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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ASHLEY CARROLL, individually and on behalf of all others similarly situated, Plaintiff, v. MYRIAD GENETICS, INC., Defendant.	Case No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Ashley Carroll ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendant Myriad Genetics Inc. ("Defendant" or "Myriad"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based upon personal knowledge.

NATURE OF THE ACTION

1. This is a putative class action lawsuit on behalf of purchasers of Myriad's Prequel Prenatal Screen ("Prequel Test" or collectively, the "Tests"). Defendant markets and sells the Tests as genetic, prenatal screening tests for pregnant women that screen for various chromosomal and genetic conditions affecting a baby's health. Defendant markets these tests as accurate. However, unbeknownst to consumers, Prequel Test results indicating a genetic disorder are incorrect approximately 85 percent of the time.[1] Thus, the Tests are worth far less than their market price. In addition, as a result of these false results, expecting mothers are often unnecessarily subjected to further diagnostic testing, genetic counseling, and the even erroneous termination of a viable pregnancy.

2. Prenatal testing in recent years has moved towards non-invasive methods to determine the fetal risk for genetic disorders, including Non-Invasive Prenatal Testing ("NIPT").[2]

3. NIPT analyzes DNA fragments from the blood of a pregnant women to estimate the risk that the fetus will be born with certain genetic abnormalities, including chromosomal disorders like Down Syndrome and Trisomy 18, or other, more rare disorders, like Prader-Willi and Angelman Syndrome.

4. NIPT is incredibly popular. However, many of these tests are often inaccurate, giving pregnant women false positive results for genetic conditions that their fetuses do not have.

[1] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545823/

5. In fact, a recent New York Times investigation found that for every 15 times an NIPT screening correctly identifies a fetal disorder, the screening is wrong 85 times, meaning that 85 percent of all positive results are false positives.[3]

6. Despite this inaccurate testing, Defendant falsely advertises their findings as reliable, accurate and offering peace of mind for patients regarding the viability of their pregnancies. These false positives can lead to devastating personal consequences and painful decisions that are premised upon this wrong information.

7. Plaintiff and Class Members purchased the Tests designed, marketed, manufactured, distributed, and sold by Defendant as accurate and reliable. Plaintiff and Class Members would not have purchased Defendant's Tests – or, at minimum, would have paid significantly less for the Tests– had they known the Tests were inaccurate. Plaintiff and Class Members thus suffered monetary damages as a result of Defendant's deceptive and false representations.

PARTIES

8. Plaintiff Ashley Carroll is a resident of Menlo Park, California and has an intent to remain there, and is therefore a domiciliary of California. In or about June 2021, Plaintiff visited her doctor's office in California, where she received a brochure about Defendant's Myriad Prequel Test. After reviewing Defendant's brochure, Plaintiff decided to purchase Defendant's Prequel Test in California because Defendant described the Test as accurate. Specifically, Defendant represented that the Test "has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure." Defendant further represented that its Tests are "more accurate than maternal serum screening" and tells women that the Tests will "reduc[e] the chances you'll need an unnecessary invasive follow-up test." Plaintiff paid $295 for the Prequel Test out of pocket. Plaintiff relied on Defendant's representations and warranties in deciding to purchase the Prequel Test. Accordingly, Defendant's

[3] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

representations and warranties were part of the basis of the bargain, in that she would not have purchased the Prequel Test on the same terms had she known the Test's representations about accuracy and trustworthiness were not true, or at least would have paid significantly less for the Prequel Test.

9. Defendant Myriad Genetics, Inc. is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business in Salt Lake City, Utah. Myriad is a molecular diagnostic company specializing in genetic tests that determine the risk of developing disease, assess the risk of disease progression, and guide treatment decisions.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000.00, exclusive of interest and costs, there are over 100 members of the putative class, and Plaintiff, as well as most members of the proposed class, are citizens of states different from Defendant.

11. This Court has personal jurisdiction over Defendant because it conducts substantial business within California, such that Defendant has significant, continuous, and pervasive contacts within the State of California and because a substantial portion of the events that gave rise to this cause of action occurred here.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant transacts significant business within this District and because Plaintiff purchased and used the Prequel Test in this District.

