draws.

310. R.C. did not know that Defendants drew his blood for the purpose of
 research and product development and he did not consent to such procedure for such
 purpose.

A 311. R.C. believed that the services he got were ready-for-market and reliable.
He had no contemporaneous knowledge about the unreliability and litany of problems
with Theranos testing, facilities, and equipment, alleged herein. He relied on the
Defendants' omissions in this respect. Had he known of this concealed information, he
would not have submitted to this "testing."

9 312. On information and belief, R.C.'s "tiny" blood samples were utilized at
10 Theranos's Newark, California laboratory.

11 313. Having been led to believe the "test" results were reliable, R.C. relied on12 them, using the results to make decisions concerning his health.

314. The results from his Theranos tests indicated that R.C. was in good health.
Based on these results, his doctor recommended that R.C. maintain his current medication
regimen and to return in one year for repeat testing, and R.C. believed his current lifestyle
and medication regimen was working for him and that he had been successful in getting
his heart health under control.

18

315. The Theranos tests that R.C. purchased were unreliable and/or inaccurate.

316. Less than one month later, R.C. suffered a heart attack. R.C. was admitted
to the hospital, had two stents placed, and had numerous follow up medical appointments.
R.C. and his cardiologist were particularly concerned that R.C. had suffered a heart attack
given that his blood panels came back clear (from his Theranos tests) less than a month
prior. Additional blood work performed during his hospitalization strongly suggested that
the near-contemporaneous Theranos blood tests were inaccurate.

25 317. Subsequently, as alleged above, Theranos voided the results of all of the
26 "tiny" blood tests, including R.C.'s "tests."

27 318. Since his 2015 heart attack, R.C. has been receiving medical care using
28 traditional blood testing procedures from companies other than Theranos.

1	319. Plaintiff R.C. would not have purchased any Theranos test if he had known
2	that the Theranos testing facilities were not as described, and that Theranos's tests were
3	inaccurate or unreliable. Plaintiff R.C. would not have submitted to Theranos tests if he
4	had known that Walgreens and Theranos were using his blood tests for research and
5	product development.
6	320. Plaintiff R.C. was battered, injured, damaged and harmed by Defendants'
7	misconduct.
8	321. Plaintiff R.C. suffered damages as a result of Defendants' conduct, in an
9	amount to be proven at trial.
10	322. In addition to the other harm described herein, Plaintiff R.C. suffered pain,
11	emotional distress, stress, anxiety as a result of the unreliable Theranos blood tests he
12	purchased and the invasion of his body under false pretenses and without his consent, and
13	harm to his human dignity connected to being subjected to battery.
14	323. Any purported consent by R.C. to have his blood drawn by Defendants was
15	induced by fraud, concealment and misrepresentation, and was not effective.
16	Plaintiff R.G.
17	324. On or around September 10, 2015, Plaintiff R.G. purchased Theranos blood
18	tests at a Walgreens Pharmacy in Gilbert, Arizona. He had his blood drawn at this
19	Walgreens store. The tests that he purchased included tests regarding his sexual health.
20	R.G. purchased Theranos tests to get accurate and reliable results about his health. He
21	trusted Theranos and Walgreens to provide accurate and reliable test results.
22	325. R.G. had seen and heard advertisements for Theranos that caused him to
23	believe it was a revolutionary technology and market-ready. R.G. specifically recalls
24	hearing advertisements for Theranos on the radio prior to September 2015, and viewing
25	advertisements on multiple occasions in 2015 at the baggage claim carousal of the
26	Phoenix International Airport. In choosing to have his blood tested by Theranos, he relied
27	on marketing by Theranos and Walgreens regarding the reliability of their services,
28	

including as specified above. He also expected tests conducted at Walgreens to be
 trustworthy and reliable.

3

326. R.G. paid approximately \$121.63 out of pocket for the Theranos tests.

327. When he purchased Theranos tests, one or more vials of blood were drawn
from a vein in R.G.'s arm. R.G. did not know that Defendants drew his blood for the
purpose of research and product development and he did not consent to such procedure for
such purpose.

8 328. R.G. believed that Defendants' services were ready-for-market and reliable.
9 He had no contemporaneous knowledge about the unreliability and litany of problems
10 with Theranos testing, facilities, and equipment, alleged herein. He relied on the
11 Defendants' omissions in this respect. Had he known of this concealed information, he
12 would not have submitted to this testing.

13 329. On information and belief, one or more of R.G.'s tests were conducted at
14 Theranos's Newark, California laboratory.

15 330. Having been led to believe the results were reliable, R.G. relied on them,16 using the results to make decisions concerning his health.

17 331. The results from his Theranos tests indicated that he had tested positive for
18 HIV (specifically, the HIV 1+2 Antigen/Antibody Combo was "reactive").

19 332. After receiving the test results from Theranos, R.G., he was extremely
20 concerned and visited his physician, began doing research about HIV/AIDS, and had his
21 blood re-tested by two different companies. These test results came back negative.

22

333. The Theranos tests that R.G. purchased were unreliable and/or inaccurate.

334. Plaintiff R.G. would not have purchased any Theranos test if he had known
that the Theranos testing facilities were not as described, and that Theranos's tests were
inaccurate or unreliable. Plaintiff R.G. would not have submitted to Theranos tests if he
had known that Walgreens and Theranos were using his blood tests for research and
product development.

335. Plaintiff R.G. was injured, damaged and harmed by Defendants'
 misconduct.

3 336. Plaintiff R.G. suffered damages as a result of Defendants' conduct, in an
4 amount to be proven at trial.

5 337. In addition to the other harm described herein, Plaintiff R.G. suffered
6 emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he
7 purchased and the invasion of his body under false pretenses and without his consent.

8 338. Any purported consent by R.G. to have his blood drawn by Defendants was
9 induced by fraud, concealment and misrepresentation, and was not effective.

10

Plaintiff S.J.

339. In or around July 2015, Plaintiff S.J. purchased her first Theranos blood test
and urinalysis at a Theranos Wellness Center located at a Walgreens retail store in Mesa,
Arizona. She had her blood drawn and urine sample taken at this Walgreens store. The
tests that she purchased were for a routine health check including diabetes and triglyceride
levels. S.J. purchased Theranos tests to get accurate and reliable results about her health.
She trusted Theranos and Walgreens to provide accurate and reliable test results.

17 340. S.J. was referred to Theranos by her physician, based on her financial needs 18 and Theranos's reputation for affordable testing. In choosing to have her blood tested by 19 Theranos, S.J. relied on marketing by Theranos and Walgreens regarding the nature and 20 reliability of their services, including, she specifically recalls, in materials that she saw at 21 the Walgreens store, before having her blood drawn, which portrayed and gave the clear 22 impression that the services being advertised were ready, reliable, and for legitimate 23 testing purposes. She also expected tests conducted at Walgreens to be trustworthy and 24 reliable.

341. To the best of her recollection, the first time S.J. had her blood drawn at the
Walgreens store, it was via "tiny" blood draws. Pursuant to this, a needle was stuck into
her finger, penetrating her skin and tissue, and blood was drawn from her body. The
"tiny" blood draw was administered by an individual who worked at the Walgreens store

and who identified themselves as being affiliated with Theranos testing. Plaintiff S.J.
 alleges that this individual was a Walgreens employee or worked for both Walgreens and
 Theranos.

4 342. As discussed below, S.J. also purchased Theranos tests during a second visit
5 to the same Walgreens store, in or around November 2015. Her best recollection is that
6 during this second visit, one or more vials of blood were drawn from a vein in her arm.

7 343. Throughout her visits to the Walgreens store, and throughout the process of
8 preparing for and having her blood drawn, S.J. was consistently led to believe that the
9 blood draws were for legitimate blood testing purposes. No suggestion was made to the
10 contrary.

11 When S.J. agreed to submit to the "tiny" blood draw (and to the venous 344. 12 blood draw as well), she understood and believed that the purpose of the blood draws was 13 legitimate blood testing. Her consent to these draws was based on this belief. This belief 14 was based on, among other things, marketing from Walgreens and Theranos that she saw 15 at the Walgreens stores before getting her blood drawn, which clearly portrayed and gave 16 the impression that the services were market-ready and reliable, and the blood draws he 17 was submitting to as being for legitimate testing purposes. This belief was also based on 18 the design and nature of, and the infrastructure and signage at, the Wellness Centers where 19 her blood draws were conducted, which gave the definitive, if not obvious, impression 20 that the purpose of the blood draws she was submitting to was legitimate blood testing. 21 The fact that these services were being offered at a Walgreens store, given its prominence 22 and the nature of its business as a pharmacy, reinforced her belief that the service was 23 market-ready and for legitimate testing purposes.

345. As alleged herein, the essential nature and purpose of the "tiny" blood draw
S.J. submitted to was not legitimate blood testing, and indeed could not have been given
the decidedly unready state of Edison. S.J. agreed to submit to the "tiny" blood draw
under false pretenses and under a substantial mistaken belief as to the essential nature and
purpose of the draw.

1 346. S.J. had no contemporaneous knowledge that the Edison technology was 2 still in-development, not market-ready, and not in a position to serve the purpose of blood 3 testing, nor did she have contemporaneous knowledge that the "tiny" blood draw she was 4 submitting to had a nature or purpose other than legitimate blood testing. This 5 information was concealed from her and she relied on Defendants' omissions in this 6 respect. Had she known the truth, she would not have consented to "tiny" blood draw. 7 347. S.J. did not know that Defendants drew her blood for the purpose of 8 research and product development and she did not consent to such procedure for such 9 purpose. 10 348. S.J. believed that the services she got were ready-for-market and reliable. 11 She had no contemporaneous knowledge about the unreliability and litany of problems 12 with Theranos testing, facilities, and equipment, alleged herein. She relied on the 13 Defendants' omissions in this respect. Had she known of this concealed information, she 14 would not have submitted to this "testing." 15 On information and belief, S.J.'s "tiny" blood samples were utilized at 349. Theranos's Newark, California laboratory. 16 17 350. S.J.'s results from her first Theranos "test" indicated that she had diabetes, 18 and S.J.'s physician immediately ordered her to be placed on diabetic medications. 19 S.J. firmly believed she did not have diabetes and obtained a re-test. For the 351. 20 re-test, she went back to the same Theranos Wellness Center located at a Walgreens retail 21 store in Mesa, Arizona. Again, she had her blood drawn at this Walgreens store. 22 S.J. paid for her Theranos tests through Medicare. 352. 23 Having been led to believe the "test" results were reliable, and following 353. 24 two similarly reported Theranos tests, S.J. and her physician relied on the results to make 25 decisions concerning her health, including a course of medications which ultimately made 26 S.J. very ill. S.J. became so ill that she was treated at urgent care where she made the 27 decision to cease all medications prescribed for diabetes. 28

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 86 of 132

1	354. Following her reaction to the diabetes medication, along with her original	
2	belief that she did not have diabetes, S.J. began seeing another physician who ordered	
3	repeat lab testing to be done at a non-Theranos facility. The results confirmed that S.J.	
4	did not have diabetes, and had been improperly diagnosed and treated based on the	
5	Theranos test results.	
6	355. The Theranos tests that S.J. purchased were unreliable and/or inaccurate.	
7	356. Subsequently, as alleged above, Theranos voided the results of all of the	
8	"tiny" blood tests, including S.J.'s "tiny" "tests."	
9	357. Plaintiff S.J. would not have purchased any Theranos test if she had known	
10	that the Theranos testing facilities were not as described, and that Theranos's tests were	
11	inaccurate or unreliable. Plaintiff S.J. would not have submitted to Theranos tests if she	
12	had known that Walgreens and Theranos were using her blood and urine tests for research	
13	and product development.	
14	358. Plaintiff S.J. was battered, injured, damaged and harmed by Defendants'	
15	misconduct.	
16	359. Plaintiff S.J. suffered damages as a result of Defendants' conduct, in an	
17	amount to be proven at trial.	
18	360. In addition to the other harm described herein, Plaintiff S.J. suffered	
19	emotional distress, stress, and anxiety as a result of the unreliable Theranos tests she	
20	purchased and the invasion of her body under false pretenses and without her consent, and	
21	harm to her human dignity connected to being subjected to battery.	
22	361. Any purported consent by S.J. to have her blood drawn or her urine	
23	collected by Defendants was induced by fraud, concealment and misrepresentation, and	
24	was not effective.	
25	Plaintiff S.L.	
26	362. On or about February 19, 2015, and October 5, 2015, Plaintiff S.L.	
27	purchased Theranos blood tests at a Walgreens Pharmacy in Chandler, Arizona. In both	
28	instances, he had his blood drawn at this Walgreens store. The tests that he purchased	
	SECOND AMENDED CONSOLIDATED	

1 included tests regarding diabetes and his liver. S.L. purchased Theranos tests to get 2 accurate and reliable results about his health. He trusted Theranos and Walgreens to 3 provide accurate and reliable test results.

