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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMANDA DAVIS, individually and on behalf of all others similarly situated,

Plaintiff,

vs.

NATERA, INC.,

Defendant.

Case No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

I. INTRODUCTION

1. During a pregnancy, prenatal testing is used to determine whether chromosomal disorders are present in the fetus. These disorders include Down syndrome, as well as other serious conditions that can result in intellectual disability, a shortened lifespan, and other serious complications. Expectant mothers and their doctors rely on the results of prenatal testing to make potentially life-altering decisions, such as whether to continue with the pregnancy. In the past decade, advances in noninvasive prenatal testing or NIPT have allowed companies to offer tests that can detect developmental deficiencies earlier in the pregnancy by testing a sample of the expectant mother's blood.

2. Defendant Natera, Inc. markets and sells NIPT tests for pregnant women that screen for various chromosomal and genetic conditions affecting a baby's health. Natera markets its NIPT tests as the most reliable non-invasive method of screening for genetic conditions. Although NIPT testing is generally effective at screening for Down syndrome, an investigation by the New York Times has revealed that positive test results for some rare genetic conditions are incorrect 85 percent of the time or more—up to 98 percent.

3. A false positive on a prenatal test can have severe consequences for expecting parents. Besides unnecessarily enduring anxiety, stress, and anguish about the health of their child, pregnant women are subjected to invasive and expensive further diagnostic testing and the additional expense of genetic counseling and consulting with doctors specializing in high-risk pregnancies. In addition, because NIPT testing is generally performed relatively early in the pregnancy, diagnostic testing is not immediately available to confirm the test results. In some states, diagnostic testing may not become available until after the period when a pregnancy may be legally terminated, meaning some expectant parents must rely entirely on the results of the NIPT testing to make an extremely difficult decision on whether to proceed with the pregnancy. And even if it is available, follow-up testing is highly invasive and carries the risk of causing a miscarriage. According to the New York Times investigation, some expectant mothers have even terminated a viable pregnancy based on a false positive from NIPT testing.

4. Natera has known for years that its NIPT tests are susceptible to false positives, yet it

continues to promote its NIPT test as a reliable detector of rare abnormalities. It also claims that its NIPT test produces fewer false positives than competing tests without revealing the extent to which pregnant women and their doctors may be induced to make health decisions based on inaccurate test results.

5. Natera processes more than 400,000 NIPT tests each year, meaning that it tests about one in ten pregnant women in the United States. Each patient is led to believe that they will receive accurate results. Users of Natera's NIPT test, however, have not received what they paid for given the numerous problems that have come to light and many—including Plaintiff—have been subjected to unnecessary stress and anxiety, and additional medical costs due to a false positive indications of rare disorders.

II. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 of the Class Action Fairness Act of 2005 because: (i) there are 100 or more class members, (ii) the aggregate amount in controversy exceeds $5,000,000 exclusive of costs and interest, and (iii) there is minimal diversity because at least one plaintiff and one defendant are citizens of different states. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

7. This Court has personal jurisdiction over Defendant because its principal place of business is in this judicial district, it operates a clinical testing laboratory that processes NIPT tests in this district, and Defendant has otherwise conducted substantial business in this judicial district.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391 because Natera is headquartered and regularly transacts business in this district, is subject to general personal jurisdiction in this district, and therefore is deemed to be a citizen of this district. Additionally, Natera received substantial revenue and profits from its sales of NIPT tests in this district. As such, a substantial part of the events and/or omissions giving rise to the claims at issue occurred, in part, within this district.

III. INTRADISTRICT ASSIGNMENT

9. Assignment to the San Francisco or Oakland Division is appropriate under Local Rule

3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in San Mateo County.

IV. PARTIES

10. Plaintiff Amanda Davis is a resident and citizen of Youngstown, Ohio.

11. Defendant Natera, Inc. is a Delaware corporation with its principal place of business at 201 Industrial Rd., San Carlos, California 94070.