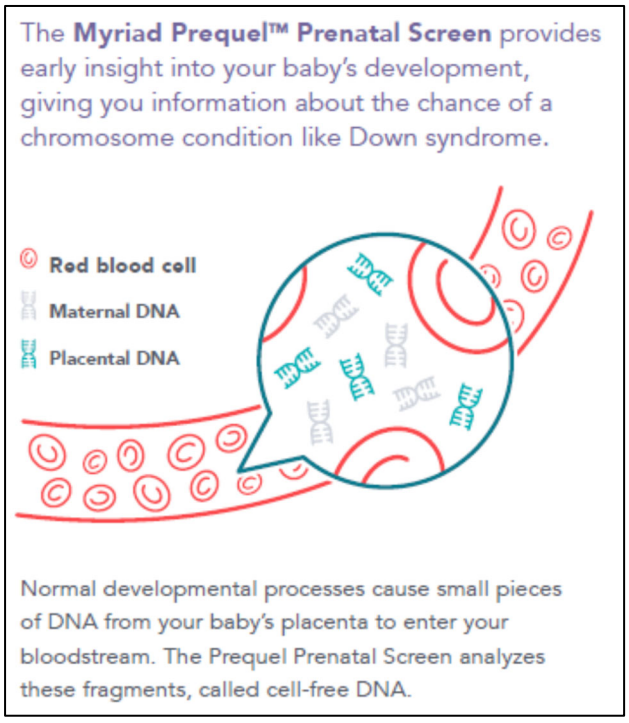
FACTUAL ALLEGATIONS

A. Myriad's "Prequel" NIPT

13. The discovery of fetal DNA in maternal blood has led to changes in prenatal screening. Following this discovery, many companies began working on blood tests, otherwise

known as NIPT, aimed at detecting chromosomal abnormalities without the invasive and risky nature of amniocentesis and chorionic villus sampling ("CVS").[4]

14. Myriad's Prequel Prenatal Screen NIPT is a noninvasive blood screen for pregnant women to find out if their babies have an increased risk for chromosomal conditions like Down syndrome (Trisomy 21) and Edwards Syndrome (Trisomy 18).



[4] https://blog.seracare.com/ngs/evolution-of-non-invasive-prenatal-testing-nipt-testing

15. In 2019, Myriad announced an expansion of its Prequel Test, claiming that the Tests would now check all 23 chromosome pairs rather than just the standard five chromosomes (13, 18, 21, X and Y) previously tested.[5]

16. Prequel also claims the ability to "assess if your baby is missing a tiny piece of a chromosome (called a 'microdeletion'), which can lead to birth defects and intellectual disabilities."

> **Your healthcare provider can help you decide whether you may want to screen for additional conditions**
>
> The Prequel Prenatal Screen can also assess if your baby has the correct number of sex chromosomes, which can impact health issues like fertility. Additionally, the screen can assess if your baby is missing a tiny piece of a chromosome (called a "microdeletion"), which can lead to birth defects and intellectual disabilities.

17. In 2020, Myriad launched its propriety "AMPLIFY" technology, which Myriad claimed further increased the performance of its Prequel test, thereby reducing the rate of false positive and false negative results.

18. Nicole Lambert, president of Myriad International, Oncology and Women's Health, claimed:

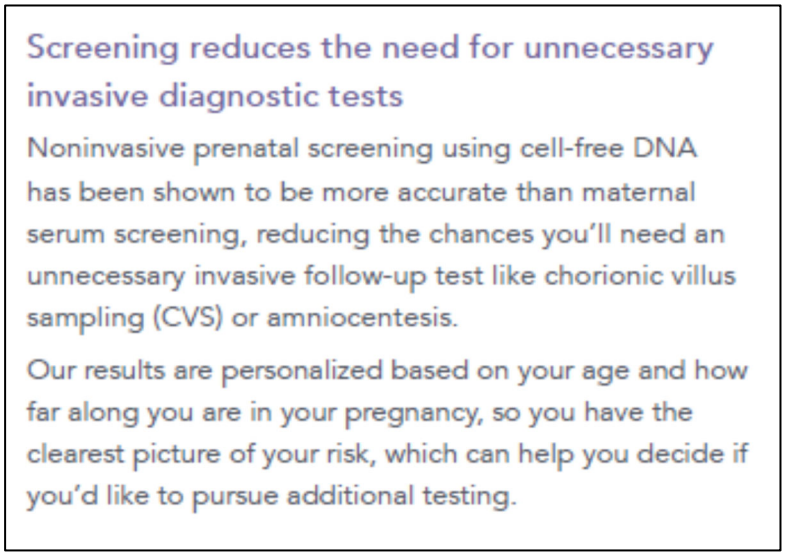
> Prequel already provided ***highly accurate*** results and this proprietary technology further increases the sensitivity of our test … With AMPLIFY, Prequel maintains its industry-leading low rate of failed samples—delivering results to 99.9 percent of patients. The important clinical benefits are that each woman who receives the test can expect ***highly accurate*** NIPS results, regardless of body mass index (BMI), race, or ethnicity."[6]