- 4 Prior to each visit, S.L. had seen and heard advertisements for Theranos that 363. 5 caused him to believe that Theranos test results would be as reliable as other labs' results, 6 and that Theranos was the cheapest and least invasive alternative option for blood testing. 7 S.L. specifically recalls seeing a pamphlet advertisement and visiting the Theranos 8 website in or around January and October 2015 and viewing representations to the effect 9 that Theranos was "as reliable" as other laboratories. In choosing to have his blood tested 10 by Theranos, he relied on marketing from Theranos and Walgreens regarding the 11 reliability of their services, including as specified above. He also expected tests 12 conducted at Walgreens to be trustworthy and reliable.
- 13

364. S.L. paid approximately \$100 out of pocket for the Theranos tests.

14 When he purchased Theranos tests, one or more vials of blood were drawn 365. 15 from a vein in S.L.'s arm. S.L. did not know that Defendants drew his blood for the 16 purpose of research and product development and he did not consent to such procedure for 17 such purpose.

18 S.L. believed that Defendants' services were ready-for-market and reliable. 366. 19 He had no contemporaneous knowledge about the unreliability and litany of problems 20 with Theranos testing, facilities, and equipment, alleged herein. He relied on the 21 Defendants' omissions in this respect. Had he known of this concealed information, he 22 would not have submitted to this testing.

23

Having been led to believe the results were reliable, S.L. relied on them, 367. 24 using the results to make decisions concerning his health.

25 The results from his Theranos test indicated certain levels that were elevated 368. 26 from the prior year and that he was diabetic. His doctor ordered an ultrasound of the liver, 27 and he took medication for diabetics.

28

369. The Theranos tests that S.L. purchased were unreliable and/or inaccurate.

1	370. At his doctor's direction, S.L. had his blood re-tested by another company	
2	and his results were in the normal range, including showing he was pre-diabetic,	
3	significantly different from his Theranos tests.	
4	371. Plaintiff S.L. would not have purchased any Theranos test if he had known	
5	that the Theranos testing facilities were not as described, and that Theranos's tests were	
6	inaccurate or unreliable. Plaintiff S.L would not have submitted to Theranos tests if he	
7	had known that Walgreens and Theranos were using his blood tests for research and	
8	product development.	
9	372. Plaintiff S.L. was injured, damaged and harmed by Defendants' misconduct.	
10	373. Plaintiff S.L. suffered damages as a result of Defendants' conduct, in an	
11	amount to be proven at trial.	
12	374. In addition to the other harm described herein, Plaintiff S.L. suffered	
13	emotional distress, stress, and anxiety as a result of the unreliable Theranos blood tests he	
14	purchased and the invasion of his body under false pretenses and without his consent.	
15	375. Any purported consent by S.L. to have his blood drawn by Defendants was	
16	induced by fraud, concealment and misrepresentation, and was not effective.	
17	V. <u>CLASS ACTION ALLEGATIONS</u>	
18	376. Plaintiffs bring this action on behalf of themselves and proposed the Class	
19	and Subclasses, pursuant to Federal Rules of Civil Procedure Rule 23, defined as follows:	
20	Class : All purchasers of Theranos testing services, including	
21	consumers who paid out-of-pocket, through health insurance,	
22	or through any other collateral source (collectively, "purchasers").	
23	Arizona Subclass: All purchasers of Theranos testing	
24	services in Arizona.	
25	California Subclass: All purchasers of Theranos testing	
26	services in California.	
27	Edison Subclass: All purchasers of Theranos testing services who were subjected to "tiny" blood draws.	
28		

377. This action is brought as a class action and may properly be so maintained
 pursuant to the provisions of Rule 23 of the Federal Rules of Civil Procedure. Plaintiffs
 reserve the right to amend or modify the Class and Subclass descriptions with greater
 specificity or further division into subclasses or limitation to particular issues, based on
 the results of discovery. Excluded from the Class and Subclasses are Defendants, their
 affiliates, employees, officers and directors, persons or entities, and the Judge(s) assigned
 to this case.

8 378. <u>Numerosity</u> – The members of the Class and Subclasses are so numerous
9 that their individual joinder is impracticable. On information and belief, there are at least
10 thousands of members in each Class/Subclass. The membership of the Class and
11 Subclasses are determinable by objective criteria using Defendants' own records.

12 379. <u>Common Question of Fact and Law</u> – There are questions of law and fact
13 common to the Class and Subclasses. These questions predominate over any questions
14 affecting only individual Class members. These common legal and factual issues include,
15 but are not limited to:

- a. Whether Defendants intentionally concealed material information
 about the reliability of Theranos test results and/or about the
 compliance of Theranos's testing facilities and/or equipment;
- Whether Defendants had a duty to disclose to Plaintiffs and the Class material information regarding the reliability of Theranos's testing services;
 - c. Whether Theranos and/or Walgreens had contractual obligations with Plaintiffs and the Class regarding Theranos's testing services;
 - d. Whether Theranos and Walgreens were obligated to provide testing services and test results that were reliable;
 - e. Whether Defendants together constitute an association-in-fact enterprise within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c);
- 28

16

17

18

19

20

21

22

23

24

25

26

	Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 90 of 132
1 2	f. Whether Theranos and Walgreens concealed, falsely portrayed and/or
2	misrepresented the state of the Edison technology and the purpose of
3 4	the "tiny" blood draws;g. Whether legitimate blood testing was the essential nature and purpose
5	g. Whether legitimate blood testing was the essential nature and purpose of the "tiny" blood draws;
6	h. Whether Defendants' conduct violates the laws as set forth in the
7	causes of action;
8	i. Whether Plaintiffs and the Class have been harmed as a result of
9	Defendants' conduct alleged herein; and
10	j. Whether Defendants have been unjustly enriched as a result of their
11	conduct alleged herein.
12	380. <u>Typicality</u> – The claims of the representative Plaintiffs are typical of the
13	claims of the Class and corresponding Subclasses. Plaintiffs and the Class and Subclasses
14	were subject to the same common pattern of conduct by Defendants, and the Plaintiffs,
15	like the other members of the Class and Subclasses, have sustained damages arising from
16	Defendants' violations of the law, as alleged herein.
17	381. <u>Adequacy</u> – The representative Plaintiffs will fairly and adequately
18	represent and protect the interests of the Class and Subclass members and have retained
19	counsel who are experienced and competent trial lawyers in complex litigation and class
20	action litigation. There are no material conflicts between the claims of the representative
21	Plaintiffs and the members of the Class and Subclasses that would make class certification
22	inappropriate. Counsel for the classes will vigorously assert the claims of all Class and
23	Subclass members.
24	382. <u>Predominance and Superiority</u> – This suit may be maintained as a class
25	action under Federal Rule of Civil Procedure 23(b)(3) because questions of law and fact
26	common to the Class and Subclasses predominate over the questions affecting only
27	individual members, and a class action is superior to other available means for the fair and
28	efficient adjudication of this dispute. The damages suffered by individual Class and

I

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 91 of 132

1 Subclass members are small compared to the burden and expense of individual 2 prosecution of the complex and extensive litigation needed to address Defendants' 3 conduct. Further, it would be virtually impossible for each of the Class members to 4 individually redress effectively the wrongs done to them. Even if Class members 5 themselves could afford such individual litigation, the court system could not. In addition, 6 individualized litigation increases the delay and expense to all parties and to the court 7 system resulting from complex legal and factual issues of the case. Individualized 8 litigation also presents a potential for inconsistent or contradictory judgments. By 9 contrast, the class action device presents far fewer management difficulties; allows the 10 hearing of claims which might otherwise go unaddressed because of the relative expense 11 of bringing individual lawsuits; and provides the benefits of single adjudication, 12 economies of scale, and comprehensive supervision by a single court. Plaintiffs anticipate 13 no unusual difficulties in managing this class action.

14 383. Plaintiffs contemplate the eventual issuance of notice to the proposed Class
15 and Subclass members setting forth the subject and nature of the instant action. On
16 information and belief, Defendants' own business records and electronic media can be
17 utilized for the contemplated notice. To the extent that any further notice may be
18 required, Plaintiffs would contemplate the use of additional media and/or mailings.

19 20

VI. <u>CAUSES OF ACTION</u>

FIRST CAUSE OF ACTION

(Arizona Consumer Fraud Act, A.R.S. § 44-1521, et seq.)Plaintiffs incorporate the
 substantive allegations contained in all prior and succeeding paragraphs as if fully set
 forth herein.

385. To the extent this claim is based directly on affirmative misrepresentations,
 it is brought by Plaintiffs on behalf of themselves and the Arizona Subclass against
 Defendants Theranos and Walgreens. Otherwise, Plaintiffs bring this claim on behalf of
 themselves and the Arizona Subclass against all Defendants.

386. Walgreens, Theranos, Holmes, and Balwani are "persons" within the
 meaning of A.R.S. § 44-1521(6).

3 387. Theranos lab panels and blood and other clinical tests sold in Arizona are
4 "merchandise" within the meaning of A.R.S. § 44-1521(5).

388. As alleged herein, Walgreens, Theranos, Holmes, and Balwani have
engaged in deception, unfair acts or practices, fraud, false pretenses, false promises,
misrepresentation, concealment, suppression and omission of material facts, as prohibited
by A.R.S. § 44-1522(A).

389. Throughout the relevant time period, Walgreens and Theranos marketed and
sold unreliable Theranos testing services that they knew to be unreliable and/or which
they failed to take sufficient steps to ensure the reliability of, and encouraged consumers
to rely on such tests to make decisions about their health and treatment.

13 390. Throughout the relevant time period, Walgreens and Theranos marketed
14 Theranos testing services as being ready-for-market, when they knew such testing was not
15 ready for market.

16 391. Throughout the time that "tiny" blood draws were being administered, and
17 in the time leading up to same, Walgreens and Theranos pervasively advertised and
18 portrayed, expressly and by clear implication, the Edison technology as being market19 ready and reliable, and the "tiny" blood draws as being for blood testing purposes, when
20 none of that was true.

392. Throughout the relevant time period, Walgreens and Theranos concealed the
truth about the unready, still-in-development state of the Edison technology and the true
essential nature and purposes of the "tiny" blood draws.

393. Walgreens and Theranos owed a duty to the Edison Subclass to tell themthis material information about Edison and the "tiny" blood draws.

394. Walgreens, Theranos, Holmes, and Balwani each knew that Plaintiffs and
the Arizona Subclass would reasonably expect Theranos tests to be reliable, given, *inter*

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 93 of 132

1 *alia*, the nature and importance of blood and other clinical testing, Defendants'

2 representations, and the involvement of Walgreens.