V. FACTUAL BACKGROUND

A. Prenatal Testing

12. Prenatal testing is used to assess a pregnant patient's risk of carrying a child with chromosomal disorders that can affect the baby's health. When tests provide accurate information, prenatal genetic testing provides valuable information to pregnant patients about the health of their unborn child. The genetic conditions these tests are intended to detect can make a pregnancy non-viable or have serious impacts on the health of a surviving newborn, such as structural anomalies, intellectual disabilities, and a shortened lifespan. For example, DiGeorge syndrome is associated with heart defects and intellectual disability and Patau syndrome is "a condition that babies often do not survive beyond a week."[1]

13. A pregnant patient whose child has one of these conditions faces serious questions about risks in continuing the pregnancy, the viability of the pregnancy, and the prognosis and quality of life for any surviving newborn. Some patients choose to terminate a pregnancy that has chromosomal abnormalities.

14. Prenatal testing generally includes both diagnostic tests and the more recently developed screening tests. NIPT is a screening test that uses a sample of a pregnant patient's blood (which includes DNA of the fetus) to screen for a number of genetic conditions caused by an abnormal number of chromosomes.[2]

15. Screening tests differ from diagnostic tests in several ways. Although they provide much more accurate results, diagnostic tests are highly invasive. For example, one diagnostic test is

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

[2] https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test

amniocentesis, where a needle is inserted through the abdominal wall into the uterus to extract amniotic fluid surrounding the fetus.[3] Another, called chorionic villus sampling, tests a sample of the placenta that is removed through the cervix or abdomen.[4] In addition to being physically invasive, these diagnostic tests are also associated with risks, including a small risk of miscarriage.[5]

16. In contrast, screening tests are not invasive, requiring only a blood sample, and can be performed at a much earlier stage in a pregnancy. Because different states impose different time restrictions on when a pregnancy can be terminated, NIPT—which can be done much sooner than diagnostic testing—takes on additional importance. NIPT can be done as early as 9 or 10 weeks of pregnancy.[6] These key differences make screening tests important to pregnant patients. But screening tests generally lack the higher accuracy of a diagnostic test. Properly understood and utilized, screening tests are "tool to determine if that pregnancy may warrant additional diagnostic testing due to the increased risk of a genetic condition."[7]

17. The Positive Predictive Value ("PPV") of each test is the likelihood that a positive screening result is accurate—i.e., that the test result is positive *and* that the fetus actually has the tested-for condition.[8]

18. NIPT is reasonably accurate at identifying the most common conditions like Down syndrome (approximately 1 in 700 live births) and Edward syndrome (about 1 in 3,000 live births).[9] The American College of Obstetricians and Gynecologists ("ACOG") reported in 2019 that for high-risk pregnant women, NIPT for Down syndrome had a Positive Predictive Value of 83%, meaning

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[3] https://my.clevelandclinic.org/health/treatments/4206-genetic-amniocentesis

[4] https://www.mayoclinic.org/tests-procedures/chorionic-villus-sampling/about/pac-20393533

[5] https://www.forbes.com/sites/ellenmatloff/2022/01/06/what-the-nytimes-got-wrong-on-prenatal-screening/?sh=94aebd037a76

[6] https://www.natera.com/womens-health/panorama-nipt-prenatal-screening); https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test.

[7] https://www.forbes.com/sites/ellenmatloff/2022/01/06/what-the-nytimes-got-wrong-on-prenatal-screening/?sh=94aebd037a76

[8] https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/screening-for-fetal-chromosomal-abnormalities

[9] *Id.*

83% of women who test positive actually have babies with Down syndrome.[10] But for low-risk pregnant women, only 33% of positive test results were accurate.