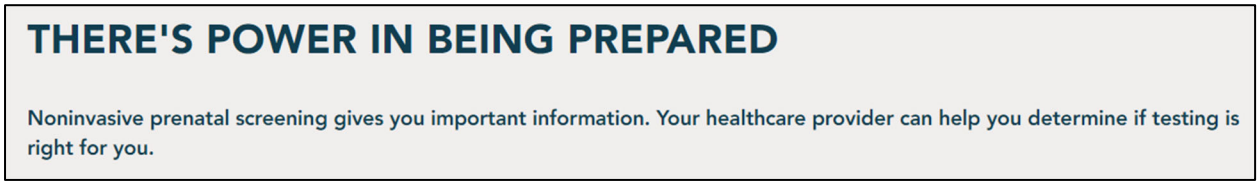
19. Myriad also claims that Prequel reduces the need for unnecessary invasive diagnostic testing like amniocentesis and CVS testing and tells women that there is "power in

[5] https://investor.myriad.com/news-releases/news-release-details/myriad-announces-prequeltm-prenatal-screen-expanded-aneuploidy

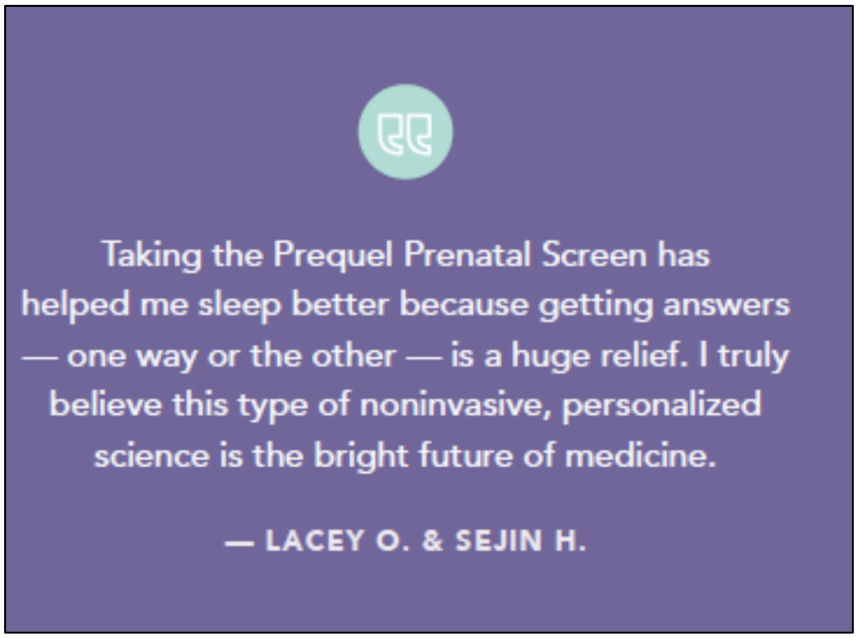
[6] https://investor.myriad.com/news-releases/news-release-details/myriad-launches-proprietary-amplifytm-technology-further (emphasis added).

being prepared" for the birth of their babies. Myriad also touts that its Tests are "more accurate than maternal serum screening" and "reduc[e] the chances you'll need an unnecessary invasive follow-up test."





20. Further, Myriad advertises Prequel as providing patients with peace of mind regarding the viability of their pregnancies by posting customer testimonials praising the Test:



21. NIPT screening tests like Prequel are costly, with an average out-of-pocket cost of $279.[7]

B. Defendant's False Advertising of the Tests

22. Since the launch of Prequel, Defendant has consistently advertised the Tests as "highly accurate" and trustworthy. Unfortunately for pregnant women, the Tests are alarmingly inaccurate.

23. A recent investigation by the New York Times found that despite the Tests and other NIPT tests being advertised as "reliable," "highly accurate," and offering "total confidence" and "peace of mind" for patients, the tests are inaccurate more than 85 percent of the time.

24. Specifically, the tests are unable to accurately discover microdeletions like the ones Defendant claims Prequel can correctly detect. Microdeletions can have a wide range of symptoms, including intellectual disability, a shortened life span, and a high infant mortality rate.

