INTRODUCTION

1. This is an action under the District of Columbia Consumer Protection Procedures Act ("CPPA") for declaratory and injunctive relief against EpicGenetics for its false and misleading advertising of the Tests.

2. The Tests are laboratory-developed tests ("LDT"), a category of diagnostic tests that in practice receive virtually no government oversight, particularly as it relates to their performance.

3. EpicGenetics, the Tests' manufacturer and developer, claims the FM/a Test and the 100Sure Test accurately diagnose Fibromyalgia ("FM") and something EpicGenetics calls "Immune Deficiency Disease" ("IDD"), respectively.

4. Despite the different names and claimed applications, upon information and belief, the Tests are functionally identical.

5. EpicGenetics claims the Tests can diagnose FM and the so-called IDD by documenting a lower-than-normal immune response among patients with either FM or IDD and that the Tests' efficacy has been demonstrated in three studies (the "Studies").

6. Each study has flaws and does not provide adequate support for the claims EpicGenetics makes. However, even setting those deficiencies aside, EpicGenetics makes a number of demonstrably false and misleading claims about the Studies' findings and the Tests' performance.

7. The Studies, taken at face value, indicated that the FM/a Test detected FM when it was present 93% of the time and performed poorly in distinguishing between FM and diseases with similar symptoms. For example, one study found the FM/a Test, when conducted on

individuals with rheumatoid arthritis ("RA") and systemic lupus erythematosus ("SLE"), produced false positive results nearly one-third of the time.

8. Nonetheless, EpicGenetics positions the FM/a Test as the first, objective, and accurate measure of FM, providing far superior results to traditional diagnostic methods. Indeed, EpicGenetics falsely claims that the FM/a Test is "99 percent accurate," provides a "definitive diagnosis," and gives patients the "truth once and for all."

9. Beginning with its name, EpicGenetics' claims with respect to the "100Sure" Test are even more bold. Indeed, when patients visit the 100Sure Test's website, the first thing they see is a large claim inviting them to "Take a 100% accurate test."

10. These, and similar statements, touting the accuracy of the 100Sure Test are false and misleading for a subtly different reason than Defendant's claims about the FM/a Test.

11. As noted above, the 100Sure Test claims to diagnose what EpicGenetics' terms IDD. This is not a medically recognized disease, but instead a term created by EpicGenetics.

12. In circular logic, EpicGenetics characterizes an individual as having so-called IDD if that individual tests positive using the 100Sure Test.

13. That is, EpicGenetics, having failed to create a test that accurately diagnoses FM (the FM/a Test), has now created a disease (the so-called IDD) that fits that test's results, and released a rebranded version of the underlying test (the 100Sure Test) as a diagnosis for this manufactured disease.

14. Still more, Defendant has for years and, upon information and belief, continues to make false promises to individuals with positive Tests that they will be able to volunteer to enroll in experimental treatment trials that could potentially cure their FM or so-called IDD.

15. As one journalist who investigated EpicGenetics put it in 2021: EpicGenetics has "been using [a nonexistent] trial to sell an unproven test to people who were desperate after years of being told their disease was in their heads." Eric Boodman, *In a sea of skeptics, this physician was one of fibromyalgia patients' few true allies. Or was he?*, STAT (Oct. 20, 2021), https://bit.ly/40IxLcI.

16. In the absence of these false and misleading claims, District of Columbia consumers would not have purchased the Tests or paid as much for the Tests, which currently cost $1,080 each.

17. Moreover, as explained in a Food and Drug Administration ("FDA") report identifying 20 problematic LDTs that caused or may have caused significant harm to patients, including the FM/a Test (the "FDA Case Study Report"), these false and misleading claims can cause significant public health harms. *See* FDA, The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies at 19 (2015), https://bit.ly/3Q2gBE1.

18. Most significantly, according to the FDA, an inaccurate diagnosis of FM can result in patients "suffering from a different, treatable condition with similar symptoms . . . [not receiving] effective therapies . . . ." *See id.*

19. Plaintiff brings this case on behalf of the interests of District of Columbia consumers that have been or will be misled by EpicGenetics' false and misleading claims, and seeks, *inter alia*, an injunction to halt these unlawful practices.

PARTIES

20. Plaintiff CSPI is a non-profit, public interest organization headquartered in Washington, D.C. CSPI has worked since 1971 to improve the public's health by advocating for

sound science, truthful advertising, and science-based policies in the food, dietary supplement, drug, and medical device spaces.

21. CSPI is supported by grants from foundations and its more than 280,000 members, including donors and individuals who subscribe to its health and nutrition newsletter, *Nutrition Action*, which is received as a CSPI membership benefit.

22. As part of its broader mission, CSPI engages in public education and advocacy related to medical devices, including LDTs. This body of work includes developing and disseminating information to CSPI's members and the public regarding LDTs and advocating for Congress and federal agencies to strengthen the regulation of LDTs. *See, e.g.*, CSPI, Fact Sheet: The Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021 (2022), https://shorturl.at/egkp7; CSPI *et al.* letter to Robert M. Califf, Commissioner, FDA, *Stakeholder Groups Urge the FDA to Pass Regulation on Laboratory-Developed Tests* (May 30, 2023), https://bit.ly/466zwCT.

23. District of Columbia consumers have, or may in the future, purchase these Tests or pay more for the Tests than they would otherwise in reliance on EpicGenetics' false and misleading claims.