- 3 395. Walgreens and Theranos made affirmative misrepresentations, as alleged
 4 herein, including:
- 5 False and misleading statements that Theranos tests were reliable, a. 6 CLIA-certified, and validated and compliant with federal guidelines; 7 False and misleading statements that Theranos's testing facilities and b. 8 equipment were compliant with laws and regulations; 9 c. False and misleading statements that Theranos's testing services were 10 industry leading in quality; 11 d. False and misleading statements that Theranos's testing services were 12 ready-for-market; 13 e. False and misleading statements portraying, expressly and by clear 14 implication, the Edison technology as being market-ready and 15 reliable, and the "tiny" blood draws as being for blood testing 16 purposes, when none of that was true. 17 396. Theranos's and Walgreens' affirmative misrepresentations were pervasive, 18 and included their broad marketing campaign, as described herein, which was intended to 19 broadly reach consumers throughout the pertinent geographic areas and their medical 20 providers. Plaintiffs and the Class were exposed to this broad marketing campaign. 21 397. Although not the direct basis for their liability under this claim, Holmes and 22 Balwani also knowingly made certain false and misleading statements regarding Theranos 23 testing as alleged herein. 24 Throughout the relevant time period, Theranos, Walgreens, Holmes and 398.

Balwani concealed material information from Plaintiffs and the Arizona Subclass, asalleged herein, including:

a. Failure to disclose and intentional concealment of known material
information about the unreliability of Theranos's testing services;

1	b.	Failure to disclose and intentional concealment of known material
2		information about deficiencies and non-compliance of Theranos's
3		testing facilities and/or equipment;
4	с.	Failure to disclose and intentional concealment of the fact that
5		Theranos's testing services were not ready-for-market and that
6		Theranos and Walgreens were using the tests conducted on
7		consumers for research and product development;
8	d.	Failure to disclose and intentional concealment of the fact that
9		Walgreens had agreed not to require or obtain objective proof that
10		Theranos's testing services were reliable despite the fact that it had
11		identified numerous red flags and concerns that put it on notice of the
12		problems;
13	e.	Failure to disclose and intentional concealment of the fact that
14		Walgreens had agreed to conduct no oversight of Theranos's
15		laboratory testing practices despite the fact that it had identified
16		numerous red flags and concerns that put it on notice of the problems;
17	f.	Failure to disclose and intentional concealment of the fact that
18		Theranos employees were not adequately trained to perform their job
19		functions without endangering patients, including as described in
20		letters from CMS;
21	g.	Failure to disclose and intentional concealment of the fact that
22		Theranos manipulated its internal proficiency testing process and
23		covered up known reliability problems; and
24	h.	Failure to disclose and intentional concealment of the fact that
25		Theranos's internal validation tests showed that Theranos testing was
26		unreliable.
27		
28		
		SECOND AMENDED CONSOLIDATED

2

3

1

i.

Failure to disclose and intentional concealment of the truth about the unready, still-in-development state of the Edison technology and the true essential nature and purposes of the "tiny" blood draws.

399. Walgreens and Theranos, Holmes, and Balwani knew that their promises
and representations were false and misleading and material, and that the facts they failed
to disclose and concealed were material.

7 400. Walgreens, Theranos, Holmes, and Balwani owed a duty to Plaintiffs and 8 the Arizona Subclass to provide them material information about the unreliability of 9 Theranos tests, including but not limited to because they had exclusive and far superior 10 knowledge regarding the material information, because of the nature of the information in 11 question, because they knew that customers would rely on them to provide accurate and 12 complete material information about the reliability and readiness of the tests, and because 13 they had disseminated pervasive false and/or partial representations about Theranos 14 testing that were misleading absent full disclosure.

401. Walgreens, Theranos, Holmes, and Balwani's respective misrepresentations
and omissions, alleged herein, were likely to deceive and had a tendency to deceive
reasonable consumers, and have deceived Plaintiffs and the Arizona Subclass. The facts
misrepresented and concealed by Walgreens, Theranos, Holmes, and Balwani would be
material to a reasonable consumer. Defendants' misrepresentations and omissions were
pervasive.

402. Walgreens, Theranos, Holmes, and Balwani intended for Plaintiffs and
Arizona Subclass members to rely on their misrepresentations, false promises, and
omissions concerning Theranos testing.

403. Plaintiffs and the Arizona Subclass members have reasonably relied on the
false promises, material misrepresentations and omissions made by Defendants, including
but not limited to by paying (out-of-pocket and/or through health insurance or another
collateral source) for Theranos testing services, permitting Defendants to take blood

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 96 of 132

1	samples from them under false pretenses, and relying on unreliable Theranos test results
2	to make decisions about their health.
3	404. Defendants' conduct was wanton and reckless, and Defendants
4	demonstrated reckless indifference to the rights, health, and safety of Plaintiffs and
5	members of the Arizona Subclass.
6	405. As a result of the A.R.S. § 44-1522(A) violations described above, Plaintiffs
7	and each and every Arizona Subclass member have suffered actual damages.
8	406. On behalf of themselves and Arizona Subclass members, Plaintiffs seek
9	relief as prayed for below.
10	SECOND CAUSE OF ACTION
11	(Fraud)
12	407. Plaintiffs incorporate the substantive allegations contained in all prior and
13	succeeding paragraphs as if fully set forth herein.
14	408. To the extent this claim is based directly on affirmative misrepresentations,
15	it is brought by Plaintiffs on behalf of themselves and the Class against Defendants
16	Theranos and Walgreens. Otherwise, Plaintiffs bring this claim on behalf of themselves
17	and the Class against all Defendants.
18	409. Throughout the relevant time period, Walgreens and Theranos marketed and
19	sold unreliable Theranos testing services that they knew to be unreliable and/or which
20	they failed to take sufficient steps to ensure the reliability of, and encouraged consumers
21	to rely on such tests to make decisions about their health and treatment.
22	410. Throughout the relevant time period, Walgreens and Theranos marketed
23	Theranos testing services as being ready-for-market when they knew such testing was not
24	ready for market.
25	411. Throughout the time that "tiny" blood draws were being administered, and
26	in the time leading up to same, Walgreens and Theranos pervasively advertised and
27	portrayed, expressly and by clear implication, the Edison technology as being market-
28	
l	

ready and reliable, and the "tiny" blood draws as being for blood testing purposes, when
 none of that was true.

412. Throughout the relevant time period, Walgreens and Theranos concealed the
truth about the unready, still-in-development state of the Edison technology and the true
essential nature and purposes of the "tiny" blood draws.

413. Walgreens and Theranos owed a duty to the Edison Subclass to tell them
this material information about Edison and the "tiny" blood draws.

8 414. Walgreens, Theranos, Holmes, and Balwani each knew that Plaintiffs and
9 the Class would reasonably expect Theranos tests to be reliable, given, *inter alia*, the
10 nature and importance of blood and other clinical testing, Defendants' representations,
11 and the involvement of Walgreens.

415. Walgreens and Theranos made affirmative misrepresentations, as allegedherein, including as summarized in the prior cause of action and described above.

416. Theranos's and Walgreens' affirmative misrepresentations were pervasive,
and included their broad marketing campaign, as described herein, which was intended to
broadly reach consumers throughout the pertinent geographic areas and their medical
providers. Plaintiffs and the Class were exposed to this broad marketing campaign.

417. Although not the direct basis for their liability for this claim, Holmes and
Balwani also knowingly made certain false and misleading statements regarding Theranos
testing as alleged herein.

418. Throughout the relevant time period, Theranos Walgreens, Holmes and
Balwani concealed material information from Plaintiffs and the Class, as alleged herein,
including as summarized in the prior cause of action and described above.

419. Walgreens, Theranos, Holmes, and Balwani knew that their promises and
representations were false and misleading and material, and that the facts they failed to
disclose and concealed were material.

420. Walgreens, Theranos, Holmes, and Balwani owed a duty to Plaintiffs and
the Class to provide them material information about the unreliability of Theranos tests,

including but not limited to because of the reasons summarized in the prior cause of action
 and described above.

421. Walgreens, Theranos, Holmes, and Balwani's respective misrepresentations
and omissions, alleged herein, were likely to deceive and had a tendency to deceive
reasonable consumers, and have deceived Plaintiffs and the Class. The facts
misrepresented and concealed by Walgreens, Theranos, Holmes, and Balwani would be
material to a reasonable consumer. Defendants' misrepresentations and omissions were
pervasive.

9 422. Walgreens, Theranos, Holmes, and Balwani intended for Plaintiffs and
10 Class members to rely on their misrepresentations, false promises, and omissions
11 concerning Theranos testing.

423. Walgreens, Theranos, Holmes and Balwani, who had superior knowledge
regarding Theranos testing, were in a unique position to prevent harm to their customers.
Instead, Walgreens, Theranos, Holmes and Balwani made false and misleading
representations to Plaintiffs and the Class about Theranos tests and the accuracy and
reliability of same, and concealed material information from them regarding the true
nature of Theranos tests and Theranos's facilities and equipment, as alleged herein.

424. At all relevant times, Walgreens, Theranos, Holmes and Balwani had a duty
to disclose all facts material to Plaintiffs' and the Class members' submission to Theranos
testing, purchase of Theranos testing, and reliance upon Theranos test results.

425. Walgreens also deliberately ignored and intentionally remained ignorant of
details concerning the unreliability of Theranos testing.

426. Plaintiffs and the Class members have reasonably relied on the false
promises, material misrepresentations and omissions made by Defendants. Plaintiffs and
the Class were actually misled and deceived. As a direct result of conduct by Walgreens,
Theranos, Holmes and Balwani, they were induced to undergo blood draws they would
not have undergone, to pay for Theranos products and/or services that they would not
have purchased (out-of-pocket and/or through health insurance or another collateral

1 source), and to rely on unreliable Theranos test results they would not have relied upon 2 had they known the truth, to make decisions concerning their health. 3 427. As a foreseeable and natural consequence of conduct by Walgreens, 4 Theranos, Holmes and Balwani, Plaintiffs and the Class have suffered actual damages. Defendants' misconduct alleged herein was intentional, deliberate, and 5 428. 6 willful. 7 429. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for 8 below. 9 THIRD CAUSE OF ACTION (Battery) 10 11 430. Plaintiffs incorporate the substantive allegations contained in all prior and 12 succeeding paragraphs as if fully set forth herein. 13 Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and 431. 14 the Edison Subclass against Defendants Walgreens and Theranos. 15 Defendants Walgreens and Theranos both engaged in acts that resulted in 432. 16 harmful and offensive contact with Plaintiffs B.P., R.C., and S.J., and the members of the 17 Edison Subclass. 18 433. Plaintiffs B.P., R.C., and S.J., and all of the Edison Subclass members each 19 submitted to one or more so-called "tiny" blood draws at the Wellness Centers. Pursuant 20 to these blood draws, a needle was stuck into their bodies, penetrating their skin and tissue, and blood was drawn from their bodies. 21 22 The vast majority of these "tiny" blood draws occurred in Walgreens stores, 434. 23 and a small portion of them occurred in Theranos Wellness Centers. 24 435. For the Edison Subclass member "tiny" blood draws that were conducted at 25 Walgreens stores, the blood draws were administered by a Walgreens employee or an 26 individual working for both Walgreens and Theranos, often with the assistance and in the 27 presence of a Theranos employee. In all such cases, *both* Walgreens *and* Theranos did 28 acts that resulted in the blood draws and that encouraged the blood draws—including, but SECOND AMENDED CONSOLIDATED

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 100 of 132

not limited to, through their pervasive marketing and encouragement of same, through
their provision of the space, infrastructure, support, personnel, and equipment used for the
blood draws and related services, and through their direct assistance and involvement with
the blood draws and their in-store interactions with the subjects. Both Walgreens and
Theranos, including through their respective employees, did acts that caused the harmful
and offensive touching of each of these subjects, and both companies caused each of these
touchings to occur.