25. As a result of these false positive screenings, women are forced to undergo the very invasive testing that Defendant claims its Tests help women avoid, including amniocentesis

[7] http://www.motherofmicrobes.com/the-nipt-test-costs-less-than-you-think-but-beware-of-insurance-surprises/

and CVS. During an amniocentesis, a needle is used to remove amniotic fluid from the uterus for testing. Similarly, during a CVS procedure, a catheter or needle is used to biopsy placental cells that are derived from the same fertilized egg as the fetus. Both procedures include an increased risk of miscarriage.[8]

26. Many women also have abortions after obtaining positive results from NIPT screens, even though those results may very well be inaccurate. For example, a 2014 study found that six percent of patients who screened positive obtained an abortion without getting another test to confirm the result.[9]

27. Consumers are therefore paying hundreds of dollars for testing that is highly inaccurate and untrustworthy.

28. Plaintiff brings this action on behalf of herself and the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of implied warranty; (iii) unjust enrichment; (iv) fraud; (v) fraudulent omission; (vi) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*; (vii) violation of California's Consumers Legal Remedies Act ("CLRA"), Civil Code §§ 1750, *et. seq.*; and (viii) violation of California's False Advertising Law ("FAL"), Cal. Bus & Prof Code § 17500.

CLASS ALLEGATIONS

29. Plaintiff seeks to represent a class defined as all persons in the United States who purchased a Prequel test (the "Nationwide Class").

30. Plaintiff also seeks to represent a class defined as all persons who reside in the state of California who purchased a Prequel test (the "California Subclass") (collectively with the Nationwide Class, "Class").

31. Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children,

[8] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

[9] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

32. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

33. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendant and may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

34. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Prequel manufactured, distributed, and sold by Defendant was unfit for use as screening test, thereby breaching express and implied warranties made by Defendant and making the Prequel Test unfit for its intended purpose;

(b) whether Defendant knew or should have known that the Prequel Test would often provide false positive results prior to selling the Tests, thereby constituting fraud and/or fraudulent omission;

(c) whether Defendant is liable to Plaintiff and the Class for unjust enrichment;

(d) whether Plaintiff and the Class have sustained monetary loss and the proper measure of that loss;

(e) whether Plaintiff and the Class are entitled to declaratory and injunctive relief;

(f) whether Plaintiff and the Class are entitled to restitution and disgorgement from Defendants; and

(g) whether the marketing, advertising, packaging, labeling, and other promotional materials for Prequel are deceptive.

35. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class in that Defendant mass marketed and sold defective Prequel tests to consumers throughout the United States. This defect was present in all of the Prequel tests manufactured, distributed, and sold by Defendants. Therefore, Defendant breached their express and implied warranties to Plaintiff and Class members by manufacturing, distributing, and selling the defective Prequel tests. Plaintiff's claims are typical in that she was uniformly harmed in purchasing and using defective a Prequel Test. Plaintiff's claims are further typical in that Defendant deceived Plaintiff in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendant that are unique to Plaintiff.

36. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class.

37. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues

in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

38. In the alternative, the Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I
Breach Of Express Warranty

39. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

40. Plaintiff brings this claim individually and on behalf of the Class against Defendant.

41. In connection with the sale of the Tests, Defendant, as the designer, manufacturer, marketers, distributor, and/or seller issued written warranties by representing that the Tests "ha[ve] the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure." Defendant further represents that its Tests are "more accurate than maternal serum screening" and tells women that the Tests will "reduc[e] the chances you'll need an unnecessary invasive follow-up test."

42. In fact, the Tests do not conform to the above-referenced representations because the tests are inaccurate approximately 85 percent of the time.

43. Plaintiff and Class Members were injured as a direct and proximate result of Defendant's breaches because they would not have purchased the Tests if they had known that the Tests did not work as warranted.

44. On January 20, 2022, prior to the filing of this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an express warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1**.

COUNT II
Breach Of Implied Warranty

45. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

46. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

47. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the Tests were suited for use to detect chromosomal abnormalities with a high degree of accuracy. Defendant breached the warranty implied in the contract for the sale of the Tests because the Tests could not "pass without objection in the trade under the contract description," the Tests were not "of fair average quality within the description," the Tests were not "adequately contained, packaged, and labeled as the agreement may require," and the Tests did not "conform to the promise or affirmations of fact made on the container or label." *See* U.C.C. § 2-314(2) (listing requirements for merchantability). As a result, Plaintiff and Class Members did not receive the goods as impliedly warranted by Defendant to be merchantable.