B. The Increased Use of NIPT Testing

19. Although historically only offered to patients considered to be high risk because of their age or personal or family history, prenatal screening has expanded significantly in the last decade. NIPT was developed and grew until the ACOG changed its guidance in 2020 to recommend that all pregnant patients "be offered both screening and diagnostic testing options."[11] The ACOG's guidance is that "[t]esting for chromosomal abnormalities should be an informed patient choice based on provision of adequate and accurate information, and the patient's clinical context, accessible health care resources, values, interests, and goals."[12]

20. "In just over a decade, the tests have gone from laboratory experiments to an industry that serves more than a third of the pregnant women in America. The tests initially looked for Down syndrome and worked very well."[13] But, as the New York Times reported, "as manufacturers tried to outsell each other, they began offering additional screenings for increasingly rare conditions."[14]

21. Adding screening tests for rarer conditions caused by genetic microdeletions—tiny pieces of missing DNA at the sub-chromosomal level—have helped companies competing in the market to grow. As the New York Times reported, "[a]ll the screenings could run on the same blood draw, and doctors already order many tests during short prenatal care visits, meaning some probably thought little of tacking on a few more."[15] Despite no added burden on the patient or doctors for including these additional tests, the upside for testing companies was significant: "adding

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[10] According to ACOG, "High risk" is defined as women 35 years or older; women whose previous ultrasound exam showed a possible problem with the fetus; women with a previous child with one of these disorders or who themselves have a chromosomal problem that increases the risk of having a child with trisomy 21 or trisomy 13; or women with a previous positive first-trimester or second-trimester screening test result. *See* https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test.

[11] *Id.*

[12] *Id.*

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

[14] *Id.*

[15] *Id.*

microdeletions can double what an insurer pays — from an average of $695 for the basic tests to $1,349 for the expanded panel, according to the health data company Concert Genetics."[16]

22. The market for prenatal testing is sizeable and growing, estimated to range from $600 million into the billions, with the number of women taking these tests expected to double by 2025.[17]

23. Natera has become a leader of this expanding market. "Natera has performed more than two million screenings for Down syndrome since 2013. It went public in 2015, and the value of its stock has grown to $8.8 billion."[18] Natera "said that in 2020 it performed more than 400,000 screenings for one microdeletion — the equivalent of testing roughly 10 percent of pregnant women in America."[19]

24. The expanded panel of screenings has played a significant role in Natera's growth, which it expects to continue. Natera's chief executive, Steve Chapman, reportedly said at an investor conference last January, "This is a really significant moment for the microdeletions business."[20] Natera's "2020 revenues were $391 million, and it projected its 2021 revenues to exceed $615 million. But if more insurers begin paying for microdeletion tests, Mr. Chapman said, the potential is 'enormous' — it could bring in up to another $300 million every year."[21]

25. By the end of the third quarter of 2021, Chapman claimed in an earnings call that Natera's market share in NIPT was up to 40%.[22] In a July 2021 interview, he said Natera was "by far the market leader, testing roughly 25% of all pregnancies in the U.S. and growing rapidly."[23]

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[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *Id.*

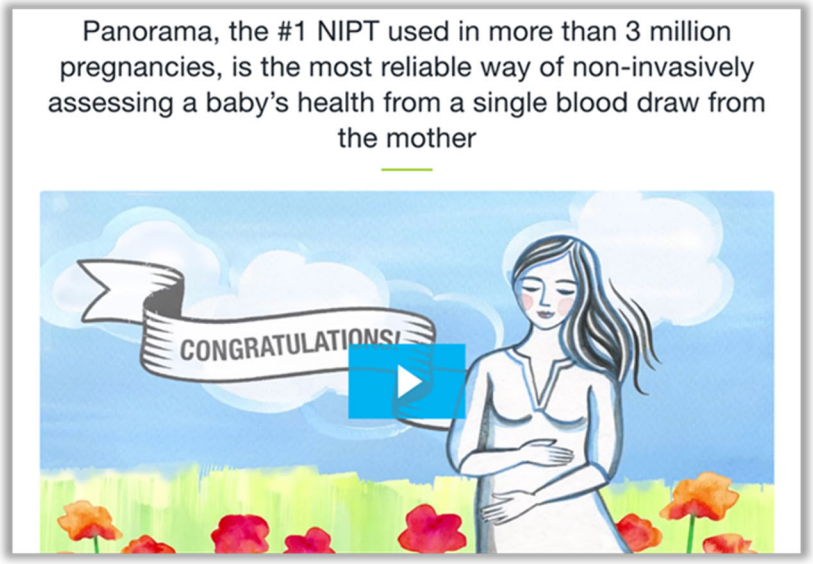
[22] Natera, Inc. Q-4 earnings Call transcript, Nov. 4, 2021, *available at* https://www.fool.com/earnings/call-transcripts/2021/11/05/natera-inc-ntra-q3-2021-earnings-call-transcript/.