8

9

436. For the "tiny" blood draws that were conducted at Theranos Wellness Centers, the blood draws were administered by Theranos employees.

437. The acts engaged in by Walgreens and Theranos that caused the "tiny"
blood draws, were all done intentionally, and also with the intent and knowledge that they
would result in harmful and offensive contact.

438. The touchings (i.e., the "tiny" blood draws) that Plaintiffs B.P., R.C., and
S.J., and the Edison Subclass were subjected to were harmful and offensive. A reasonable
person in their situation would have been offended by the touchings under the
circumstances.

439. Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members did not
consent to these touchings. Any ostensible "consent" they provided was vitiated under the
circumstances and not effective.

440. Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members agreed to
submit to these "tiny" blood draws," but, as alleged herein, they each did so under false
pretenses and under a substantial mistaken belief as to the essential nature and purpose of
the blood draws. Moreover, as alleged herein, their consent was procured by fraud,
misrepresentations, and material omissions by Theranos and Walgreens.

441. Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members reasonably
believed, contemporaneously when they agreed to submit to their "tiny" blood draws, that
the essential nature and purpose of such blood draws was legitimate blood testing.

442. Theranos and Walgreens both knew contemporaneously that Plaintiffs B.P.,
 R.C., and S.J., and the Edison Subclass members agreed to submit to the "tiny" blood
 draws under a substantial mistaken belief as to essential nature and purpose of such blood
 draws. Theranos and Walgreens both knew that these consumers mistakenly and
 reasonably believed that the essential nature and purpose of these "tiny" blood draws was
 legitimate blood testing.

7 443. As alleged herein, pervasive affirmative misrepresentations by Theranos and 8 Walgreens, in the time leading up to and throughout the time the "tiny" blood draws were 9 being administered, substantially contributed to Plaintiffs B.P., R.C., and S.J.'s, and the 10 Edison Subclass members' mistaken belief regarding the essential nature and purpose of 11 their "tiny" blood draws. This included a pervasive joint marketing campaign carried out 12 by Theranos and Walgreens throughout the relevant time period, that encouraged 13 consumers to pay for and submit to "tiny" blood draws for the very purpose of blood 14 testing. The fundamental premise of this campaign was the portrayal of the "tiny" blood 15 draws and Edison, and of the services generally, as market-ready and reliable and being 16 for legitimate blood testing purposes.

17 As alleged herein, also substantially contributing to Plaintiffs' B.P., R.C., 444. 18 and S.J.'s, and the Edison Subclass members' mistaken belief regarding the essential 19 nature and purpose of their "tiny" blood draws was the entire context, nature, design, and 20 infrastructure of the Wellness Centers in which the "tiny" blood draws were conducted, 21 which both Theranos and Walgreens designed, and which were intentionally designed by 22 Theranos and Walgreens to give the impression, and which did give the clear impression 23 to consumers, that the blood draws being conducted there were for legitimate blood 24 testing purposes.

445. As alleged herein, the concealment of material information by Theranos and
Walgreens also substantially contributed to the Edison Subclass members' mistaken belief
regarding the essential nature and purpose of their "tiny" blood draws. Throughout the
relevant time period, even though both Walgreens and Theranos knew that the subjects of

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 102 of 132

these "tiny" blood draws were agreeing to submit to them under a substantial mistaken belief as to the essential nature and purpose of the blood draws, and were thus going to be touched in a harmful and offensive way, neither Walgreens nor Theranos took any steps to correct this mistaken belief or to avoid the harmful and offensive contact. To the contrary, both companies intentionally concealed material information about Edison and the "tiny" blood draws, and actively encouraged, caused, and assisted the contact.

446. Both Walgreens and Theranos intentionally concealed and failed to disclose, *inter alia*: the truth about the unready Edison technology; that the essential nature and
purpose of the "tiny" blood draws was not, and could not have been, legitimate blood
testing; and the true essential nature and purposes of the "tiny" blood draws.

11 447. The "tiny" blood draws were not intended by Walgreens and Theranos to
12 provide reliable blood test results (i.e., "legitimate blood testing").

The essential nature and purpose of the "tiny" blood draws was not 13 448. 14 legitimate blood testing and, indeed, could not have been legitimate blood testing because, 15 as alleged herein and unbeknownst to the subjects at the time they gave their consent, the 16 Edison technology was still in development, still in prototype, not ready-for-market, and 17 nowhere near in a position to serve that purpose. Theranos and Walgreens each knew this 18 to be the case throughout the entire time "tiny" blood draws were being conducted at 19 Walgreens and Theranos facilities. To the extent Walgreens lacked any more detailed 20 knowledge, it was by virtue of its own deliberate choices to ignore and/or avoid such 21 details.

449. As alleged in more detail herein, the true essential nature and purposes of
the "tiny" blood draws was to assist efforts to research and develop the still-indevelopment Edison technology, expedite the narrative of Edison as a "disruptive"
technology in the industry, and woo and appease investors, potential investors, and coinvestors by creating the false impression that Edison was a market-ready, breakthrough
technology.

1	450. Theranos and Walgreens knew, but Plaintiffs B.P., R.C., and S.J., and the
2	Edison Subclass members could not reasonably have known, the true nature and purposes
3	of the "tiny" blood draws.

4 451. Any purported consent that Plaintiffs B.P., R.C., and S.J. and the Edison
5 Subclass members gave for the "tiny" blood draws, was given under a substantial mistake
6 as to the essential nature and purpose of the draws, was induced by fraud, concealment,
7 and misrepresentations, and was not effective.

8 452. Plaintiffs B.P., R.C., and S.J., and Edison Subclass members did not consent
9 to be subjects for experimentation, research, product development, or other undisclosed
10 objectives.

453. Theranos and Walgreens willfully and tortiously battered B.P., R.C., and
S.J., and the Edison Subclass members.

454. Moreover, Theranos and Walgreens each aided and abetted the other in
committing the battery through their conduct alleged herein. Both had actual knowledge
of the harmful and offensive, non-consensual contact that was occurring, and both took
steps that enabled, substantially assisted, encouraged, and were a substantial factor in, the
other carrying out the touching and causing the touching to occur. Both Theranos and
Walgreens are directly liable for battery as to the Edison Subclass members, and are also
liable as aiders and abettors.

455. Theranos and Walgreens knew or should have known that their conduct
alleged herein regarding the "tiny" blood draws, including but not limited to sticking them
with needles, drawing their blood, and willfully experimenting upon Plaintiffs and the
Edison Subclass under false pretenses and without obtaining their consent, would be an
affront to the dignity of Plaintiffs B.P., R.C., S.J., and the Edison Subclass members as
human beings.

456. Theranos's and Walgreens' misconduct alleged herein was intentional,
deliberate, and willful.

1	457. Plaintiffs B.P., R.C., and S.J., and the members of the Edison Subclass were
2	harmed and injured by this harmful and offensive touching.
3	458. As a foreseeable, proximate, and direct result of Theranos's and Walgreens'
4	conduct, Plaintiffs B.P., R.C., and S.J. and the Edison Subclass members each have
5	suffered a battery and have been damaged, including as otherwise set forth in this
6	Complaint, and by invasion of their privacy and bodily integrity without their consent,
7	severe emotional stress and anxiety, and harm to their human dignity and corresponding
8	damages therefrom.
9	459. On behalf of themselves and the Edison Subclass, Plaintiffs B.P., R.C., and
10	S.J. seek relief as prayed for below.
11	FOURTH CAUSE OF ACTION
12	(Negligence)
13	460. Plaintiffs incorporate the substantive allegations contained in all prior and
14	succeeding paragraphs as if fully set forth herein.
15	461. Plaintiffs bring this claim on behalf of themselves and the Class against
16	Defendants Walgreens and Theranos, and as appropriate bring this claim in the
17	alternative.
18	462. Walgreens and Theranos owed a duty of care to Plaintiffs and the Class, to
19	provide testing services that were safe, reliable, and compliant with applicable laws and
20	regulations. Such duty arose from, inter alia, the nature of their relationship to, and
21	bargain with, the consumers, the medical related nature of the services at issue, and the
22	special position of trust occupied by Theranos and Walgreens in the context of blood and
23	clinical testing.
24	463. Walgreens and Theranos both breached their duty of care by designing
25	and/or selling services that were unreliable, not ready-for-market, not safe for consumers
26	to rely on, conducted in a manner that did not satisfy applicable laws, regulations, and/or
27	standards for quality control, conducted in laboratories that did not meet applicable laws,
28	

regulations, and/or standards for safety and training, and conducted on inadequately
 maintained and calibrated equipment.

464. Theranos additionally breached these duties by conducting "tests" on known
unready technology, and in a manner that did not satisfy applicable laws, regulations,
and/or standards for quality control, in laboratories that did not meet applicable laws,
regulations, and/or standards for safety and training, and on inadequately maintained and
calibrated equipment.

8 465. At all relevant times, Walgreens additionally had a duty to Plaintiffs and the
9 Class to take reasonable steps to ensure that Theranos testing was reliable and safe prior to
10 offering Theranos services for sale in its stores.

466. Walgreens breached this duty and acted unreasonably by deliberately
ignoring and intentionally remaining ignorant of material facts about Theranos testing,
despite the fact that it had identified numerous red flags and concerns that put it on notice
of the problems, without requiring objective evidence from Theranos that the tests were
reliable, and while deliberately and knowingly maintaining no oversight of Theranos's
testing services.

467. With full knowledge that consumers would rely on its endorsement of
Theranos, Walgreens failed to take reasonable steps to prevent consumers from submitting
to, paying for, and relying upon unreliable and unsafe Theranos testing services.

468. By permitting Theranos tests to be conducted in Walgreens stores, despite
identifying numerous red flags and concerns that put it on notice about the unreliability of
Theranos tests, and when it had knowledge that the tests were in fact unreliable,

23 Walgreens acted unreasonably under the circumstances.

24 469. Plaintiffs and the Class were damaged as a direct and proximate result of25 Walgreens' and Theranos's negligent conduct.

26 470. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for27 below.

2

1

FIFTH CAUSE OF ACTION (Negligent Misrepresentation)

Plaintiffs incorporate the substantive allegations contained in all prior and 471. 3 succeeding paragraphs as if fully set forth herein. 4

472. Plaintiffs bring this claim on behalf of themselves and the Class against 5 Defendants Walgreens and Theranos, and as appropriate bring this claim in the alternative 6 7 to their claims alleging affirmative misrepresentations.

Walgreens and Theranos each made false statements of fact and provided 473. 8 false information to Plaintiffs and the Class regarding Theranos testing, including as 9 summarized in the First Cause of Action and as described above. These false statements 10 and false information included pervasive marketing by both companies which falsely 11 portrayed Edison and the "tiny" blood draws as being market-ready and for legitimate 12 blood testing purposes, as well as pervasive marketing which falsely characterized 13 Theranos testing as reliable and certified by and compliant with government and industry 14 standards. 15

474. These false statements and false information were provided in the context of 16 a business transaction—namely, to induce Plaintiffs and the Class to purchase testing 17 services. 18

Theranos and Walgreens knew that Plaintiffs and the Class would rely on 475. 19 these false statements and false information, and intended for them to do so. 20

476. Theranos and Walgreens failed to exercise reasonable care in obtaining and 21 22 communicating the false statements and false information.