48. Plaintiff and the Class Members purchased the Tests in reliance upon Defendant's skill and judgment in properly packaging and labeling the Tests.

49. The Tests were not altered by Plaintiff and Class Members.

50. The Tests were not fit for their intended purpose when they left the exclusive control of Defendant.

51. Defendant knew that the Tests would be purchased and used without additional testing by Plaintiff and Class Members.

52. The Tests were defectively designed and unfit for their intended purpose, and Plaintiff and Class Members did not receive the Tests as warranted.

53. Plaintiff and Class Members and Subclass Members were injured as a direct and proximate result of Defendant's breach because (i) they would not have purchased the Tests if they had known that the Tests were highly inaccurate, not dependable, and therefore unsuitable for their stated and advertised purpose of detecting chromosomal abnormalities with a high degree of accuracy, and (ii) they overpaid for the Tests on account of its misrepresentations that it was capable of detecting chromosomal abnormalities with a high degree of accuracy.

54. On January 20, 2022, prior to the filing of this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1**.

COUNT III
Unjust Enrichment

55. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

56. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

57. Plaintiff and the Class conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective Prequel tests.

58. Defendant voluntarily accepted and retained this benefit.

59. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for the purpose in which they were sold, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT IV
Fraud

60. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

61. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

62. As discussed above, Defendant provided Plaintiff and Class members with materially false or misleading information about the Prequel tests manufactured, distributed, and sold by Defendant. Specifically, Defendant had knowledge of the fact that Prequel tests were highly inaccurate, often causing false positive results. Defendant nevertheless actively represented to consumers that the Prequel tests were fit for their intended purpose.

63. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class members to purchase defective Prequel tests.

64. The fraudulent actions of Defendant caused damage to Plaintiff and Class members, who are entitled to damages and other legal and equitable relief as a result.

65. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT V
Fraudulent Omission

66. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

67. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

68. As discussed above, Defendant failed to disclose that the Tests would frequently provide false positive results.

69. The false and misleading omissions were made with knowledge or their falsehood. Defendant is a national genetics laboratory that specializes in genetic testing and therefore knew the Tests would provide an unnecessarily high number of false positive results. Nonetheless, Defendant continued to sell its worthless Tests to unsuspecting consumers.

70. The false and misleading omissions were made by Defendant, upon which Plaintiff and members of the proposed Class reasonably and justifiably relied, and were intended to induce and actually induced Plaintiff and Class Members to purchase the tests.

71. The fraudulent actions of Defendant caused damage to Plaintiff and Class Members, who are entitled to damages and punitive damages.

COUNT VI
Violation of California's Unfair Competition Law
California Business and Professions Code § 17200 *et seq*.

72. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

73. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

74. By committing the acts and practices alleged herein, Defendant has violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*, as to the California Subclass, by engaging in unlawful, fraudulent, and unfair conduct.

75. Defendant has violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of the CLRA, FAL, and by committing fraud, unjust enrichment, and breaching express and implied warranties, as alleged herein.

76. Defendant's acts and practices described above also violate the UCL's proscription against engaging in fraudulent conduct. As more fully described above, Defendant's misleading marketing, advertising, packaging, and labeling of the Tests is likely to deceive reasonable consumers.

77. Plaintiff and the other California Subclass members suffered a substantial injury by virtue of buying the Tests that they would not have purchased absent Defendant's unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the accuracy of the Tests, or by virtue of paying an excessive premium price for the unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled Tests.

78. There is no benefit to consumers or competition from deceptively marketing and omitting material facts about the highly inaccurate nature of the Tests.

79. Plaintiff and the other California Subclass members had no way of reasonably knowing that the Tests they purchased were not as marketed, advertised, packaged, or labeled. Thus, they could not have reasonably avoided the injury each of them suffered.

80. The gravity of the consequences of Defendant's conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiff and the other members of the California Subclass.

81. Plaintiff, on behalf of herself and the California Subclass, seeks injunctive relief to require Defendant to: (1) provide notice to every class member that the NIPT test they purchased is not suited for its intended purpose; and (2) either provide a refund to Plaintiff and the California Subclass for their NIPT test in an amount to be determined at trial.