[23] Paul Moss, Steve Chapman of Natera: Five Things You Need to Create a Highly Successful Startup, *Authority Magazine*, July 7, 2021, *available at https://medium.com/authority-magazine/steve-chapman-of-natera-five-things-you-need-to-create-a-highly-successful-startup-5815f3621ace.*

C. Natera's Marketing of its NIPT Test

26. Natera advertises its NIPT test, "Panorama," as "the most reliable way of non-invasively assessing a baby's health" and claims that Panorama is "overall the most accurate NIPT commercially available in the United States."[24]

27. Natera's marketing—both to patients and to doctors—highlights the test's "greater accuracy" and represents it to be "the most rigorously validated NIPT."[25] Natera's website, for example, advertises Panorama having been tested with "the largest prospective NIPT study" with outcomes of "~90% samples with genetic truth."[26] The page also lists the numerous rare abnormalities Panorama screens for: Down Syndrome, Edwards Syndrome, Patau Syndrome, Turner Syndrome, Klinefelter Syndrome, Triple X Syndrome, Jacob's Syndrome, 22Q11.2 Deletion Syndrome, Prader-Willi Syndrome, Angelman Syndrome, 1P36 Deletion Syndrome, Cri-du-Chat Syndrome, and Triploidy.[27]

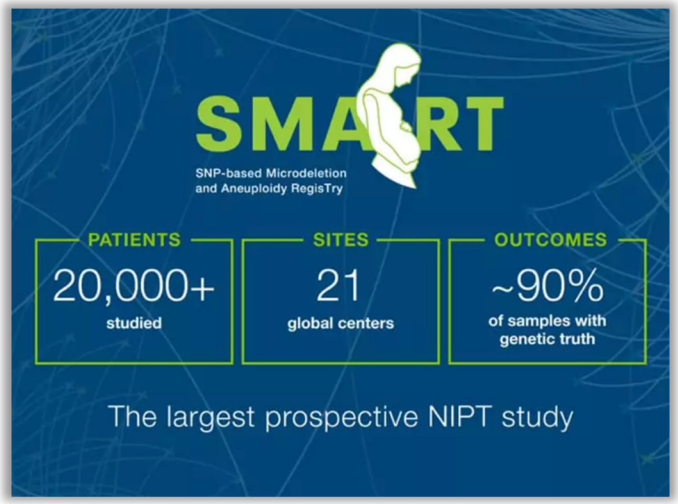


[24] Natera, Inc., 2020 10-K, Feb. 26, 2021 at 9, available at https://investor.natera.com/sec-filings/sec-filing/10-k/0001558370-21-001907.

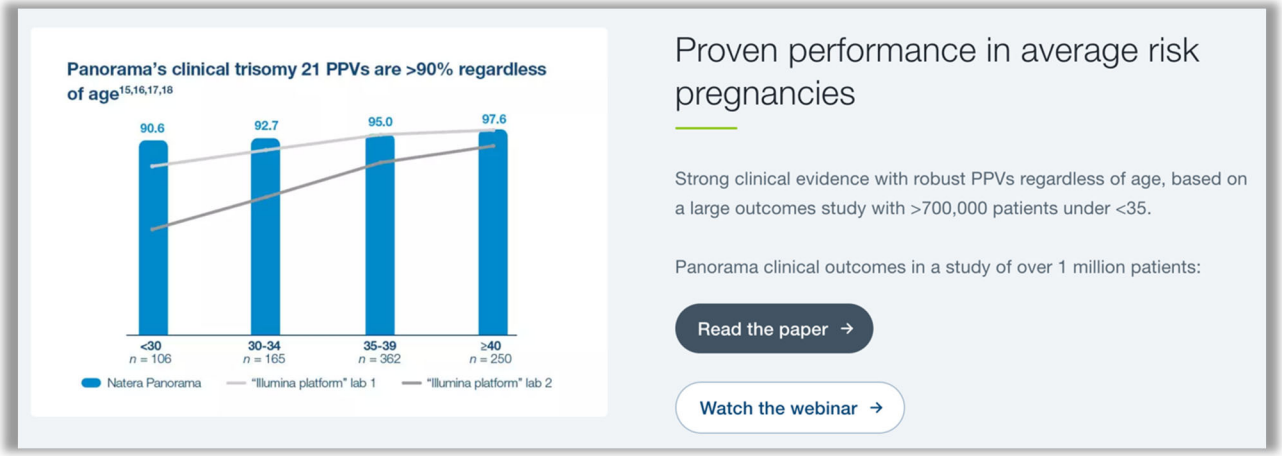
[25] https://www.natera.com/womens-health/panorama-nipt-prenatal-screening