24. Defendant EpicGenetics is a corporation, organized and existing under the laws of the State of Delaware, with its principal place of business in Los Angeles, California. EpicGenetics was founded and is operated by Dr. Bruce Gillis.

25. Defendant manufactures, sells, markets, and performs the analysis for the FM/a and 100Sure Tests.

JURISDICTION AND VENUE

26. This Court has subject matter jurisdiction over this action and venue is proper in this Court pursuant to D.C. Code § 11-921 and § 28-3905(k).

27. This Court has personal jurisdiction over the parties in this case.

28. CSPI is headquartered in the District of Columbia and consents to this Court having personal jurisdiction over it and this matter.

29. This Court has personal jurisdiction over Defendant pursuant to D.C. Code § 13-423. EpicGenetics has sufficient minimum contacts with the District of Columbia to establish personal jurisdiction because, *inter alia*, it is engaged in deceptive schemes and acts directed at persons residing in the District of Columbia and has purposefully availed itself of the laws of this District through its marketing and sales of the Tests in this District.

FACTUAL AND LEGAL BACKGROUND

I. The Regulation of LDTs in the United States

30. LDTs are a type of in vitro clinical test ("IVCT") that are developed and used in a single laboratory, distinguishing them from other IVCTs that are used by multiple laboratories and conventionally manufactured as medical devices. *See* FDA Case Study Report at 3.

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA has the authority to review medical devices, including LDTs, to ensure they are safe and effective before they are marketed. *See* FDA, Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) at 5 (2014), https://www.fda.gov/media/89316/download.

32. However, because LDTs historically were "relatively simple" and "available on a limited basis," FDA exercised its enforcement discretion and did not require LDTs to go through

pre-market review or comply with other applicable FDCA requirements. FDA, *Laboratory Developed Tests* (Sept. 27, 2018), https://bit.ly/3HKK27X.

33. Advances in science and technology have enabled greater availability and complexity of LDTs, however, and they are frequently used to diagnose common, serious medical conditions, such as cancer or FM. As a result, it is crucial that LDTs are reliable, as inaccurate tests can lead, on the one hand, to failure to diagnose critical diseases or conditions and, on the other, to inappropriate treatment. FDA Case Study Report at 3.

34. In 2015, for example, the FDA published the Case Study Report that identified 20 problematic LDTs that caused or may have caused significant harm to patients. The FM/a Test, as discussed below, was among the 20 problematic LDTs identified in the Report.

35. Dr. Peter Lurie, CSPI's President and Executive Director, and the former Associate Commissioner for Public Health Strategy and Analysis at the FDA, was the Report's lead author.

II. Background Statistical Concepts

36. Diagnostic tests, such as LDTs, are used to differentiate between individuals with and without a disease or other condition of interest. Jacob Shreffler & Martin R. Huecker, *Diagnostic Testing Accuracy: Sensitivity, Specificity, Predictive Values and Likelihood Ratios*, National Institutes of Health (Mar. 6, 2023), https://bit.ly/3XVq7e2.

37. A completely error-free test would produce two results: "true positives" and "true negatives." These are results which, whether positive or negative, accurately reflect whether or not the individual has the disease. *Id.*

38. However, all tests inevitably make some errors. There are likewise two erroneous results: "false positives" and "false negatives." A "false negative" occurs when someone has the

disease, but the test says they do not; conversely, a "false positive" occurs when someone does not have the disease, but the test says they do. *Id.*

39. Depending on the circumstances, either mistake can be critical. For example, a false negative test for a fatal infection with an available cure may cause an individual to forgo lifesaving treatment. A false positive test on the other hand could lead to unnecessary procedures or treatments, some of which may have harmful side effects.

40. The four possible outcomes are summarized in this table:

	Patient Tests Positive	**Patient Tests Negative**
Patient has the Disease	True Positive	False Negative
Patients does not have the Disease	False Positive	True Negative

41. There are several statistical measures derived from these four results used to calculate the performance of a diagnostic test, including those referred to as "sensitivity," "specificity," and "diagnostic accuracy." *Id.*; Ana-Maria Šimundiü, *Measures of Diagnostic Accuracy: Basic Definitions*, National Institutes of Health (Jan. 19, 2009), https://bit.ly/3PYmCBr.

42. "Sensitivity" is the probability that a test detects the disease if it is present. In other words, it is the percentage of true positives out of all patients with the condition (true positives + false negatives). Shreffler & Huecker, *Diagnostic Testing Accuracy*, National Institutes of Health (Mar. 6, 2023). A test with high sensitivity produces a high percentage of true positives. A test that has low sensitivity produces a high percentage of false negatives.

43. "Specificity," in turn, is the percentage of true negatives out of all people without the disease (true negatives + false positives). *Id.* A test with high specificity produces a high

percentage of true negatives. A test that has low specificity produces a high percentage of false positives.

44. "Diagnostic accuracy" is the percentage of true results (true negatives + true positives) out of all results (true negatives + true positives + false negatives + false positives). 1LPXQGL, ü*Measures of Diagnostic Accuracy*, National Institutes of Health (Jan. 19, 2009). In other words, diagnostic accuracy is a weighted average of specificity and sensitivity.

45. The importance of a diagnostic test returning a high percentage of true positive results (a highly sensitive test) is self-evident.

