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IN THE SUPERIOR COURT FOR THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, *ex rel.* MARK BRNOVICH, Attorney General, Plaintiff, v. THERANOS, INC., a Delaware Corporation, Defendant.	Case No. _____ **CIVIL COMPLAINT**

Plaintiff, State of Arizona, *ex rel.* Mark Brnovich, Attorney General (the "State"), alleges the following:

PARTIES AND JURISDICTION

1. Plaintiff is the State of Arizona, *ex rel.* Mark Brnovich, who is authorized to bring this action under the Arizona Consumer Fraud Act, Ariz. Rev. Stat. ("A.R.S.") §§ 44-1521 – 44-1534 (the "Consumer Fraud Act").

2. Theranos is a Delaware corporation with its corporate headquarters at 1701 Page Mill Road, Palo Alto, California 94304.

3. At all relevant times, Theranos ("Defendant") did business in Arizona by marketing, selling, promoting, and providing its laboratory tests and services to Arizona

consumers.

4. This Court has jurisdiction over the Complaint and the parties.

5. Venue is proper in Maricopa County, Arizona.

ALLEGATIONS

Background

6. Theranos is a consumer healthcare technology company that offered hundreds of different types of blood tests to consumers in Arizona.

7. Theranos gained popularity and sales through marketing its proprietary laboratory machines, which it referred to as "Edison" devices.

8. Theranos represented that its Edison devices could run blood tests using a few drops of blood obtained via a finger-prick, rather than the typical method of using multiple vials of blood obtained via a venous draw from the arm.

9. Theranos had laboratories in Newark, California and Scottsdale, Arizona.

10. In or about September 2013, Theranos began offering laboratory tests to Arizona consumers.

11. Until June 2016, Theranos ran over 40 testing centers housed in Walgreens stores in the Phoenix area.

12. Until October 2016, Theranos ran four non-Walgreens testing centers in the Phoenix area.

13. Consumers could go to those testing centers, get their blood tested, and receive blood test results, even without a doctor's order.

14. Doctors also referred consumers to Theranos for testing.

15. Theranos conducted some blood tests using commercially available laboratory machines.

16. Theranos conducted other blood tests using its proprietary laboratory machines, the Edison devices.

17. Theranos also conducted some blood tests using proprietary, modified protocols on commercially available laboratory machines.

Theranos' Advertising

18. In the course of advertising and selling blood tests to Arizona consumers, Theranos misrepresented the method of its blood testing.

19. Theranos advertised that most or all of its testing would be done using the finger-prick method and the Edison devices, or another proprietary method such as conducting tests using modified protocols on commercially available devices.

20. Theranos' statements and representations that Theranos conducted most or all of its testing via the finger-prick or other proprietary method were false and misleading.

21. Theranos did not conduct most or all of its testing via the finger-prick or other proprietary method.

22. In the course of advertising and selling blood tests to Arizona consumers, Theranos misrepresented the accuracy of its blood testing.

23. Theranos advertised that its tests were of the highest levels of accuracy.

24. Theranos' advertisements about the accuracy of its tests were false and misleading.

25. Theranos systemically failed to ensure the accuracy of thousands of tests it conducted at its laboratories.

26. In the course of advertising and selling blood tests to Arizona consumers, Theranos misrepresented the reliability of its blood testing.

27. Theranos advertised that the reliability of its tests was routinely demonstrated through continuous proficiency testing that was required by federal regulations.

28. Theranos' advertisements about the reliability of its tests were false and misleading.

29. Theranos systematically failed to ensure the reliability of thousands of tests it conducted at its laboratories.

30. Because of Theranos' failure to ensure the accuracy and reliability of its tests, it provided false and misleading test results to consumers and their healthcare providers.

Theranos' Proprietary Technology

31. Much of Theranos' advertising to consumers centered around the supposed advantages of the Edison devices, but Theranos' statements and representations were false.

32. Theranos claimed that it could run blood tests with tiny samples, such as "one tiny drop" of someone's blood, collected into a tiny vial Theranos called a "nanotainer."

33. Theranos also frequently advertised both the availability and benefits of Theranos' proprietary technology.

34. For example, Theranos stated on its website that, due to the company's "breakthrough advancements," Theranos could run "the full range" of lab tests with tiny samples.

35. Theranos' statements that it could run every type of blood test, or even most types of blood tests, with its proprietary technology were false.

36. Theranos typically used venous draws for testing, and stopped using the Edison devices completely in or about June 2015.

37. Nevertheless, Theranos continued making statements to the contrary through at least September 12, 2015.

38. Theranos also claimed that, despite the fact that it was collecting a small amount of blood, its tests could deliver "the highest levels of accuracy."

39. Theranos' claim that it conducted accurate testing on its proprietary technology was false because of its failure to implement a quality control program that ensured that patients received accurate test results.

40. As to all of its tests, Theranos represented to consumers that it was subject to and compliant with relevant federal regulations and oversight pertaining to laboratories.

41. These representations were false.

42. From at least November 6, 2013 through October 23, 2016, Theranos was out of compliance with multiple federal regulations contained in the Clinical Laboratory Improvement Amendments ("CLIA") of 1988.

43. CLIA regulations are meant to ensure quality lab testing, including ensuring that laboratories provide consumers with accurate and reliable test results.

44. Because of its failure to comply with CLIA regulations, Theranos' tests were often inaccurate.

45. Because of its failure to comply with CLIA regulations, Theranos' tests were often unreliable.

46. Theranos represented that all its tests were "developed and validated under and to the . . . FDA['s]" standards.

47. These representations were false and misleading because, with one exception, Theranos' proprietary tests had not received FDA approval.