82. Defendant's conduct has caused substantial injury to Plaintiff, California Subclass Members, and the public. Defendant's conduct is ongoing and will continue absent a permanent injunction. Accordingly, Plaintiff seeks an order enjoining Defendant from committing such unlawful, unfair, and fraudulent business practices. Plaintiff further seeks an order granting restitution to Plaintiff and the California Subclass members in an amount to be proven at trial. Plaintiff further seeks an award of attorneys' fees and costs under Cal. Code Civ. Proc. § 1021.5.

83. Plaintiff and the general public lack an adequate remedy at law to remedy and/or mitigate the totality of the injuries and misconduct described herein.

84. Absent injunctive relief, Defendant will continue to injure Plaintiff and the California Subclass members. Defendant's conduct and omissions of material fact are ongoing. And, even if such conduct were to cease, it is behavior that is capable of repetition or reoccurrence by Defendant yet evades review.

85. In order to prevent injury to the general public, Plaintiff, in her individual capacity, seeks a public injunction requiring Defendant to stop advertising, and to instruct its resellers to stop advertising, any NIPT test, other than tests for Down Syndrome or Edwards Syndrome, as being highly accurate.

COUNT VII
Violation of California's False Advertising Law
California Business and Professions Code § 17500, *et seq.*

86. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

87. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

88. Defendant has engaged in false or misleading advertising in violation of California's statutory False Advertising Law ("FAL").

89. Defendant's conduct as described herein is misleading, and/or has a capacity, likelihood or tendency to deceive reasonable consumers.

90. Defendant, with intent directly or indirectly to dispose of personal property or to perform services, or to induce the public to enter into any obligation relating thereto, makes, disseminates, has made or disseminated, causes to be made or disseminated, and/or has caused to be made or disseminated, before the public in California, in newspaper or other publication, or other advertising device, or by public outcry or by proclamation, or in any other manner or means, including over the internet, statements concerning that personal property or those services, and/or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which are untrue or misleading and which are known (or which by the exercise of reasonable care should be known) to be untrue or misleading.

91. Defendant made, disseminated, makes, disseminates, caused to be made or disseminated and/or causes to be made or disseminated any statements concerning the disposition of personal property or the performance of services, and/or concerning any circumstance or matter of fact connected with such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, as advertised.

92. With respect to omissions, Defendant at all relevant times had a duty to disclose the information in question because, *inter alia*: (a) Defendant had exclusive knowledge of material information that was not known to Plaintiff and the California Subclass; (b) Defendant concealed material information from Plaintiff and the California Subclass; and/or (c) Defendant made partial representations which were false and misleading absent the omitted information.

93. Defendant committed such violations of the FAL with actual knowledge that its advertising was misleading, or Defendant, in the exercise of reasonable care, should have known that its advertising was misleading.

94. Plaintiff and the California Subclass reasonably relied on Defendant's representations and/or omissions made in violation of the FAL.

95. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent conduct, Plaintiff and each member of the California Subclass suffered injury-in-fact and lost money.

96. But for Defendant's deceptive conduct and omissions of material facts, Plaintiff and the California Subclass would not have purchased the subject NIPT tests and/or would have purchased an appropriate NIPT test from one of Defendant's competitors instead.

97. Defendant should be ordered to disgorge or make restitution of all monies improperly accepted, received, or retained.

98. Defendant's conduct has caused substantial injury to Plaintiff, members of the California Subclass, and the public. Defendant's conduct is ongoing and will continue and recur absent a permanent injunction. Accordingly, Plaintiff seeks an order enjoining Defendant from committing such violations of the FAL. Plaintiff further seeks an order granting restitution to

Plaintiff and the California Subclass in an amount to be proven at trial. Plaintiff further seeks an award of attorneys' fees and costs under Cal. Code Civ. Proc. § 1021.5.

99. Plaintiff, on behalf of herself and the California Subclass, seeks injunctive relief to require Defendant to: (1) provide notice to every class member that the NIPT test they purchased is not suited for its intended purpose; and (2) either provide a refund to Plaintiff and the California Subclass for their NIPT test in an amount to be determined at trial.

100. Absent injunctive relief, Defendant will continue to injure Plaintiff and the California Subclass members. Even if such conduct were to cease, it is behavior that is capable of repetition or reoccurrence by Defendant yet evades review.

101. In order to prevent injury to the general public, Plaintiff, in her individual capacity, seeks a public injunction requiring Defendant to stop advertising, and to instruct its resellers to stop advertising, any NIPT test, other than tests for Down Syndrome or Edwards Syndrome, as being highly accurate.