46. The following hypothetical explains why sensitivity *and* specificity are critical. If a company marketed a thermometer as a COVID-19 diagnostic test (a disease in which many people have elevated temperatures), the thermometer might be "positive" for a high percentage of individuals with COVID-19, and negative for most healthy individuals. But it, of course, would not be able to distinguish between COVID-19 and other fever-causing illnesses.

47. Such a "test" might have reasonably high sensitivity (it would be positive for a relatively high percentage of individuals with COVID-19), but it would have low specificity (it would also be positive for many individuals with non-COVID illnesses).

48. Such a test would, of course, be of limited value compared to alternatives because a positive result would provide little information about whether a patient had COVID-19 or some other illness. Even a negative test, while likely ruling out many fever-causing illnesses, would miss some cases of COVID-19.

49. Accurately studying a test's sensitivity and specificity requires that the studied population reflect the real-world population that will receive the test.

50. For example, in the hypothetical COVID-19 diagnostic test above, if a study were designed to analyze the test's performance that only included healthy individuals and individuals

with COVID-19 (*i.e.*, it excluded individuals with other illnesses), that study would inaccurately find that the test had both high sensitivity and specificity for COVID-19.

51. However, if the studied population reflected the real-world population that would receive the test (*i.e.*, healthy individuals, those with COVID-19, and those with other illnesses), it would show that, although the test had a reasonably high sensitivity, it had a low specificity, resulting in many false positives.

52. As demonstrated below, this hypothetical has a number of parallels to the FM/a Test and 100Sure Test as well as the studies EpicGenetics performed to evaluate the Tests' performance. Specifically, the FM/A Test is similarly unable to effectively distinguish between FM and diseases with similar symptoms, and the studies performed to evaluate the FM/a Test's performance failed to use real-world populations leading to inaccurate and incomplete performance data.

III. Fibromyalgia

53. FM is a chronic disorder affecting approximately 4 million US adults that causes body-wide pain and fatigue. FM can significantly impair patients' quality of life and ability to take part in everyday activities. *See* Centers for Disease Control and Prevention, *Fibromyalgia* (Jan. 6, 2020), https://bit.ly/3DntIbr.

54. Although there is no cure for FM and scientists do not fully understand what causes it, symptoms can be managed with FDA-approved medications, exercise, and therapy. *Id.*

55. The condition is typically diagnosed based on a physician's history and physical examination, in addition to diagnostic testing to rule out other conditions with similar symptoms. *Id.*

56. An inaccurate diagnostic test for FM can have significant public health consequences. As explained in the FDA Case Study Report, making an inaccurate diagnosis of FM can result in patients "suffering from a different, treatable condition with similar symptoms . . . [not receiving] effective therapies . . . . Moreover, patients wrongly diagnosed with fibromyalgia may take unnecessary medications for that condition and be exposed to associated adverse effects." FDA Case Study Report at 18-19.

57. Moreover, patients who test negative but who have FM, may not avail themselves of FM treatments and may undergo unnecessary diagnostic tests in search of another cause of their symptoms.

THE FM/A AND 100SURE TESTS

I. The Tests

a. The FM/a Test

58. The FM/a Test is an LDT that claims to accurately diagnose FM.

59. Like other LDTs, in practice, it receives virtually no government oversight, particularly as it relates to the FM/a Test's performance.

60. The FM/a Test is made by EpicGenetics, and currently costs $1,080.

61. To get the FM/a Test, patients must complete an application on EpicGenetics' website (fmtest.com) and submit to EpicGenetics a physician authorization form, which form is also available on EpicGenetics' website. EpicGenetics offers to assist patients in locating a healthcare provider to authorize the FM/a Test. *See Answers to Questions You May Have*, EpicGenetics, https://www.fmtest.com/faq-3/.

62. Once an application is approved, EpicGenetics sends District of Columbia consumers a FM/a Test kit via FedEx, speaks with patients over the phone to help prepare them

for the Test, such as advising patients to stop taking certain medications, and arranges a blood draw with a local Quest laboratory. The laboratory sends the blood sample back to EpicGenetics, which analyses the specimen and mails results to the patient and their physician. *Id.*

63. EpicGenetics claims the FM/a Test can diagnose FM by documenting a lower-than-normal immune response in FM patients. According to EpicGenetics, the Test is a composite score based on the concentrations of four cytokines in the blood, where a score above 50 indicates a positive result. *See id.* Cytokines are proteins that play an important role in the immune system by signaling to immune cells to fight off infections. Cleveland Clinic, *Cytokines* (Jan. 3, 2023), https://bit.ly/3PWzPus.

b. The 100Sure Test

64. The 100Sure Test is also made by EpicGenetics, and upon information and belief, is identical to the FM/a Test. The current cost of the 100Sure Test is also $1,080.

65. The 100Sure Test and the FM/a Test are described in nearly identical language by EpicGenetics, and appear to rely on the same scientific studies to support their claims.

66. For example, EpicGenetics describes the FM/a Test as follows on fmtest.com:

> Patients with fibromyalgia have been shown to have an irregular pattern of chemokine and cytokine proteins in their immune system. The FM/a® fibromyalgia test analyzes these patterns in the immune system's white blood cells. Test results are based on a 1-100 scoring system, with scores above 50 indicating a positive fibromyalgia diagnosis.