[26] *Id.*

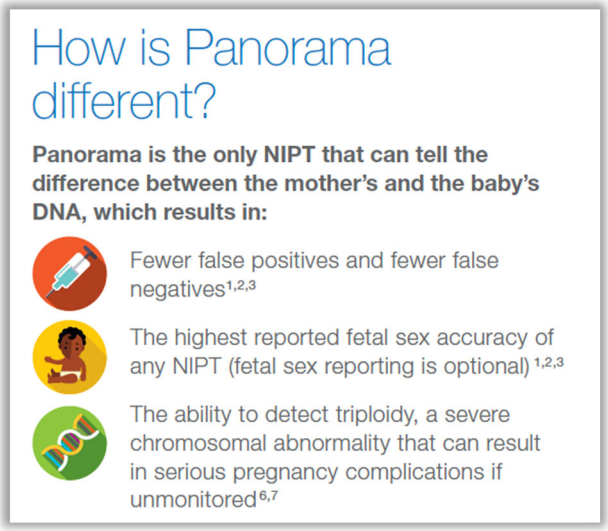
[27] *Id.*



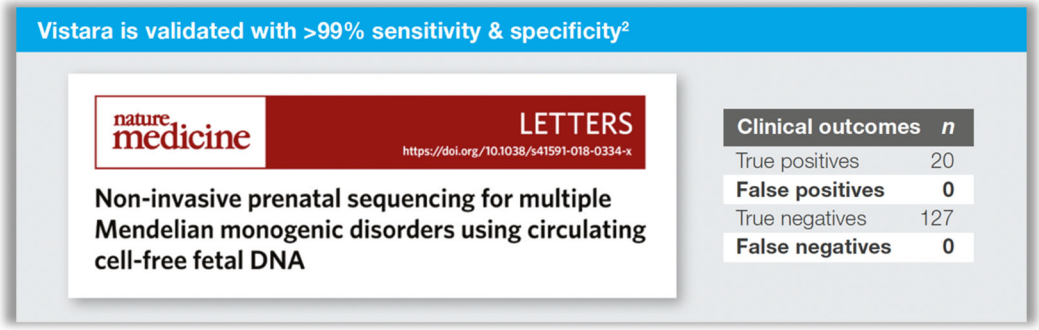
28. Natera specifically highlights the high "positive predictive value" or PPV of Panorama for Down syndrome. Yet it never discloses the fact that the PPV for the rarer genetic conditions Panorama screens for is as low as 2-5%.



29. Panorama's patient brochure further touts that it has "fewer false positives and fewer false negatives."



30. In a similar brochure targeted at doctors, Natera makes similar claims about the accuracy of its products, boasting that its tests are "validated with >99% sensitivity & specificity." Natera urges, "[f]or more clinically relevant information, combine Panorama, with Vistara, the next innovation in NIPT technology."[28]