102. Plaintiff and the general public lack an adequate remedy at law to remedy and/or mitigate the totality of the injuries and misconduct described herein.

COUNT VIII
Violation of California's Consumers Legal Remedies Act
California Civil Code § 1750 *et seq.*
(Injunctive Relief Only)

103. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

104. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

105. Defendant is a "person," as defined by California Civil Code § 1761(c).

106. Plaintiff and members of the California Subclass are "consumers," as defined by California Civil Code § 1761(d).

107. The NIPT tests purchased by the Plaintiff and the members of the California Subclass are "goods" as defined by California Civil Code § 1761(a).

108. The purchases by the Plaintiff and the members of the California Subclass constitute "transactions," as defined by California Civil Code § 1761(e).

109. The unlawful methods, acts or practices alleged herein to have been undertaken by Defendant were all committed intentionally and knowingly. The unlawful methods, acts or practices alleged herein to have been undertaken by Defendant did not result from a *bona fide* error notwithstanding the use of reasonable procedures adopted to avoid such error.

110. With regard to this count of the pleading which alleges one or more violations of the CLRA, venue is proper in the state or federal court having jurisdiction over Santa Clara County, California (the county in which this action has been commenced) pursuant to Section 1780(d) of the California Civil Code because, without limitation, Santa Clara County is a county in which Defendant is doing business and is the county in which a substantial portion of the events that gave rise to this cause of action occurred. A declaration establishing that this Court has proper venue for this count is attached hereto as **Exhibit 2**.

111. Defendant's methods, acts and/or practices, including Defendant's misrepresentations, omissions, active concealment, and/or failures to disclose, violated and continue to violate the CLRA in ways including, but not limited to, the following:

(a) Defendant misrepresented that its products had characteristics, benefits, or uses that they did not have (Cal. Civ. Code § 1770(a)(5));

(b) Defendant misrepresented that its products were of a particular standard, quality, grade, or of a particular style or model when the products were of another (Cal. Civ. Code § 1770(a)(7));

(c) Defendant advertised its products with an intent not to sell them as advertised (Cal. Civ. Code § 1770(a)(9)); and

(d) Defendant represented that its products were supplied in accordance with previous representations when they were not (Cal. Civ. Code § 1770(a)(16)).

112. Specifically, Defendant advertised and represented that these NIPT tests were suitable for the particular purpose when in fact the NIPT tests other than tests for Down Syndrome or Edwards Syndrome, were not as highly accurate as stated.

113. With respect to omissions, Defendant at all relevant times had a duty to disclose

the information in question because, *inter alia*: (a) Defendant had exclusive knowledge of material information that was not known to Plaintiff and the California Subclass; (b) Defendant concealed material information from Plaintiff and the California Subclass; and/or (c) Defendant made partial representations which were false and misleading absent the omitted information.

114. Defendant's misrepresentations and nondisclosures deceive and have a tendency and ability to deceive the general public.

115. Defendant's misrepresentations and nondisclosures are material, in that a reasonable person would attach importance to the information and would be induced to act on the information in making purchase decisions. Indeed, the utility and value of Defendant's NIPT tests are significantly reduced, to the point of worthlessness, because these tests should not and cannot be used for their intended and advertised purpose.

116. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent conduct, Plaintiff and the California Subclass suffered injury-in-fact and lost money.

117. But for Defendant's deceptive conduct and omissions of material facts, Plaintiff and the California Subclass would not have purchased the subject NIPT tests and/or would have purchased an appropriate NIPT test from one of Defendant's competitors instead. Defendant's conduct as alleged herein caused substantial injury to Plaintiff, California Subclass Members, and the public. Defendant's conduct is ongoing and will continue and recur absent a permanent injunction. Accordingly, Plaintiff and the California Subclass seek an order enjoining Defendant from committing such practices.

118. If not enjoined by order of this Court, Defendant is free to resume its unlawful behavior and injure Plaintiff and consumers through the misconduct alleged herein once more. Defendant has a duty to speak truthfully or in a non-misleading manner.

119. Plaintiff will be harmed if, in the future, they are left to guess as to whether Defendant's representations are accurate and whether there are omissions of material facts regarding the features or specifications of the NIPT tests.

120. In order to prevent injury to the general public, Plaintiff, in their individual

capacities, seek a public injunction requiring Defendant to stop advertising, and to instruct its resellers to stop advertising, any NIPT test, other than tests for Down Syndrome or Edwards Syndrome, as being highly accurate.