67. EpicGenetics describes the 100Sure Test on 100sure.com in the following functionally identical language:

> Patients with Immune Deficiency Disease have been shown to have an irregular pattern of chemokine and cytokine protein production in their immune systems. 100SURE analyzes these patterns in the immune system's white blood cells. Test results are based on a 1-100 scoring system, with scores above 50 indicating a positive Immune Deficiency Disease diagnosis.

68. The only difference between the Tests appears to be their names and their claimed applications.

69. While EpicGenetics claims the FM/a Test can accurately diagnose FM, it markets the 100Sure Test as an accurate diagnostic test of "Immune Deficiency Diseases" or "Immune Deficiency Disease."

70. IDD appears to be a novel term, unrecognized in the medical community. Although there are various diseases that cause and/or are related to deficiencies in the immune system, including FM, *see Primary Immune Deficiency Diseases*, NIH, https://bit.ly/3tdzafd (last visited Sept. 28, 2023), Plaintiff is not aware of any official disease or category of diseases termed IDD. IDD, for example, is not listed in the ICD-10, a medical classification list managed by the World Health Organization. *See* https://www.icd10data.com/ICD10CM/Codes.

71. From EpicGenetics' description of IDD on 100sure.com, it appears EpicGenetics uses the term to describe numerous diseases and symptoms ranging from FM to interstitial cystitis (an inflamed bladder wall). *See* https://100sure.com/.

II. Studies on the Tests

A. The 2012 Study

72. In 2012, EpicGenetics founder Dr. Gillis co-authored a small study (110 FM patients, 91 controls) that reported a lower-than-normal cytokine immune response among patients with FM compared to the healthy controls (the "2012 Study"). Frederick G. Behm *et al.*, *Unique Immunologic Patterns in Fibromyalgia*, 12 BioMed Central Clinical Pathology 1 (2012), https://bit.ly/40UOg5I.

73. Although the study was titled "Unique Immunologic Patterns in Fibromyalgia," it did not and could not have established a "unique" pattern.

74. As Fred Wolfe, director of the National Databank for Rheumatic Disease, noted at the time, the FM/a Test compared the cytokine levels of individuals with FM to healthy individuals. But, "cytokine levels are abnormal in many physical and mental conditions," and the 2012 Study did not attempt to determine if the cytokine pattern it found was actually unique to FM. Fred Wolfe, *Junk Science-Junk Ethics*, The Fibromyalgia Perplex (Feb. 25, 2013), https://bit.ly/3pV1ku6.

75. As Wolfe put it, "[w]e have no idea if these markers would be found in people with other illnesses." *Questions Arise Over New Diagnostic Test for Fibromyalgia*, Fox News (Oct. 25, 2015), https://bit.ly/44Pxkyt.

76. In other words, generally speaking, the 2012 Study could not tell researchers if this cytokine pattern was any better at distinguishing between FM and conditions like RA or SLE than a thermometer is at distinguishing between COVID-19 and the flu. No RA or SLE patients were included in the study.

77. Indeed, as one of the 2012 Study's peer-reviewers noted, the title of the study was "misleading and not well based by the data shown and the methodology used." Nurcan Üçeyler, Review Report (Oct. 17, 2012), https://bit.ly/43xXchx.

78. But rather than waiting to further investigate these preliminary findings, Dr. Gillis and EpicGenetics went right to market, releasing the FM/a Test shortly after the 2012 Study was published.

79. In 2015, based on the above concerns, among others, the FDA included the FM/a Test in the Case Study Report. The Agency noted that, due to the "improper clinical trial design [used] to validate the test," there was a risk the FM/a Test would lead to "inaccurate diagnosis of

fibromyalgia," which would be "especially harmful" to patients "suffering from a different, treatable condition with similar symptoms." *See* FDA Case Study Report at 18-19.

B. The 2014 Study

80. In 2014, after marketing the FM/a Test for over a year, EpicGenetics decided to undertake a second study, perhaps to partially address the deficiencies in the 2012 Study (the "2014 Study"). The 2014 Study, unlike the 2012 Study, included patients with diseases that have similar symptoms to FM. *See* Daniel J. Wallace *et al.*, *Cytokine and Chemokine Profiles in Fibromyalgia, Rheumatoid Arthritis and Systemic Lupus Erythematosus: A Potentially Useful Tool in Differential Diagnosis*, 35 Rheumatology International 991 (2015), https://bit.ly/3OjSjnK.

81. Specifically, the 2014 Study evaluated the FM/a Test on 160 individuals with FM, 119 healthy control patients, 98 individuals with RA, and 100 individuals with SLE.

82. The 2014 Study indicated that the FM/a Test had a 93% sensitivity, meaning, out of 160 FM patients, the test was positive for 149. That is, the Study concluded that the Test had a 7% false negative rate.

83. As will be shown below, this 93% figure, which is the high-water mark of any statistical measure of the FM/a Test in any study, is well below EpicGenetics' claims about the FM/a Test's performance.

84. Even though the 2014 Study purported to show a 93% sensitivity, it also showed that the FM/a Test performed poorly at distinguishing between FM and RA and SLE. Although the FM/a Test provided a true negative for 89% of healthy individuals (*i.e.*, it had an 11% false positive rate among healthy patients), the true negative rate dropped to only approximately 70%

for individuals with RA and SLE. In other words, approximately one-third of individuals with RA and SLE had a false positive result.