Theranos Voids and Corrects Tens of Thousands of Inaccurate Test Results

48. Theranos provided consumers with unreliable, inaccurate, and misleading test results.

49. Between 2013 and 2016, Theranos sold approximately 1,545,339 blood tests to Arizona consumers, which yielded 7,862,146 test results.

50. Theranos voided or corrected approximately 834,233 of these test results.

51. For example, Theranos conducted thousands of consumer blood tests in 2014 and 2015 using an Edison device the laboratory referred to as Theranos Proprietary System 3.5 ("TPS 3.5").

52. On or about January 2016, Theranos conducted an internal analysis of the performance of the TPS 3.5.

53. That analysis revealed "a global and long-term failure of the quality control program for this instrument, as well as failures of related quality assurance procedures that should have alerted the laboratory to correct such an unstable process."

54. Because of Theranos' failure to implement adequate quality control procedures, as required by federal law, every test conducted on the TPS 3.5 in 2014 and 2015 is unreliable.

55. Because of Theranos' failure to implement adequate quality control procedures, as required by federal law, the accuracy of every test conducted on the TPS 3.5 in 2014 and 2015 cannot be determined.

56. In May 2016, Theranos voided all of the consumer blood tests it conducted on the TPS 3.5.

57. On or about July 7, 2016, Theranos stopped conducting patient testing at its Newark lab.

58. On or about October 5, 2016, Theranos closed all of its testing centers.

59. On or about October 24, 2016, Theranos closed its Scottsdale lab.

60. Theranos was forced to correct or void many, if not all, of these tests because it systematically failed to ensure that its tests were conducted accurately and reliably, despite its statements and representations to the contrary.

61. Theranos did not disclose to consumers that it systematically failed to ensure that its tests were conducted accurately and reliably.

62. Theranos intended for consumers to rely on its misrepresentations, omissions, and concealments in their decision to purchase its testing services.

FIRST CLAIM FOR RELIEF
VIOLATIONS OF THE ARIZONA CONSUMER FRAUD ACT
A.R.S. § § 44-1521 – 44-1534

63. Plaintiff realleges the prior allegations of the complaint as if set forth fully herein.

64. In connection with the advertisement and sale of blood testing services, Defendant engaged in the act, use or employment of deception, deceptive or unfair acts or practices, fraud, false pretenses, false promises, misrepresentations or the concealment, suppression or omission of material facts with the intent that consumers rely upon such concealment, suppression or omission, including but not limited to the following:

65. Defendant made false, deceptive, misleading, and unfair claims to consumers that their tests would be performed using a finger-prick method, rather than a venous draw.

66. Defendant made false, deceptive, misleading, and unfair claims to consumers that their tests would be run using Theranos' proprietary technology, including the Edison devices, rather than on commercially available machines not utilizing any proprietary methods.

67. Defendant made false, deceptive, misleading, and unfair claims to consumers that their tests would be accurate.

68. Defendant made false, deceptive, misleading, and unfair claims to consumers that their tests would be reliable.

69. Defendant engaged in deceptive and unfair acts and practices by providing consumers with inaccurate and unreliable test results.

70. Defendant engaged in deceptive and unfair acts and practices by failing to disclose facts showing that its laboratory tests were unreliable, inaccurate, and unproven.

71. Defendant engaged in deceptive and unfair acts and practices by failing to inform consumers, in a timely fashion, that their tests may not be accurate or reliable.

72. Defendant concealed, suppressed, or omitted material facts with the intent that others rely on such concealment, suppression, or omission by failing to disclose that many of its tests were inaccurate and unreliable and that most of its tests were conducted using venous draws run conventionally on commercially available instruments.

73. Defendant engaged in deceptive and unfair acts and practices by voiding tens of thousands of tests, without adequately compensating consumers for their losses.

74. Defendant engaged in deceptive and unfair acts and practices by correcting tens of thousands of tests, without adequately compensating consumers for their losses.

75. While engaging in the acts and practices alleged in this Complaint, Defendant was at all times acting willfully as provided by A.R.S. § 44-1531.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, State of Arizona *ex rel.* Mark Brnovich, Attorney General,

respectfully requests that this Court:

76. Permanently enjoin, restrain, and prohibit the Defendant, those persons acting with Defendant, Defendant's agents, servants, employees, attorneys, and any entity established by the Defendant, whether a partnership, corporation, or limited liability company, who receive this Court's order, from engaging in any deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of material fact in violation of the Consumer Fraud Act as currently written or as amended in the future.

77. Pursuant to A.R.S. § 44-1528(A)(2), order Defendant to pay restitution of monies that were acquired by any practice alleged in this Complaint that violated the Consumer Fraud Act.

78. Pursuant to A.R.S. § 44-1528(A)(3), order Defendant to disgorge any profits, gain, gross receipts or other benefit obtained by means of any unlawful act or practice as alleged in this Complaint, to be paid to the State for deposit in the consumer remediation subaccount of the consumer restitution and remediation revolving fund.

79. Pursuant to A.R.S. § 44-1531, order Defendant to pay the State a civil penalty of not more than $10,000 for each willful violation of the Consumer Fraud Act.

80. Pursuant to A.R.S. § 44-1534, order Defendant to reimburse the Attorney General for the costs of investigation and reasonable attorneys' fees.

81. Enter an order providing that this Court retain jurisdiction of this action in order to implement and carry out the terms of all orders and decrees that may be entered herein, and in order to entertain any suitable applications or motions by Plaintiff for additional relief within the jurisdiction of the Court.

82. Enter orders for such other and further relief as provided by the Consumer Fraud Act, A.R.S. §§ 44-1521 – 44-1534.

83. Order such other relief as the Court deems just and proper.

DATED this 18th day of April.

MARK BRNOVICH
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