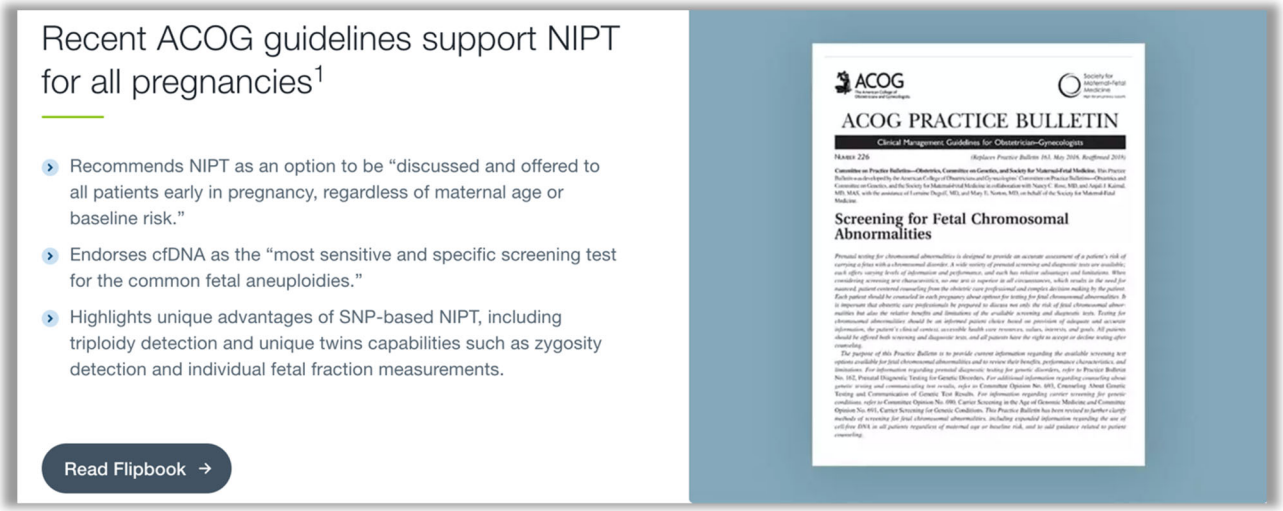
31. In response to the question "what are the benefits of having the panorama prenatal screen?" on a FAQ page, Natera says: "Non-invasive and highly accurate, Panorama identifies more than 99% of pregnancies affected with Down syndrome and has the lowest reported false positive rate of any prenatal screening test for the commonly screened chromosomal abnormalities: trisomy 21, trisomy 18, and trisomy 13."[29]

[28] https://www.natera.com/resource-library/panorama/panorama-vistara-physician-brochure

[29] https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/faq/#pg-menu-tabs

32. Natera advertises that its NIPT test does not pose the risks associated with the more accurate diagnostic test, touting that "Panorama poses no risk to the baby compared to amniocentesis or chorionic villus sampling (CVS)."[30] It also prominently advertises that its test can be performed "as early as nine weeks gestation."[31]

33. Natera also refers to recently changed ACOG guidelines, which now recommend screening be offered in all pregnancies, not just high risk ones. This recommendation increased the popularity of Natera's NIPT tests and others in the market, but it was paired with a recommendation that accurate information be provided about the strengths and weaknesses of the various screening tests available.



D. The Truth About the Accuracy and Reliability of Natera's NIPT Tests

34. In the past decade, NIPT has expanded beyond Down syndrome to screen for chromosomal microdeletions. For these rare genetic conditions, unfortunately, there is a precipitous drop in the positive predictive value of NIPT. Despite the steep drop off in the accuracy of the tests, Natera continues to stress their reliability.

35. The Times report explains how, "[i]n the detection of rare disorders, reliability rates can be misleading."[32] Because "reliability" is different than the positive predictive value of a test, a

[30] https://www.natera.com/womens-health/panorama-nipt-prenatal-screening
[31] *Id.*
[32] https://www.nytimes.com/2022/02/10/learning/lesson-plans/the-misleading-math-of-prenatal-tests.html

statement that results are "99.9% reliable"—a claim commonly made for NIPT—can be statistically true but highly misleading. When "99.9% reliable" means that "99.9 percent of fetuses with the disorder test positive, and 99.9 percent of fetuses without the disorder test negative," the number of false positives for a very rare disorder will still dwarf the number of true positive results.[33]