121. The balance of the equities favors the entry of permanent injunctive relief against Defendant. Plaintiff and the general public will be irreparably harmed absent the entry of permanent injunctive relief against Defendant. Plaintiff and the general public lack an adequate remedy at law. A permanent injunction against Defendant is in the public interest. Defendant's unlawful behavior is capable of repetition or re-occurrence absent the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

(a) For an order certifying the nationwide Class under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as representative of the Class, and naming Plaintiff's attorneys as Class Counsel to represent the Class;

(b) For an order declaring the Defendants' conduct violates the statutes referenced herein;

(c) For an order finding in favor of Plaintiff and the Class on all counts asserted herein;

(d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

(e) For prejudgment interest on all amounts awarded;

(f) For an order of restitution and all other forms of equitable monetary relief;

(g) For injunctive relief as pleaded or as the Court may deem proper; and

(h) For an order awarding Plaintiff and the Class their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: February 3, 2022

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ L. Timothy Fisher*
L. Timothy Fisher

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EXHIBIT 1

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January 20, 2022

Via Fed Ex and Certified Mail - Return Receipt Requested

Myriad Genetics, Inc.
320 Wakara Way
Salt Lake City, UT 84108

CT Corporation System
1108 E South Union Ave
Midvale, UT 84047

Re: *Demand Letter Pursuant to California Civil Code § 1782*;
U.C.C. §§ 2-313, 2-314; and all other applicable laws

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Myriad Genetics, Inc. ("You" or "Defendant") pursuant to numerous provisions of California law, including but not limited to subsections (a)(5), (7), and (9) of the Consumers Legal Remedies Act, Civil Code § 1770 and U.C.C. § 2-607(3)(A) concerning the breaches of warranty described herein on behalf of our client, Ashley Carroll, and all other similarly situated purchasers.

You have participated in the marketing and sale of the Prequel Prenatal Screen (the "Product"). Defendant markets and sells the Tests as genetic, prenatal screening tests for pregnant women that screen for various chromosomal and genetic conditions affecting a baby's health. Defendant markets these tests as safe and accurate. However, these tests are incorrect about 85 percent of the time, subjecting expecting mothers to further diagnostic testing, genetic counseling, and the potential for erroneous termination of a viable pregnancy. Thus, the Product is unsuitable for its intended and advertised purpose, and Your representations are false and misleading.

Ms. Carroll purchased the Product based on the Product's representations.

Ms. Carroll is acting on behalf of a class defined as all persons in the United States who purchased the Product. Ms. Carroll is also acting on behalf of a subclass of persons who purchased the Product in the State of California.

To cure these defects, we demand that you make full restitution to all purchasers of the Product of all money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the design, development, and/or testing of the Product;

2. All documents concerning the advertisement, labeling, marketing, or sale of the Product;

3. All documents concerning communications with purchasers of the Product, including but not limited to customer complaints; and

4. All documents concerning your total revenue derived from sales of the Product in California and the United States.

5. All communications with the FDA and other regulatory agencies about the Product.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Joshua D. Arisohn

EXHIBIT 2

CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, L. Timothy Fisher, declare as follows:

1. I am counsel for Plaintiff, and I am a partner at Bursor & Fisher, P.A.. I make this declaration to the best of my knowledge, information, and belief of the facts stated herein.

2. The complaint filed in this action is filed in the proper place for trial under California Civil Code Section 1780(d) because a substantial part of the events or omissions giving rise to these claims occurred in this District.

3. Plaintiff Ashley Carroll alleges that in or about July 2021, she purchased Defendant Myriad Genetics, Inc.'s ("Defendant") Prequel Test in California. *See* Compl. ¶ 8. Plaintiff further alleges that she purchased the Prequel Test because Defendant described the Prequel Test as accurate. Specifically, Defendant represented that the Prequel Test "has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure." Defendant further represented that its Prequel Tests are "more accurate than maternal serum screening" and tells women that the Prequel Tests will "reduc[e] the chances you'll need an unnecessary invasive follow-up test." Plaintiff relied on Defendant's representations and warranties in deciding to purchase the Prequel Test. Accordingly, Defendant's representations and warranties were part of the basis of the bargain, in that she would not have purchased the Prequel Test on the same terms had she known the Test's representations about accuracy and trustworthiness were not true, or at least would have paid significantly less for the Prequel Test.

I declare under the penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct. Executed on February 3, 2022 in Walnut Creek, California.

/s/ *L. Timothy Fisher*
L. Timothy Fisher