85. Those individuals, according to the American Academy of Family Physicians, are "a more appropriate comparison group" because doctors will naturally perform the FM/a Test on individuals experiencing FM symptoms. Liza Straub & Anne Mounsey, *FM/a Blood Test for Diagnosis of Fibromyalgia*, 103 AAFP 566 (May 1, 2021), https://bit.ly/3K78ovf. Such individuals can actually have other illnesses, such as RA or SLE. Doctors are unlikely to perform the test on patients with no symptoms.

86. Although not calculated by the 2014 Study's authors, using the formula described above, *see supra* Factual and Legal Background Para. 44, the 2014 Study indicates that the diagnostic accuracy of the FM/a Test is 83% (394 true results out of 477 total results).

87. There is also reason to believe that these results overstate the FM/a Test's true accuracy.

88. The FM group, for example, was required to forego FM-related medications for two weeks prior to the study, but there was no similar requirement for the RA and SLE group. *See Id.* at 995 ("Most of the autoimmune patients['] disease was under good control with medication."). Because these medications may have masked immune deficiencies in the RA and SLE group, it is possible that the 30% false positivity rate is an underestimate.

89. Moreover, there was a significant statistical issue in the 2014 Test. The researchers, all EpicGenetics employees or consultants, had used one set of patients to develop the formula behind FM/a Test's 1-100 scoring system, and then used the very same patients to evaluate how well that formula worked.

90. This created something of a self-fulfilling prophecy; the formula was bound to work best on the set of patients whose data the researchers utilized to create it.

91. As Jenny Doust, a University of Queensland epidemiologist, put it, "This is clearly going to overestimate the accuracy and predictive values of the test." Boodman, *In a sea of skeptics, this physician was one of fibromyalgia patients' few true allies. Or was he?*, STAT (Oct. 20, 2021).

92. More broadly, the 2014 Study, with its selection of three specific control groups, was never designed to, and could not, evaluate how the FM/a Test would perform on a real-world population of individuals with symptoms common to numerous diseases who might take such a test. *Id.*

C. The 2021 Study

93. Another study, funded by EpicGenetics but conducted by doctors within the Mayo Clinic's FM group, was conducted in 2021 (the "2021 Study").

94. The 2021 Study evaluated the performance of the FM/a Test by administering it to fifty patients whom the Mayo Clinic had previously diagnosed with FM.

95. The 2021 Study is unpublished. A draft of the study was submitted by EpicGenetics in a court filing and is attached as Exhibit A.

96. The Study concluded that the Test has a 90% sensitivity (the test was positive for 45 out of 50 FM patients), less than the 93% figure from the 2014 Test.

97. However, the 2021 Study was performed only on FM patients. As a result, several key performance indicators, such as specificity and diagnostic accuracy, cannot be determined from the 2021 Study.

III. False and Misleading Claims by EpicGenetics

98. Even assuming all three Studies were well performed and appropriate for their intended purpose, which they were not, EpicGenetics makes a number of demonstrably false and misleading claims about the Studies' findings and the Tests' performance, as set forth below.

99. Defendant also has and, upon information and belief, continues to make false promises to individuals with positive Tests that they will be able volunteer to enroll in experimental treatment trials that could potentially cure their FM or so-called IDD.

a. False and Misleading Claims about the FM/A Tests' Performance

100. As the above makes clear, the Studies indicated that the FM/a Test only detected FM when it was present 90% or 93% of the time and performed poorly in distinguishing between FM and diseases with similar symptoms (with a 30% false positive rate).

101. Nonetheless, EpicGenetics positions the FM/a Test as the first, objective, and accurate measure of FM, providing far superior results to traditional diagnostic methods.

102. Indeed, Defendant falsely claims on its website, on its social media page, and in its brochures that the FM/a Test is "99 accurate," provides a "definitive diagnosis," and gives patients the "truth once and for all."

103. For example, on the FM/A Tests' Facebook page, on May 25, 2018, EpicGenetics posted the following message:

> It's impossible – there cannot be an accurate and objective blood test to diagnose #fibromyalgia, right? Wrong! We are faced with this sentiment sometimes. And we're here to tell you that this is simply not correct. With the FM/a® Test, we can now accurately diagnose #fibromyalgia with almost 99% accuracy.

The FM Test, Facebook (May 25, 2018), https://bit.ly/44SCcTM.

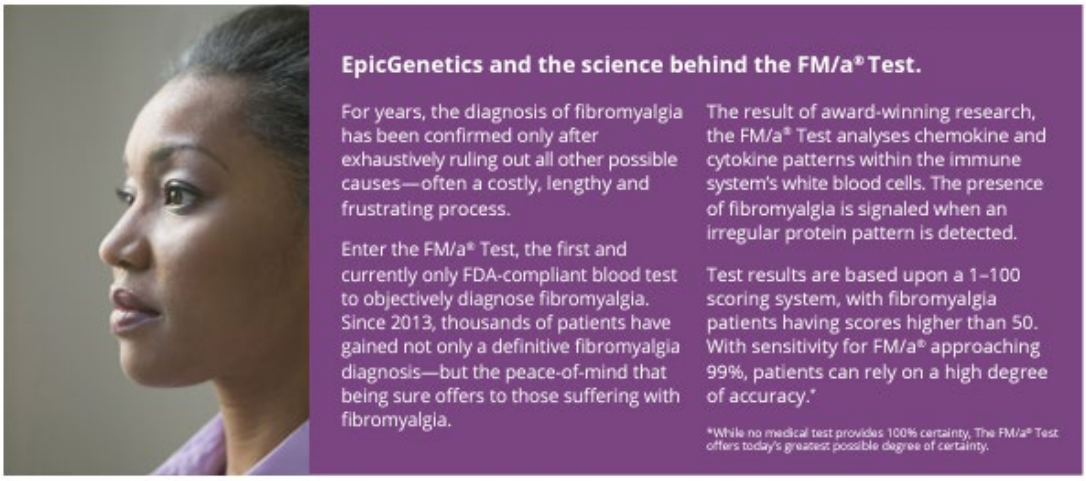
104. That post was accompanied by the following image (Image 1):