23

477. At all relevant times, Walgreens and Theranos had a duty to disclose all facts material to Plaintiffs' and the Class members' submission to Theranos testing, 24 purchase of Theranos testing, and reliance upon Theranos test results. 25

478. Walgreens and Theranos specifically and expressly misrepresented material 26 facts to Plaintiffs and the Class, as alleged herein, including by, *inter alia*, promoting and 27 selling as safe and reliable, tests that were unreliable, not ready-for-market, not safe for 28

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 107 of 132

consumers to rely on, conducted in a manner that did not satisfy applicable laws,
 regulations, and/or standards for quality control, conducted in laboratories that did not
 meet applicable laws, regulations, and/or standards for safety and training, and conducted
 on inadequately maintained and calibrated equipment.

- 479. Walgreens and Theranos knew, or in the exercise of reasonable diligence
 should have known, that their express representations regarding Theranos testing were
 false and misleading. Walgreens and Theranos made such statements without reasonable
 grounds for believing them to be true.
- 9

21

22

480. The misrepresentations made by Walgreens and Theranos were pervasive.

481. The misrepresentations made by Walgreens and Theranos were likely to
deceive and had a tendency to deceive reasonable consumers, and have deceived Plaintiffs
and the Class. The facts misrepresented by Walgreens and Theranos would be material to
a reasonable consumer.

482. Plaintiffs and the Class reasonably and justifiably relied on Walgreens' and
Theranos's false statements and false information, in purchasing and submitting to
Theranos testing.

483. As a result of Walgreens' and Theranos's conduct, Plaintiffs and the Classhave suffered actual damages.

19 484. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for20 below.

SIXTH CAUSE OF ACTION (Breach of Contract)

485. Plaintiffs incorporate the substantive allegations contained in all prior and
succeeding paragraphs as if fully set forth herein.

486. Plaintiffs bring this claim on behalf of themselves and the Class against
Defendants Walgreens and Theranos.

27487. To Plaintiffs and the Class, Walgreens and Theranos offered to provide

28 reliable, ready-for-market testing services in exchange for submission to blood draws and

other clinical procedures and payment of financial compensation, paid out-of-pocket by
 the consumer and/or paid through the consumer's health insurance or other collateral
 sources.

4 The promises and obligations by Walgreens and Theranos were set forth in 488. 5 pervasive marketing materials disseminated by Walgreens and Theranos regarding 6 Theranos's testing services, as alleged herein. Moreover, the direct testing order forms 7 and guide to direct testing (Ex. 11) that some Class members (whose test orders did not 8 come directly from a physician (including Plaintiffs M.P. and R.G.)) received and 9 submitted at the Wellness Centers reinforced some of these assurances, including that 10 blood samples were collected "for the purpose of clinical laboratory tests," in order to "get 11 vital information about [patients'] health when it matters most," among other things.

489. Each Plaintiff and Class member accepted Theranos's and Walgreens' offer
for services, and thereby formed an express and/or implied contract. For those who
purchased services at a Walgreens store, their acceptance formed an express and/or
implied contract between themselves and both Walgreens and Theranos. For those who
purchased services at a Theranos-owned facility, their acceptance formed an express
and/or implied contract between themselves and Theranos.

490. In the context of consumer purchases of blood and clinical testing services,
even if Walgreens and Theranos had not represented and promised that their testing
services were ready-for-market and reliable (which they did), such attributes are implied
terms of the purchase contract. A reasonable consumer would not purchase blood or
clinical testing services unless such services were expected to be reliable.

491. Plaintiffs and the Class relied on Theranos's and Walgreens' promises and
covenants regarding Theranos testing services in agreeing to have their blood and urine
tested by Theranos.

492. Plaintiffs and the Class performed all of their obligations under their
contracts with Theranos and/or Walgreens. They each submitted to blood draws and/or
other clinical procedures. They each paid money for the services, either out of pocket or

through their health insurance or other collateral sources. Revenue from services 1 2 purchased at Walgreens stores were divided between Walgreens and Theranos.

3	493. Walgreens and Theranos breached their respective contracts with Plaintiffs			
4	and the Class by, inter alia: (1) failing to deliver testing services that were ready-for-			
5	market or, at least in some cases, even for legitimate testing purposes; (2) failing to			
6	deliver testing services and test results that were reliable or of the quality promised; (3)			
7	not ensuring that Theranos's equipment met its own and/or reasonable quality standards;			
8	(4) not ensuring that their services were tendered with reasonable care and workmanlike			
9	effort, including by failing to comply with applicable laws, regulations, and standards for			
10	laboratory testing services; and (5) failing to timely notify customers of the test results'			
11	unreliability and known inaccuracies.			
12	494. Each Class member did not receive the benefit of their bargain—including			
13	reliable test results.			
14	495. As a result of Defendants' breaches described above, Plaintiffs and the Class			
15	have suffered damages.			
16	496. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for			
17	below.			
18	SEVENTH CAUSE OF ACTION			
19	(Unjust Enrichment)			
20	497. Plaintiffs incorporate the substantive allegations contained in all prior and			
21	succeeding paragraphs as if fully set forth herein.			
22	498. Plaintiffs bring this claim on behalf of themselves and the Class against all			
23	Defendants, and as appropriate bring this claim in the alternative to their legal claims.			
24	499. Plaintiffs lost money as a result of Defendants' conduct alleged herein.			
25	500. Walgreens, Theranos, Balwani and Holmes were each unjustly enriched by			
26	their conduct alleged herein, including but not limited through revenues received in			
27	connection with Plaintiffs' and the Class members' Theranos tests, through development			
28	of their products, accumulation and storage of valuable patient information and usable			
	- 107 - SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT CASE NO. 2:16-CV-2138-HRH			

1	blood samples, and through additional business and revenues that Walgreens received by
2	virtue of having Wellness Centers in their stores.
3	501. All Defendants were unjustly enriched, including Holmes and Balwani, who
4	on information and belief personally received at least millions of dollars each as a direct
5	result of their personal conduct alleged herein, which conduct constituted a fundamental
6	part of Theranos's operations and business.
7	502. It would be inequitable and unjust for any of Walgreens, Theranos, Holmes,
8	or Balwani to retain the money that they have received by their conduct.
9	503. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for
10	below.
11	EIGHTH CAUSE OF ACTION
12	(Aiding and Abetting Fraud)
13	504. Plaintiffs incorporate the substantive allegations contained in all prior and
14	succeeding paragraphs as if fully set forth herein.
15	505. Plaintiffs bring this claim on behalf of themselves and the Class against
16	Defendant Walgreens.
17	506. Theranos, Holmes, and Balwani committed fraud resulting in injury to
18	Plaintiffs and the Class, as alleged herein. Walgreens' conduct alleged herein enabled,
19	substantially assisted, encouraged, and was a substantial factor in, the commission of such
20	fraud.
21	507. Walgreens knew that Theranos testing was not reliable and that consumers
22	should not be relying on Theranos testing in making health and treatment decisions.
23	508. Walgreens knew that the Edison technology was still-in-development and
24	not market-ready throughout the time the "tiny" blood draws were being administered.
25	509. Walgreens identified numerous red flags and concerns about Theranos
26	testing that put it on notice of the problems, but nevertheless made the deliberate choice to
27	partner with Theranos, offer Theranos testing to customers at its stores, administer blood
28	
1	

1 draws, and facilitate the transfer of blood samples and other clinical samples from 2 Walgreens customers to Theranos for use in research and product development.

3

510. Walgreens had actual knowledge of the truth and had access to more than 4 sufficient information to understand that Theranos tests were not reliable and were unsafe 5 for consumers, and that the purpose of the "tiny" blood draws was not and could not have 6 been legitimate blood testing. To the extent Walgreens lacked any more detailed 7 knowledge, it was by virtue of Walgreens' own deliberate choices and conduct in ignoring 8 the problems it identified, deliberately failing to follow up on the concerns and 9 information it had, and ceding to Theranos's requests to carry on without further 10 information being provided.

11 511. Walgreens had actual knowledge of measures that it could have taken to 12 prevent Walgreens clinics and marketing from being used to perpetrate fraud, to provide 13 consumers with accurate information, and to reduce the reach of Theranos's, Holmes' and 14 Balwani's fraudulent conduct, but nevertheless knowingly and deliberately decided not to 15 adopt such measures, and instead chose to maintain policies and practices that enabled and 16 assisted the fraud.

17 512. Before and during the commission of the fraud, Walgreens intended to aid 18 and abet, and did substantially assist, Theranos, Holmes, and Balwani in fraud perpetrated 19 on Plaintiffs and the Class members by, *inter alia*, marketing, promoting, and otherwise 20 treating Theranos testing as reliable and compliant with applicable laws and standards, 21 and portraying Edison and the "tiny" blood tests as market-ready, although Walgreens 22 knew and/or knowingly and deliberately failed to discover that this information was false, 23 by concealing material information about the reliability and safety of Theranos tests and 24 the unready state of Edison, by allowing Theranos tests to be sold and conducted in its 25 pharmacies, by administering blood draws, and by making available Walgreens 26 employees to facilitate the sale and conducting of Theranos testing services, and 27 transmission of blood samples from Walgreens customers to Theranos for use in research 28 and product development.

1	513. Walgreens' conduct alleged herein was knowing and intentional, and was				
2	carried out by Walgreens in order to benefit Walgreens, including in the form of ill-gotten				
3	revenues. Walgreens received revenue from assisting in the perpetration of fraud by				
4	Theranos, Holmes and Balwani, including through sales of Theranos tests and through				
5	increased sales of other Walgreens products to new and existing customers. Walgreens				
6	also benefited financially and reputationally as a result of being the first national retail				
7	store to provide direct-to-consumer testing services.				
8	514. Plaintiffs and the Class suffered actual damages as a result of Walgreens'				
9	conduct in aiding and abetting fraud.				
10	515. Walgreens' misconduct alleged herein was intentional, deliberate, and				
11	willful.				
12	516. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for				
13	below.				
14	NINTH CAUSE OF ACTION				
15	(Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c))				
16	517. Plaintiffs incorporate the substantive allegations contained in all prior and				
17	succeeding paragraphs as if fully set forth herein.				
18	518. Plaintiffs bring this claim on behalf of themselves and the Class against				
19	Defendants Walgreens, Theranos, Balwani and Holmes.				
20	519. 18 U.S.C. § 1962(c) makes it "unlawful for any person employed by or				
21	associated with any enterprise engaged in, or the activities of which affect, interstate or				
22					
	foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such				
23	foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity."				
23 24					
	enterprise's affairs through a pattern of racketeering activity."				
24	enterprise's affairs through a pattern of racketeering activity." 520. Theranos, Walgreens, Holmes, and Balwani are "persons" within the				
24 25	enterprise's affairs through a pattern of racketeering activity." 520. Theranos, Walgreens, Holmes, and Balwani are "persons" within the meaning of 18 U.S.C. § 1961(3).				
24 25 26	 enterprise's affairs through a pattern of racketeering activity." 520. Theranos, Walgreens, Holmes, and Balwani are "persons" within the meaning of 18 U.S.C. § 1961(3). 521. Theranos, Walgreens, Holmes, and Balwani together constitute an 				

522. The Clinic RICO Enterprise engaged in and affected interstate commerce
 within the meaning of 18 U.S.C. § 1962(c), including but not limited to commerce on the
 internet, and between residents of California, Arizona, and Pennsylvania.