36. For instance, DiGeorge syndrome, a rare disorder, affects about one out of every 4,000 births. Thus in a random sample of 100,000 births, only about 25 would be expected to have DiGeorge syndrome, and the remaining 99,975 would not.[34] A test with a "99.9% reliability" rate would thus identify about 25 true positive results (99.9% of 25) and about 100 false positives (0.1% of 99,975).[35] So, out of 125 positive test results for DiGeorge in this example, only 20 percent of the positive test results were accurate. "This means that if an expecting mother receives a positive test for DiGeorge syndrome, there is only a 20 percent chance the fetus actually has the syndrome (a far cry from 99.9 percent). In other words, there is an 80 percent chance that the test is wrong."[36]

37. Some of Natera's Panorama tests for the rarest conditions have a positive predictive value as low as 2-5%, meaning positive test results *will be wrong as much as 98% of the time*. Despite these low accuracy rates—and the significant impact the test may have on a parent's decision whether to continue with a pregnancy—Natera advertises Panorama as reliable overall, with much emphasis on the accuracy rates of the tests for more common conditions like Down Syndrome that Panorama can reasonably detect.

38. With accuracy rates this low, positive test results have little if any utility. As one obstetrician and geneticist quoted in the Times put it, "It's a little like running mammograms on kids. . . . The chance of breast cancer is so low, so why are you doing it?"[37]

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[33] *Id.*

[34] *Id.*

[35] https://int.nyt.com/data/documenttools/the-misleading-math-of-prenatal-tests-answer-key/4ace5309f9054a76/full.pdf

[36] https://www.nytimes.com/2022/02/10/learning/lesson-plans/the-misleading-math-of-prenatal-tests.html

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

39. Reproductive Biomedicine & Society Online reported that patients are increasingly relying on the internet for healthcare information, which carries a corresponding increase in the risk of reliance on unclear or misleading information about NIPT.[38] The analysis found "a high degree of variability in the presentation of information about NIPT,"[39] including "most concerningly that companies, including Natera, described NIPT as a screening or diagnostic test unevenly, a key distinction for understanding the accuracy of results and easily misunderstood by patients if not presented clearly.[40]

40. The Times similarly reported that "[g]enetic counselors who have dealt with false positives say some doctors may not understand how poorly the tests work. And even when caregivers do correctly interpret the information, patients may still be inclined to believe the confident-sounding results sheets."[41]

E. The New York Times Investigation

41. In January 2022, a New York Times investigation reported widespread misrepresentations on the accuracy of NIPT. The Times' analysis found that positive results from tests screening for rare chromosomal microdeletion disorders such as DiGeorge and Prader-Willi syndromes were incorrect approximately 85% of the time.[42]

42. The Times also reported that companies offering NIPT were not transparent about the true accuracy of their tests. "The Times reviewed 17 patient and doctor brochures from eight of the testing companies, including Natera, Labcorp, Quest and smaller competitors. Ten of the brochures never mention that a false positive can happen. Only one mentioned how often each test gets positive results wrong."[43]

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[38] Ruth M. Farrell, Patricia K. Agatisa, et.al., Online direct-to-consumer messages about non-invasive prenatal genetic testing, *Reproductive Biomedicine & Society Online*, March 10, 2016, *available at* https://www.rbmsociety.com/article/S2405-6618(16)00003-4/fulltext

[39] *Id.*

[40] https://www.documentcloud.org/documents/21179846-cfa-sec-natera-letter

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

[42] *Id.*

[43] *Id.*

43. The market for NIPT is not heavily regulated. "There are few restrictions on what test makers can offer. The Food and Drug Administration often requires evaluations of how frequently other consequential medical tests are right and whether shortfalls are clearly explained to patients and doctors. But the F.D.A. does not regulate this type of test."[44]

44. Patients and doctors are easily confused by the marketing of companies like Natera. According to the Times, a former FDA official "reviewed marketing materials from three testing companies and described them as 'problematic.'" As he put it, "These numbers are meaningless."[45]

45. Also in January 2022, the Campaign for Accountability sent a letter to the Securities and Exchange Commission ("SEC") detailing the misleading nature of NIPT marketing and asked the SEC to "investigate whether Natera, Inc. has misled investors in violation of the Securities Act of 1934."[46] The letter outlines the misleading nature of Natera's NIPT results, and encourages the SEC to investigate the "company's effort to persuade pregnant women and their doctors of the efficacy of NIPTs" to determine "whether Natera knowingly overstated the accuracy of its NIPT."[47]

F. Consequences of a False Positive Test Result

46. The impact on a pregnant patient of a positive result on a prenatal test indicating that the unborn child has a genetic abnormality is far-reaching.