Image 1

105. In a January 17, 2022 post on EpicGenetics' company website (epicgenetics.org), Defendant makes a similar claim, using the term "sensitivity" instead of "accuracy." Specifically, EpicGenetics states that the "FM/a® Test . . . can objectively make the diagnosis of fibromyalgia with up to 99% sensitivity (no blood test is 100%)." *Do you Have Fibromyalgia?*, EpicGenetics, https://bit.ly/46XqE34.

106. A similar claim is made in the FM/a Test's brochure, which states "With sensitivity for FM/a® approaching 99%, patients can rely on a high degree of accuracy.*" The asterisk leads to a small font disclosure that says "*While no medical test provides 100% certainty, the FM/a® Test offers today's greatest possible degree of certainty." *See* Image 2; EpicGenetics, the FMa Test, https://bit.ly/3K5nFf8.

Image 2



107. A similar statement claiming the FM/a Test has "sensitivity approaching 99%" can be found on Defendant's separate website for the FM/a Test (fmtest.com). *See The Science Behind the FM/a Test*, EpicGenetics, https://www.fmtest.com/research/.

108. Such statements could, until recently, be found in numerous locations on fmtest.com. Around May 2023, however, EpicGenetics became aware of CSPI's investigation into the FM/a Test. Indeed, it sent CSPI a cease-and-desist letter on May 31, 2023. At about the same time, and likely because of that investigation, EpicGenetics removed all of these demonstrably false 99% sensitivity claims from fmtest.com except for the claim described in the preceding paragraph.

109. In addition, EpicGenetics continues to make other false and misleading claims about the Test's performance on fmtest.com, epicgentics.org, and elsewhere, including the following claims (emphasis added):

i. "Give your patients a *definitive answer.* And real hope."

ii. "Know you're treating your disease appropriately. You can't be sure if you don't know *for a fact* you have it."

iii. "Take the test. Get the *proof.*"

iv. "Now there's a simple fibromyalgia test that gives you the *definitive diagnosis* you need."

v. "*Know the truth once and for all* and prove it to your boss, family and friends, and healthcare providers."

vi. "The [2014 Study] demonstrated that the fibromyalgia biomarkers that make up the FM/a® Test *do not normally occur in other rheumatic diseases such as rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).*"

110. These, and similar, statements touting the accuracy of the FM/a Test are false and/or likely to mislead reasonable District of Columbia consumers as to the actual performance of the FM/a Test.

111. Indeed, in late-2021, the Centers for Medicare and Medicaid Services ("CMS") suspended Medicare payments for the FM/a Test based on what it characterized as "credible allegations of fraud." *See EpicGenetics, LLC v. Becerra*, 22 Civ. 2741 (C.D. Cal., Apr. 25, 2022), ECF No. 1-1, 1-3.

112. CMS appears to have made this decision in part because the FM/a Test is insufficiently accurate. For example, in its letter informing EpicGenetics of the suspension, it noted that "it has been determined that the services billed are medically unnecessary because [EpicGenetics is] reporting insufficiently accurate diagnoses." *Id.*, ECF No. 1-1.

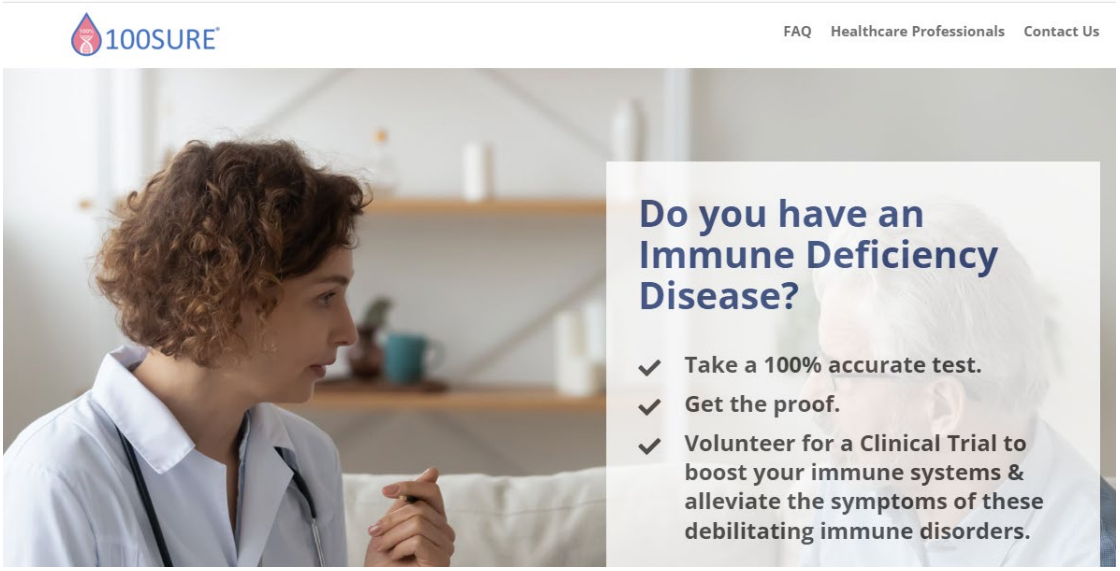
113. And, in response to EpicGenetics' objections, CMS responded that, "subject matter experts at [CMS' contractor] Qlarant are aware of guidance that disputes EpicGenetics' claims that the FM/a Test is accurate and effective in diagnosing patients with fibromyalgia." *Id.*, ECF No. 1-3.