4 The Clinic RICO Enterprise had an ongoing organization with an 523. 5 ascertainable structure, and functioned as a continuing unit with separate roles and 6 responsibilities. For example: Theranos concealed material information from consumers 7 and advertised Theranos testing services as revolutionary, ready-for-market, for legitimate 8 testing purposes, and reliable, when in fact its laboratories were staffed by inadequately 9 trained personnel, used improperly calibrated equipment, at least some of the "tests" were 10 not for legitimate testing purposes, and its test results were unreliable. Walgreens 11 concealed material information from consumers, promoted and agreed to assist in 12 promoting Theranos testing services to consumers, agreed to refrain from conducting any 13 oversight or rigorous investigation regarding Theranos or its facilities and equipment, 14 agreed to provide space for Theranos inside its stores to drive retail consumers toward its 15 services and administer blood draws, and agreed to make available Walgreens employees 16 who would facilitate the sale and performance of Theranos testing services. Holmes 17 agreed to falsely promote Theranos testing as reliable, ready-for-market, and for 18 legitimate blood testing purposes, and compliant with applicable laws and regulations, to 19 cover up internally known problems, to conceal material information from consumers, and 20 to dismiss, deny and downplay reported problems once Defendants' scheme began to 21 collapse. Balwani agreed to use consumer tests that were being falsely marketed as being 22 ready-for-market, in order to conduct research and product development and for other 23 undisclosed purposes, cover up internally known problems, conceal material information 24 from consumers, spread, repeat, and otherwise reinforce misleading representations and 25 omissions about Theranos testing, cover up quality control failures and falsify information 26 submitted to regulatory authorities, and to make every effort to prevent Defendants' 27 scheme from being reported by employees or otherwise discovered.

524. At all relevant times, Defendants operated, controlled, or managed the
 Clinic RICO Enterprise, and profited from the Clinic RICO Enterprise. Defendants were
 responsible for the content of all marketing, advertisements, and other public-facing
 representations regarding Theranos, and for the material omissions alleged herein.

5 525. The Clinic RICO Enterprise has had a common purpose: to perpetrate fraud, 6 and in particular to market and sell testing services that were unreliable and not ready-for-7 market to unwitting consumers, obtain under false pretenses blood and other clinical 8 samples for research and product development purposes, and assure customers and the 9 public that the tests were reliable—thereby becoming the primary participants in the new, 10 profitable, national market for direct-to-consumer testing services—while concealing that 11 Theranos's testing services were unreliable, unsafe, at least in some cases not for 12 legitimate testing purposes, and should not be used by consumers to make decisions about 13 their health.

14 526. Defendants conducted and participated in the conduct of the affairs of the 15 Clinic RICO Enterprise through a pattern of racketeering activity, beginning at the latest 16 in 2013, and continuing until at least 2016, and consisting of numerous and repeated 17 violations of the federal mail and wire fraud statutes, which prohibit the use of any 18 interstate or foreign mail or wire facility for the purpose of executing a scheme to defraud, 19 in violation of 18 U.S.C. §§ 1341 and 1343. Violations of the federal mail and wire fraud 20 included, but were not limited to, to: (a) the specific false statements in press releases and 21 other media statements alleged herein (the time and place of which are identified herein); 22 (b) the other specific, pervasive misrepresentations, alleged herein, that Walgreens and 23 Theranos made on their respective websites and in electronic advertisements leading up to 24 and during the time the services were being offered; and (c) the transmission of purported 25 Edison "test results," which were used to perpetuate the mistaken belief that the "tiny" 26 blood draws were for legitimate testing purposes.

27 527. All Defendants devised and furthered the scheme to defraud by use of the28 mail, telephone, and internet, and caused to be transmitted, by means of mail and wire

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 115 of 132

communications traveling in interstate commerce, writing(s), and/or signal(s), including
 the Walgreens and Theranos websites, online, mailed, televised, or other advertising, press
 releases, and Theranos "test results."

528. The conduct alleged herein was part of a scheme that Walgreens, Theranos,
Balwani and Holmes formulated to defraud Plaintiffs and the Class, to receive financial
and other benefits, and to make Theranos and Walgreens the primary participants in the
new, profitable, national market for direct-to-consumer testing services. Defendants
perpetrated this scheme with the specific intent to deceive and defraud Plaintiffs and the
Class, and Defendants did deceive and defraud Plaintiffs and the Class.

10 529. These acts of racketeering spanned at least three years and are not isolated
11 or long-ago completed events. Through the conduct of the Clinic RICO Enterprise,
12 Defendants have fraudulently sold at least many thousands of unreliable and dangerous
13 Theranos tests to consumers.

14 530. As a foreseeable and natural consequence of Defendants' scheme,
15 Defendants injured Plaintiffs and the Class, including but not limited to in the form of
16 their submission to and payment, out-of-pocket and/or through their health insurance or
17 other collateral sources, for testing services that were unreliable, did not hold the
18 promised value and were dangerous when used for their advertised purposes, and in the
19 form of steps taken and not taken by Plaintiffs and the Class in reliance upon the test
20 results and the corresponding monetary and other damages therefrom.

531. Defendants' acts also present a threat of continued racketeering activity,
including but not limited to insofar as the Clinic RICO Enterprise has not issued formal
invalidation notices for all Theranos test results.

- 24 532. On behalf of themselves and the Class, Plaintiffs seek relief as prayed for25 below.
- 26
- 27
- 28

2

1

<u>TENTH CAUSE OF ACTION</u> (Violation of California Business & Professions Code §§ 17200, *et seq.*)

533. Plaintiffs incorporate the substantive allegations contained in all prior and
succeeding paragraphs as if fully set forth herein.

5 534. To the extent this claim is based directly on affirmative misrepresentations,
6 it is brought by Plaintiff A.R. on behalf of himself and the California Subclass against
7 Defendants Theranos and Walgreens. Otherwise, Plaintiff A.R. brings this claim on
8 behalf of himself and the California Subclass against all Defendants.

9 535. California's Unfair Competition Law ("UCL") defines unfair business
10 competition to include any "unfair," "unlawful," or "fraudulent" business act or practice.

Defendants' respective unlawful, unfair, and fraudulent business acts and 536. 11 practices are described throughout this Complaint and include, but are not limited to: (a) 12 Theranos and Walgreens making affirmative misrepresentations as summarized in the 13 First Cause of Action and described above; (b) all Defendants concealing material 14 information as summarized in the First Cause of Action and described above; and (c) all 15 Defendants marketing and selling unreliable Theranos tests that they knew to be 16 unreliable and/or which they failed to take sufficient steps to ensure the reliability of, and 17 encouraging consumers to rely on such tests to make decisions about their health and 18 treatment. 19

20 537. Defendants' conduct alleged herein constitutes unlawful, unfair, and
21 fraudulent business practices.

538. Walgreens, Theranos, Balwani and Holmes have violated the "fraudulent"
prong of the UCL through their respective conduct, misrepresentations, and omissions
alleged herein. These Defendants' misrepresentations and omissions were pervasive.
Their respective misrepresentations and omissions are likely to deceive and have a
tendency to deceive reasonable consumers, and have deceived Plaintiff A.R. and the
California Subclass. The facts misrepresented and concealed by Walgreens, Theranos,
Balwani and Holmes would be material to a reasonable consumer.

539. Walgreens, Theranos, Balwani and Holmes had exclusive and superior
 knowledge regarding the material information that they concealed.

540. Plaintiff A.R. and the California Subclass reasonably relied upon
Walgreens' and Theranos's misrepresentations and on all of the Defendants' omissions to
their detriment.

541. Plaintiff A.R. specifically relied on the omissions by Walgreens, Theranos,
Holmes, and Balwani alleged herein. Had he known the information that was concealed,
he would not have submitted to Theranos testing.

9 542. All of the Defendants have also violated the "unfair" prong of the UCL
10 through their misconduct alleged herein, under both the *Cel-Tech* "tethering" test⁹⁵ and
11 "balancing" test.

543. Defendants' conduct alleged herein violates California public policy,
including but not limited to as such policy is reflected in California's Consumer Legal
Remedies Act (Cal. Civ. Code § 1750, *et seq.*), Cal. Civ. Code § 1710, Cal. Comm. Code
§§ 2314-2315, and in California common law.

16 544. Defendants' conduct alleged herein is immoral, unethical, oppressive, 17 unscrupulous, and substantially injurious to consumers. Defendants have engaged in a 18 years-long, pervasive scheme of: (a) marketing and selling unreliable Theranos tests and 19 encouraging consumers to rely on those tests in making decisions about their health; (b) 20 misrepresenting the reliability and other details about Theranos testing services, including 21 that they were ready-for-market when that was not the case; and (c) concealing from 22 consumers material information about the reliability of Theranos tests and the compliance 23 of Theranos testing with applicable laws and standards. This conduct is immoral, 24 unethical, and unscrupulous. Moreover, Defendants' conduct is oppressive and 25 substantially injurious to consumers. Among other things, as a direct result of 26 Defendants' conduct alleged herein, Plaintiff A.R. and the California Subclass have paid

- 27
- 28

⁹⁵ Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co., 20 Cal. 4th 163 (1999).

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 118 of 132

money and submitted to Theranos testing that was not only unreliable, but put their health
 and lives at risk. There is no countervailing utility to Defendants' conduct, and certainly
 none that outweighs the substantial detriment to Plaintiff A.R. and the California
 Subclass.

5 Defendants' conduct is also unlawful in that it violates Civil RICO; 545. 6 California's False Advertising Law, (Cal. Bus. & Prof. Code §§ 17500, et seq.), 7 California's Consumer Legal Remedies Act, (Cal. Civ. Code § 1750, et seq.), statutory 8 deceit, (Cal. Civ. Code § 1710), the Arizona Racketeering Act, (A.R.S. §§ 13-2301-04), 9 and common law fraud, battery, medical battery, negligence, and negligent 10 misrepresentation, which not only result in liability as to the individual causes of action, 11 they also provide a basis for a finding of liability under the UCL. 12 Furthermore, Defendants' conduct violates declared legislative policies as 546. 13 set forth by the federal government in 40 C.F.R. § 600.307(a)(ii)(A); 40 C.F.R. § 600.302-14 08(b)(4) and 16 C.F.R. § 259.2(a). 15 As a result of Defendants' violations of California's Unfair Competition 547. 16 Law, Plaintiff A.R. and the California Subclass have suffered actual damages, including 17 the loss of money and/or property in exchange for testing they would not, with knowledge

18 of the truth, have allowed to be performed, and which is unreliable, not worth the

promised value, and dangerous, and other money they have spent out-of-pocket as a result
of the unreliable test results they received.

548. Pursuant to California Business and Professions Code §§ 17200 and 17203,
on behalf of himself and the California Subclass, Plaintiff A.R. seeks relief as prayed for
below.

- 24
- 25

<u>ELEVENTH CAUSE OF ACTION</u> (Violation of California Business & Professions Code §§ 17500, *et seq.*)

26 549. Plaintiffs incorporate the substantive allegations contained in all prior and
27 succeeding paragraphs as if fully set forth herein.

1 550. To the extent this claim is based directly on affirmative misrepresentations, 2 it is brought by Plaintiff A.R. on behalf of himself and the California Subclass against 3 Defendants Theranos and Walgreens. Otherwise, Plaintiff A.R. brings this claim on 4 behalf of himself and the California Subclass against all Defendants.

5 California Bus. & Prof. Code § 17500 (the "FAL") states: "It is unlawful 551. 6 for any ... corporation ... with intent directly or indirectly to dispose of real or personal 7 property ... to induce the public to enter into any obligation relating thereto, to make or 8 disseminate or cause to be made or disseminated ... from this state before the public in 9 any state, in any newspaper or other publication, or any advertising device, ... or in any 10 other manner or means whatever, including over the Internet, any statement ... which is 11 untrue or misleading, and which is known, or which by the exercise of reasonable care 12 should be known, to be untrue or misleading."

13 552. Defendants have committed acts of untrue and misleading advertising by 14 disseminating materially misleading and deceptive information (Theranos and 15 Walgreens), and omitting material information (all Defendants), as alleged herein, for 16 purposes of inducing consumers to purchase and submit to Theranos testing services.