b. False and Misleading Claims about the 100Sure Tests' Performance

114. Beginning with its name, EpicGenetics' claims with respect to "100Sure" Test are even more bold and misleading.

115. Indeed, when patients visit the 100Sure Test's website (100sure.com), the first thing they see is a large claim inviting patients to "Take a 100% accurate test." *See* Image 3.

Image 3



116. That 100% accuracy claim is stated in numerous locations throughout the website.

117. In addition, EpicGenetics makes numerous false and misleading claims about the Test's performance on 100sure.com, including the following claims (emphasis added):

a. "Get the *proof*"

b. "100SURE is the first blood test to *definitively diagnose* the immune system deficiencies that cause chronic pain, fibromyalgia, and chronic fatigue, or immune deficiency disease [sic] it is up to *100% accurate*."

c. *Know the truth once and for all* and prove it to your boss, family and friends, and healthcare providers [sic] your diagnosis."

d. "Know you're treating your disease appropriately. You can't be sure if you don't know *for a fact* you have it."

e. "Give your patients a *definitive answer.* And real hope."

118. These, and similar, statements touting the accuracy of the 100Sure Test are false and/or likely to mislead reasonable District of Columbia consumers.

119. As noted above, the 100Sure Test claims to diagnose the made-up disease that EpicGenetics terms "Immune Deficiency Disease" or "Immune Deficiency Diseases." It is false and/or likely to mislead reasonable District of Columbia consumers that IDD is a real disease.

120. To the contrary, IDD is not a medically recognized disease, but instead a term seemingly created by EpicGenetics that, and upon information and belief, means any individual who tests positive using the 100Sure Test.

121. In other words, EpicGenetics, having failed to create a test (the FM/a Test) that accurately diagnoses FM, has now created a disease (IDD) that fits the FM/a Test's results, and released a rebranded version of the underlying test (the 100Sure Test) as a diagnosis for this manufactured disease.

122. This is false and misleading in its own right. Most significantly, patients who test positive for this 100Sure Test may, in fact, have one of many treatable diseases with varying causes, such as RA, but are being told they have a non-existent disease that, by definition, has no known treatment.

123. On information and belief, the 100Sure Test has not been shown to diagnose any disease other than possibly FM and, as described above, it is undeniably false that it can even detect FM with 100 percent accuracy.

124. The fact that the same test is now being used to diagnose multiple diseases also highlights the deceptive nature of Defendant's claims about the FM/a Test. In essence, the claims

about the 100Sure Test are an admission that the Tests cannot accurately differentiate between FM and other illnesses, including, but not limited to, RA and SLE.

125. To return to the previously discussed hypothetical company offering for sale a thermometer purporting to diagnose COVID-19, EpicGenetics' claims with regard to the 100Sure Test are as if, this hypothetical company, realizing the thermometer could not distinguish between COVID-19 and other fever-causing illnesses, rebranded the product as an accurate detector of a heretofore unknown illness called "Fever Disease," which includes all conditions that cause a fever. This, all while continuing to sell the prior, inaccurate product as a COVID-19 diagnostic test.

126. In addition, as noted above, EpicGenetics states that IDD includes FM. Because the 100Sure Test is no more accurate than the FM/a Test, the claims that EpicGenetics makes touting the accuracy of the 100Sure Test are false and/or likely to mislead reasonable District of Columbia consumers as to the actual performance of the 100Sure Test for diagnosing FM.

c. False and Misleading Claims Relating to Treatment Trials

127. EpicGenetics also has, and upon information and belief, continues to falsely and misleadingly claim that individuals with positive Tests can volunteer to enroll in an experimental treatment trial.

128. As explained in the investigative article on the FM/a Test in *STAT*, EpicGenetics' founder Dr. Gillis funded an FM treatment trial in early 2017 to be conducted at the Massachusetts General Hospital. Although the trial received FDA approval, Dr. Gillis pulled the funding in mid-2018 and the trial was canceled, as reflected in the government's database of clinical trials. *Phase II Clinical Trial: Multi-dosing the BCG Vaccine for Fibromyalgia,* Clinicaltrials.gov, https://bit.ly/3RRai4U ("Withdrawn (No funding at the current time.)").

129. Despite knowing the treatment trial would not go forward, EpicGenetics continued for years to falsely claim that people with positive FM/a Tests could volunteer "for an FDA-approved clinical trial for an investigational new treatment to reverse the disease and eliminate your symptoms." Eric Boodman, *In a sea of skeptics, this physician was one of fibromyalgia patients' few true allies. Or was he?*, STAT (Oct. 20, 2021), https://bit.ly/40IxLcI.

130. As the *STAT* article puts it: Dr. Gillis had "been using an aborted trial to sell an unproven test to people who were desperate after years of being told their disease was in their heads." *Id.*

131. Indeed, even today, despite years of no treatment trials taking place, the fmtest.com website states, "Patients with positive FM/a® Test results will be invited to volunteer to participate in upcoming treatment trials. Unlike any therapy today, this new treatment is designed to eliminate the symptoms of fibromyalgia without the negative side effects of current treatments."

132. Nearly identical language about a treatment trial can be found on the 100Sure Test's website.

133. After years of false promises, EpicGenetics now claims that a treatment trial is going to begin.

134. On its Facebook page, in a series of posts beginning in February 2023, EpicGenetics claims that an "FDA approved" treatment trial is indeed about to start and that patients with a positive FM/a Test can volunteer. *See* The FM Test, Facebook (Feb. 23, 2023), https://bit.ly/46YjNXe; Image 4 (photo accompanying post).

Image 4

135. EpicGenetics claims that the trial will test an immune-boosting "compound" developed at the University of Illinois College of Pharmacy, and that the trial will be performed at the Center for Immunology Science in Los Angeles. The FM Test, Facebook (June 2, 2023), https://www.facebook.com/TheFMTest.

136. In June, EpicGenetics claimed the trial would begin the week of July 16th, and then on July 14th said it would begin on August 10th.

137. The Center for Immunology Science LLC, which will supposedly perform this trial, is a company that Dr. Gillis created and registered in New Mexico less than a year ago.

138. CSPI has been unable to find any record of this study on clinicaltrials.gov, the government's online database for clinical research studies.

139. This study appears to meet the definition of studies that would be required to be registered on clinicaltrials.gov. *See* 42 C.F.R. § 11.22.

140. Indeed, the only reference on the internet CSPI was able to find to this trial was on the FM/a Test's Facebook page.

141. Based on the above, and EpicGenetics' prior false and misleading claims about the treatment trials, CSPI believes that this clinical trial is not occurring, not FDA approved,

and/or not testing a compound that any reasonable researcher would believe could actually treat FM let alone "eliminate the symptoms of fibromyalgia."

CLAIM FOR RELIEF

Violation of the District of Columbia Consumer Protection Procedures Act D.C. CODE § 28-3901 *et seq.*

142. Plaintiff realleges and incorporates by reference the allegations in each of the preceding paragraphs of this Complaint.

143. As a nonprofit, public interest organization with a significant interest in LDT safety, sound science, and truthful advertising, Plaintiff brings this claim pursuant to D.C. Code § 28-3905(k)(1)(D)(i-ii) on behalf of District of Columbia consumers who have been or will be misled by EpicGenetics' false and misleading advertising.

144. The facts as alleged herein demonstrate that Defendant's marketing and advertising of the Tests constitute unlawful trade practices in violation of at least the following provisions of D.C. Code § 28-3904:

a. Section 28-3904(a), which prohibits "represent[ations] that goods or services have . . . characteristics, . . . uses, benefits, or quantities that they do not have";

b. Section 28-3904(d), which prohibits "represent[ations] that goods or services are of particular standard, quality, [or] grade . . . , if in fact they are of another";

c. Section 28-3904(e), which prohibits "misrepresent[ations] as to a material fact which has a tendency to mislead";

d. Section 28-3904(f), (f-1), which prohibits "fail[ing] to state a material fact if such failure tends to mislead" and the "use of innuendo or ambiguity as to a material fact, which has a tendency to mislead"; and

e. Section 28-3904(h), which prohibits "advertis[ing] or offer[ing] goods or services . . . without the intent to sell them as advertised or offered."

145. Defendant made false and misleading representations to induce the consumer public, including District of Columbia consumers, to purchase the Tests.

146. District of Columbia consumers were likely to be deceived, and were in fact misled, by Defendants' misrepresentations and omissions.

147. Absent these misrepresentations, District of Columbia consumers would not have purchased the Tests or paid as much for the Tests.

148. As a direct and proximate result of Defendant's false and misleading claims about the Tests, District of Columbia consumers have suffered and will continue to suffer substantial injuries.

149. Plaintiffs request that this Court enter such orders or judgments as may be necessary to enjoin Defendant from continuing its unlawful business practices, and to provide such other relief as set forth below.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of the interests of District of Columbia consumers, respectfully requests that this Court enter an Order:

A. Declaring the conduct of Defendant as alleged herein to be unlawful and in violation of the CPPA;

B. Enjoining Defendant from continuing the unlawful trade practices alleged herein, including, but not limited to, ceasing to make inaccurate claims about the effectiveness of the Tests both orally and in writing;

C. Requiring Defendant to fund a corrective public education campaign to ameliorate the harm caused by its unlawful trade practices;

D. Awarding Plaintiff reasonable attorneys' fees, costs, and expenses; and

E. Awarding Plaintiff post-judgment interest to the extent the law allows.

JURY TRIAL DEMAND

Plaintiff demands a jury trial on all causes of action so triable.

Date: 10/04/2023

Respectfully submitted,

Lisa S. Mankofsky

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