17

553. Defendants' misrepresentations and omissions were pervasive.

18 554. Defendants' respective misrepresentations and omissions are likely to 19 deceive and have a tendency to deceive reasonable consumers, and have deceived Plaintiff 20 A.R. and the California Subclass. The facts misrepresented and concealed by Walgreens, 21 Theranos, Balwani and Holmes would be material to a reasonable consumer. A 22 reasonable person would attach importance to them and would be induced to act on the 23 information in making decisions.

24

555. The Defendants had exclusive and superior knowledge regarding the 25 material information that they concealed.

26 556. Plaintiff A.R. and the California Subclass reasonably relied on Walgreens' 27 and Theranos's misrepresentations and on all of the Defendants' omissions to their 28 detriment.

1	557. Plaintiff A.R. specifically relied on the omissions by Walgreens, Theranos,			
2	Holmes, and Balwani alleged herein. Had he known the information that was concealed,			
3	he would not have submitted to Theranos testing.			
4	558. As a result of Defendants' violations, Plaintiff A.R. and the California			
5	Subclass have suffered actual damages, including the loss of money and/or property,			
6	received by the Defendants, in exchange for testing they would not, with knowledge of the			
7	truth, have allowed to be performed, and which is unreliable and dangerous, and other			
8	money they have spent out-of-pocket as a result of the unreliable test results they			
9	received.			
10	559. On behalf of himself and the California Subclass, Plaintiff A.R. seeks relief			
11	as prayed for below.			
12	TWELFTH CAUSE OF ACTION			
13	(Violation of California Civil Code §§ 1750 et seq.)			
14	560. Plaintiffs incorporate the substantive allegations contained in all prior and			
15	succeeding paragraphs as if fully set forth herein.			
16	561. To the extent this claim is based directly on affirmative misrepresentations,			
17	it is brought by Plaintiff A.R. on behalf of himself and the California Subclass against			
18	Defendants Theranos and Walgreens. Otherwise, Plaintiff A.R. brings this claim on			
19	behalf of himself and the California Subclass against all Defendants.			
20	562. Walgreens, Theranos, Holmes, and Balwani are "persons" under Cal. Civ.			
21	Code § 1761(c).			
22	563. Plaintiff A.R. and the members of the California Subclass are "consumers"			
23	under Cal. Civ. Code § 1761(d).			
24	564. Plaintiff A.R. and each California Subclass member's purchase of Theranos			
25	tests constitute "transactions" under Cal. Civ. Code § 1761(e).			
26	565. Theranos tests are "goods" and/or "services" under Cal. Civ. Code § 1761			
27	(a-b).			
28				

1 566. Plaintiff A.R. and the California Subclass members purchased Theranos 2 tests for personal, family, and household purposes within the meaning of California Civil 3 Code § 1761(d).

4 567. As alleged herein, Walgreens and Theranos have engaged in unfair or 5 deceptive acts or practices that violated California's Consumer Legal Remedies Act 6 ("CLRA"), Cal. Civ. Code § 1750, et seq. by, among other things, representing that 7 Theranos testing services have characteristics, uses, benefits, and qualities which they do 8 not have; representing that Theranos testing services are of a particular standard, quality, 9 and grade when they are not; and advertising Theranos testing services with the intent not 10 to sell them as advertised. Cal Civ. Code § 1770 (5), (7), and (9).

11 568. Moreover, Walgreens, Theranos, Holmes, and Balwani actively failed to 12 disclose and concealed material facts about Theranos tests, and otherwise engaged in 13 activities with a tendency or capacity to deceive, as described herein.

14

569. Defendants' misrepresentations and omissions were pervasive.

15 Defendants' CLRA violations materially affected the decisions of Plaintiff 570. 16 A.R. and the California Subclass members. Plaintiff A.R. and the California Subclass 17 members reasonably relied upon Defendants' respective material misrepresentations and 18 omissions, and would not have purchased Theranos tests or submitted their blood for 19 testing to Defendants had they known the truth.

20 Plaintiff A.R. specifically relied on the omissions by Walgreens, Theranos, 571. 21 Holmes, and Balwani alleged herein. Had he known the information that was concealed, 22 he would not have submitted to Theranos testing.

23

As a result of the CLRA violations described herein, Plaintiff A.R. and the 572. 24 California Subclass have suffered actual damages.

25 573. On behalf of himself and the California Subclass, Plaintiff A.R. seeks attorneys' fees and costs. 26

27 In accordance with California Civil Code § 1782(a), Theranos, Walgreens 574. 28 (including Walgreen Arizona Drug Company), Balwani, and Holmes were sent notice of

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 122 of 132

their CLRA violations by certified mail, return receipt requested. (See Ex. 27 hereto).

2 Each of these Defendants has failed to provide appropriate relief for their CLRA

3 violations within 30 days of these notification letters. On behalf of himself and the

4 California Subclass, Plaintiff seeks actual and punitive damages for the CLRA violations 5 alleged herein.

6

1

575. Venue is proper under California Civil Code § 1780(d) because Defendants 7 do business in this county and a substantial portion of the transactions at issue occurred in 8 this county. Plaintiffs' declaration establishing that this Court has proper venue for this 9 action was attached as Exhibit Q to Plaintiffs' Consolidated Class Action Complaint (Dkt. 10 88).

- 11
- 12

THIRTEENTH CAUSE OF ACTION (California Civil Code §§ 1709-1710 - Deceit)

13 Plaintiffs incorporate the substantive allegations contained in all prior and 576. 14 succeeding paragraphs as if fully set forth herein.

15 To the extent this claim is based directly on affirmative misrepresentations, 577. 16 it is brought by Plaintiff A.R. on behalf of himself and the California Subclass against 17 Defendants Theranos and Walgreens. Otherwise, Plaintiff A.R. brings this claim on 18 behalf of himself and the California Subclass against all Defendants.

19 California Civil Code § 1709 provides that "[o]ne who willfully deceives 578. 20 another with intent to induce him to alter his position to his injury or risk, is liable for any 21 damage which he thereby suffers."

22 California Civil Code § 1710 defines "deceit" as (1) The suggestion, as a 579. 23 fact, of that which is not true, by one who does not believe it to be true; (2) The assertion, 24 as a fact, of that which is not true, by one who has no reasonable ground for believing it to 25 be true; (3) The suppression of a fact, by one who is bound to disclose it, or who gives 26 information of other facts which are likely to mislead for want of communication of that 27 fact; or, (4) A promise, made without any intention of performing it.

1	580. The material misrepresentations by Theranos and Walgreens and the
2	omissions by Walgreens, Theranos, Holmes, and Balwani alleged herein constitute deceit
3	under California Civil Code § 1710. Defendants' misrepresentations and omissions were
4	pervasive. Plaintiff A.R. and the California Subclass have reasonably relied on the
5	material misrepresentations and omissions made by Defendants. As a result, Plaintiff
6	A.R. and the California Subclass have suffered actual damages.
7	581. Plaintiff A.R. specifically relied on the omissions by Walgreens, Theranos,
8	Holmes, and Balwani alleged herein. Had he known the information that was concealed,
9	he would not have submitted to Theranos testing.
10	582. Each Defendant's misconduct alleged herein was intentional, deliberate, and
11	willful, and was perpetrated by the Defendants with the intent to, inter alia, cause Plaintiff
12	A.R. and the California Subclass to rely on Theranos's unreliable test results in making
13	decisions about their health and treatment.
14	583. On behalf of himself and the California Subclass, Plaintiff A.R. seeks relief
15	as prayed for below.
15 16	as prayed for below. FOURTEENTH CAUSE OF ACTION
16	FOURTEENTH CAUSE OF ACTION
16 17	FOURTEENTH CAUSE OF ACTION (Medical Battery)
16 17 18	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and
16 17 18 19	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein.
16 17 18 19 20	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and
16 17 18 19 20 21	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and the Edison Subclass against Defendants Walgreens and Theranos.
 16 17 18 19 20 21 22 	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and the Edison Subclass against Defendants Walgreens and Theranos. 586. Walgreens and Theranos are, and acted as, medical providers in conducting,
 16 17 18 19 20 21 22 23 	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and the Edison Subclass against Defendants Walgreens and Theranos. 586. Walgreens and Theranos are, and acted as, medical providers in conducting, overseeing, and assisting with the administration of the "tiny" blood draws and "tests"
 16 17 18 19 20 21 22 23 24 	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and the Edison Subclass against Defendants Walgreens and Theranos. 586. Walgreens and Theranos are, and acted as, medical providers in conducting, overseeing, and assisting with the administration of the "tiny" blood draws and "tests" conducted on Plaintiffs B.P., R.C., and S.J. and the Edison Subclass.
 16 17 18 19 20 21 22 23 24 25 	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and the Edison Subclass against Defendants Walgreens and Theranos. 586. Walgreens and Theranos are, and acted as, medical providers in conducting, overseeing, and assisting with the administration of the "tiny" blood draws and "tests" conducted on Plaintiffs B.P., R.C., and S.J. and the Edison Subclass. 587. The "tiny" blood draws conducted on Plaintiffs B.P., R.C., and S.J. and the
 16 17 18 19 20 21 22 23 24 25 26 	FOURTEENTH CAUSE OF ACTION (Medical Battery) 584. Plaintiffs incorporate the substantive allegations contained in all prior and succeeding paragraphs as if fully set forth herein. 585. Plaintiffs B.P., R.C., and S.J. bring this claim on behalf of themselves and the Edison Subclass against Defendants Walgreens and Theranos. 586. Walgreens and Theranos are, and acted as, medical providers in conducting, overseeing, and assisting with the administration of the "tiny" blood draws and "tests" conducted on Plaintiffs B.P., R.C., and S.J. and the Edison Subclass. 587. The "tiny" blood draws conducted on Plaintiffs B.P., R.C., and S.J. and the Edison Subclass, and research and experimentation conducted of the samples collected,

Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 124 of 132

- 1 588. Defendants Walgreens and Theranos both engaged in non-consensual 2 medical procedures, as alleged herein, that resulted in harmful and offensive contact with 3 Plaintiffs B.P., R.C., and S.J., and the members of the Edison Subclass.
- 4 589. Plaintiffs B.P., R.C., and S.J., and all of the Edison Subclass members each 5 submitted to one or more so-called "tiny" blood draws at the Wellness Centers. Pursuant 6 to these blood draws, a needle was stuck into their bodies, penetrating their skin and 7 tissue, and blood was drawn from their bodies.
- 8

The vast majority of these "tiny" blood draws occurred in Walgreens stores, 590. 9 and a small portion of them occurred in Theranos Wellness Centers.

10 For the Edison Subclass member "tiny" blood draws that were conducted at 591. 11 Walgreens stores, the blood draws were administered by a Walgreens employee or an 12 individual working for both Walgreens and Theranos, often with the assistance and in the 13 presence of a Theranos employee. In all such cases, *both* Walgreens *and* Theranos did 14 acts that resulted in the blood draws and that encouraged the blood draws—including, but 15 not limited to, through their pervasive marketing and encouragement of same, through 16 their provision of the space, infrastructure, support, personnel, and equipment used for the 17 blood draws and related services, and through their direct assistance and involvement with 18 the blood draws and their in-store interactions with the subjects. Both Walgreens and 19 Theranos, including through their respective employees, did acts that caused the non-20 consensual "tiny" procedures on each of these subjects, and both companies caused each 21 to occur.

22 For the "tiny" blood draws that were conducted at Theranos Wellness 592. 23 Centers, the blood draws were administered by Theranos employees.

24 593. The acts engaged in by Walgreens and Theranos that caused the non-25 consensual "tiny" procedures were all done intentionally, and also with the intent and 26 knowledge that they would result in harmful and offensive contact.

- 27
- 28

1 594. The non-consensual "tiny" procedures alleged herein that Plaintiffs B.P., 2 R.C., and S.J., and the Edison Subclass were subjected to were harmful and offensive. A 3 reasonable person in their situation would have been offended under the circumstances. 4 Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members did not 595. 5 consent to these procedures. Any ostensible "consent" they provided was vitiated under 6 the circumstances and not effective. 7 Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members agreed to 596. 8 submit to these procedures but, as alleged herein, they each did so under false pretenses 9 and under a substantial mistaken belief as to the essential nature and purpose of these 10 procedures. Moreover, as alleged herein, their consent was procured by fraud, 11 misrepresentations, and material omissions by Theranos and Walgreens. 12 Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members reasonably 597. 13 believed, contemporaneously when they agreed to submit to these "tiny" procedures, that 14 the essential nature and purpose of such procedures was legitimate blood testing. 15 Theranos and Walgreens both knew contemporaneously that Plaintiffs B.P., 598. 16 R.C., and S.J.'s, and the Edison Subclass members agreed to submit to these procedures 17 under a substantial mistaken belief as to their essential nature and purpose. Theranos and 18 Walgreens both knew that these consumers mistakenly and reasonably believed that the 19 essential nature and purpose of these "tiny" procedures was legitimate blood testing. 20 599. As alleged herein, pervasive affirmative misrepresentations by Theranos and 21 Walgreens, in the time leading up to and throughout the time these "tiny" procedures were 22 being administered, substantially contributed to Plaintiffs B.P., R.C., and S.J., and the 23 Edison Subclass members' mistaken belief regarding the essential nature and purpose. 24 This included a pervasive joint marketing campaign carried out by Theranos and 25 Walgreens throughout the relevant time period, that encouraged consumers to pay for and submit to "tiny" blood draws for the very purpose of blood testing. The fundamental 26 27 premise of this campaign was the portrayal of the "tiny" blood draws and Edison, and of 28

the services generally, as market-ready and reliable and being for legitimate blood testing
 purposes.

3 600. As alleged herein, also substantially contributing to Plaintiffs' B.P., R.C., 4 and S.J., and the Edison Subclass members' mistaken belief regarding the essential nature and purpose of these "tiny" procedures was the entire context, nature, design, and 5 6 infrastructure of the Wellness Centers in which the "tiny" blood draws were conducted, 7 which both Theranos and Walgreens designed, and which were intentionally designed by 8 Theranos and Walgreens to give the impression, and which did give the clear impression 9 to consumers, that the blood draws being conducted there were for legitimate blood 10 testing purposes.

11 601. As alleged herein, the concealment of material information by Theranos and 12 Walgreens also substantially contributed to the Edison Subclass members' mistaken belief 13 regarding the essential nature and purpose of these "tiny" procedures. Throughout the 14 relevant time period, even though both Walgreens and Theranos knew that the subjects of 15 these "tiny" blood draws were agreeing to submit to them under a substantial mistaken 16 belief as to the essential nature and purpose, and were thus going to be subject to non-17 consensual medical procedures in a harmful and offensive way, neither Walgreens nor 18 Theranos took any steps to correct this mistaken belief or to avoid the harmful and 19 offensive contact. To the contrary, both companies intentionally concealed material 20 information about Edison and the "tiny" blood draws, and actively encouraged, caused, 21 and assisted these procedures.

Both Walgreens and Theranos intentionally concealed and failed to disclose, *inter alia*: the truth about the unready Edison technology; that the essential nature and
purpose of the "tiny" blood draws was not, and could not have been, legitimate blood
testing; and the true essential nature and purposes of the "tiny" blood draws.

26 603. The "tiny" blood draws were not intended by Walgreens and Theranos to
27 provide reliable blood test results (i.e., "legitimate blood testing").

1 604. The essential nature and purpose of the "tiny" blood draws was not 2 legitimate blood testing and, indeed, could not have been legitimate blood testing because, 3 as alleged herein and unbeknownst to the subjects at the time they gave their consent, the 4 Edison technology was still in development, still in prototype, not ready-for-market, and 5 nowhere near in a position to serve that purpose. Theranos and Walgreens each knew this 6 to be the case throughout the entire time "tiny" blood draws were being conducted at 7 Walgreens and Theranos facilities. To the extent Walgreens lacked any more detailed 8 knowledge, it was by virtue of its own deliberate choices to ignore and/or avoid such 9 details.

605. As alleged in more detail herein, the true essential nature and purposes of
the "tiny" blood draws was to assist efforts to research and develop the still-indevelopment Edison technology, expedite the narrative of Edison as a "disruptive"
technology in the industry, and woo and appease investors, potential investors, and coinvestors by creating the false impression that Edison was a market-ready, breakthrough
technology.

16 606. Theranos and Walgreens knew, but Plaintiffs B.P., R.C., and S.J., and the
17 Edison Subclass members could not reasonably have known, the true nature and purposes
18 of these "tiny" procedures.

19 607. Any purported consent that Plaintiffs B.P., R.C., and S.J. and the Edison
20 Subclass members gave for these procedures was given under a substantial mistake as to
21 their essential nature and purpose, was induced by fraud, concealment, and
22 misrepresentations, and was not effective.

23 608. Plaintiffs B.P., R.C., and S.J., and Edison Subclass members did not consent
24 to be subjects for experimentation, research, product development, or other undisclosed
25 objectives.

26 609. Theranos and Walgreens willfully and tortiously battered Plaintiffs B.P.,
27 R.C., and S.J., and the Edison Subclass members.

610. Theranos and Walgreens willfully and tortiously experimented on Plaintiffs B.P., R.C., and S.J., and the Edison Subclass members.

611. Moreover, Theranos and Walgreens each aided and abetted the other in
committing the medical battery through their conduct alleged herein. Both had actual
knowledge of the harmful and offensive "tiny" procedures that were occurring, and both
took steps that enabled, substantially assisted, encouraged, and were a substantial factor
in, the other carrying out these procedures and causing these procedures to occur. Both
Theranos and Walgreens are directly liable for medical battery as to the Edison Subclass
members, and are also liable as aiders and abettors.

612. Theranos and Walgreens knew or should have known that their conduct
alleged herein regarding the "tiny" blood draws, including but not limited to sticking them
with needles, drawing their blood, and willfully experimenting upon Plaintiffs and the
Edison Subclass under false pretenses and without obtaining their consent, would be an
affront to the dignity of Plaintiffs B.P., R.C., S.J., and the Edison Subclass members as
human beings.

16 613. Theranos's and Walgreens' misconduct alleged herein was intentional,17 deliberate, and willful.

18 614. Plaintiffs B.P., R.C., and S.J., and the members of the Edison Subclass were19 harmed and injured by this conduct.

615. As a foreseeable, proximate, and direct result of Theranos's and Walgreens'
conduct, Plaintiffs B.P., R.C., and S.J. and the Edison Subclass members each have
suffered a medical battery and have been damaged, including as otherwise set forth in this
Complaint, and by invasion of their privacy and bodily integrity without their consent,
severe emotional stress and anxiety, and harm to their human dignity and corresponding
damages therefrom.

26 616. On behalf of themselves and the Edison Subclass, Plaintiffs B.P., R.C., and
27 S.J. seek relief as prayed for below.

28

1

1	VII. <u>PRAYER FOR RELIEF</u>			
2	WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class			
3	and Subclasses, demand judgment against and general and special relief from Defendants			
4	as follows:			
5	1. An order certifying that the action may be maintained as a class action under			
6	Federal Rule of Civil Procedure 23 as defined herein and appointing Plaintiffs and Interim			
7	Co-Lead Counsel to represent the defined Class and Subclasses;			
8	2. An order requiring Defendants to promptly and adequately notify absent			
9	Class members regarding the problems with, and unreliability of, their Theranos tests;			
10	3. An order awarding Plaintiffs and the Class damages, special damages,			
11	general damages, and restitution;			
12	4. An order requiring Defendants to disgorge all profits and compensation			
13	improperly obtained by Defendants as a result of such acts and practices declared by this			
14	Court to be an unlawful;			
15	5. An order requiring Defendants to pay punitive, exemplary, and treble			
16	damages;			
17	6. An order requiring Defendants to pay attorneys' fees, costs, and expenses;			
18	7. An order requiring Defendants to pay pre-judgment and post-judgment			
19	interest; and			
20	8. Such other and further relief as the Court deems appropriate.			
21	VIII. <u>DEMAND FOR JURY TRIAL</u>			
22	Plaintiffs hereby demand a trial by jury for all claims so triable.			
23	DATED this 20th day of October, 2017.			
24				
25				
26				
27				
28				

	Case 2:16-cv-02138-HRH	Document 159	Filed 10/20/17	Page 130 of 132
1		D		
1		By:	: <u>s/ Roger N. He</u> l	ller
2			chael Walter Sol ger N. Heller (<i>pr</i>	ool (pro hac vice)
3		Me	lissa Gardner (<i>p</i> EFF CABRASER H	ro hac vice)
4		& I	BERNSTEIN LLP	
5			barcadero Ctr W 5 Battery St, 29th	
6		Sar	n Francisco, CA ephone (415) 95	94111
7		Fac	simile: (415) 95	6-1008
8			ail: msobol@lch ail: rheller@lch	
9		Em	ail: mgardner@	lchb.com
10			rk D. Samson	
11		KE	ristopher Graver LLER ROHRBACH	K LLP
12)1 North Central Denix, AZ 85012	Ave., Suite 1400
		Tel	ephone: (601) 24 csimile: (602) 24	48-0088
13				kellerrohrback.com
14		Lyı	nn Lincoln Sarko	o (pro hac vice)
15			David Copley Etchen Freeman	Cappio (<i>pro hac vice</i>)
16		KE	LLER ROHRBACK	K LĹP
17		Sea	01 3rd Ave., Ste. attle, WA 98101	
18			ephone: (206) 62 simile: (206) 62	
19		Em	ail: lsarko@kell	
20				ellerrohrback.com
21		Inte	erim Co-Lead Pl	laintiffs' Counsel
22				
23				
24				
25				
26				
27				
28				
20				SECOND AMENDED CONS

	Case 2:16-cv-02138-HRH	Document 159	Filed 10/20/17	Page 131 of 132		
1	Joseph G. Sauder Matthew D. Schelkopf					
2	Joseph B. Kenney MCCUNEWRIGHT LLP					
3	555 Lancaster Avenue Berwyn, PA 19312					
4		Tel Em	ephone: (610) 20 ail: jgs@mccune ail: mds@mccun	00-0580 ewright.com		
5		Em Em	ail: mds@mccur ail: jbk@mccur	newright.com ewright.com		
6		La	rence D. King	-		
7		KA 35(PLAN FOX & I Sansome Street	KILSHEIMER LLP , Suite 400		
8		Pho	n Francisco, CA one: 415-772-470	94104 00		
9			k: 415-772-4707 ail: lking@kapla	anfox.com		
10		Ada	ditional Plaintiff.	s' Counsel		
11						
12						
13						
14						
15						
16						
17						
18						
19 20						
20 21						
21						
22						
23 24						
24 25						
23 26						
20 27						
28						
_0				SECOND AMENDED CONSOLI		
		- 1	29 -	CLASS ACTION COM CASE NO. 2:16-CV-21		

	Case 2:16-cv-02138-HRH Document 159 Filed 10/20/17 Page 132 of 132
1	
2	CERTIFICATE OF SERVICE
3	I hereby certify that on October 20, 2017, I electronically transmitted the foregoing
4	document to the Clerk's Office using the CM/ECF System for filing and transmittal of a
5	Notice of Electronic Filing to all CM/ECF registrants.
6	By: <u>s/Roger N. Heller</u>
7	Roger N. Heller
8	
9	
10	
11	
12	
13	1376272.4
14	
15	
16	
17	
18 19	
19 20	
20 21	
22	
23	
24	
25	
26	
27	
28	
	- 130 - SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT CASE NO. 2:16-CV-2138-HRH