47. Parents fear that their pregnancy may not be viable, or that even if the child survives birth, it will be seriously impacted by a genetic disorder. The health implications of these conditions on the unborn child, and the potential economic consequences of caring for a child born with genetic abnormalities are so serious that many patients with a positive result at least consider whether to terminate the pregnancy. Some patients do terminate their pregnancies as a result of the positive test results.

48. Compounding that difficult choice patients face about whether to continue the pregnancy, NIPT is usually performed early in a pregnancy before further diagnostic testing can

[44] *Id.*
[45] *Id.*
[46] https://www.documentcloud.org/documents/21179846-cfa-sec-natera-letter
[47] *Id.*

definitively confirm whether the child truly is impacted. Even if diagnostic testing is available, it is highly invasive and there is a risk that the test itself will cause a miscarriage. And in some states where terminating a pregnancy is more tightly restricted, a parent with a positive test result may not have the option to wait for a diagnostic test before deciding whether to terminate the pregnancy.

49. In addition to the anguish for the potentially compromised health of their child, parents with positive test results also must contend with expensive and stressful doctor's appointments with high-risk pregnancy specialists. Pregnant patients often incur increased costs for these extra visits and increased testing. As the Times reported, "Patients who receive a positive result are supposed to pursue follow-up testing, which often requires a drawing of amniotic fluid or a sample of placental tissue. Those tests can cost thousands of dollars, come with a small risk of miscarriage and can't be performed until later in pregnancy—in some states, past the point where abortions are legal."[48]

50. The Times also reported that "[t]he companies have known for years that the follow-up testing doesn't always happen. A 2014 study found that 6 percent of patients who screened positive obtained an abortion without getting another test to confirm the result. That same year The Boston Globe quoted a doctor describing three terminations following unconfirmed positive results."[49]

51. False positives can and do lead to tragic results: "the follow-up testing revealed the fetus was healthy. But by the time the results came, the patient had already ended her pregnancy."[50]

G. Plaintiff Receives a False Positive from Natera's NIPT Test

52. Plaintiff Davis became pregnant in 2020. When she was in her first trimester, her gynecologist highly recommended prenatal screening. Believing the full screening panel was routine, Plaintiff agreed, and submitted to a test using Natera's Panorama NIPT.

53. Plaintiff received her results at her 12-week appointment. The results showed an "atypical finding," noting there was a "[s]uspected finding outside the scope of the test, which may

[48] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html
[49] *Id.*
[50] *Id.*

include, but is not limited to, fetal mosaicism, fetal chromosome abnormality [or] maternal chromosome abnormality." The test results from Natera did not disclose that the positive predictive value for its screening for rare conditions is very low.

54. Although it was unclear to Plaintiff what this test result meant, she was shocked and immediately filled with dread about the well-being of her baby when her gynecologist described the potential results: chromosomal disorders, physical deformities, and babies that often don't survive long after birth if they make it that far. Her gynecologist said that she needed to have regular appointments with a doctor for high-risk pregnant women.

55. Having not been advised of the low positive predictive value of the test, Plaintiff relied on the results of her Natera Panorama NIP test in making decisions regarding her pregnancy and care. She also contemplated whether she would need to terminate her pregnancy.

56. During her pregnancy, Plaintiff had extra medical appointments with a high-risk pregnancy specialist doctor approximately every two weeks for ultrasounds to check for abnormalities. Each appointment brought additional stress and worry as Davis discussed the worst-case scenarios with the doctors.

57. When the first ultrasound did not show any abnormalities, Davis asked whether her test results could have been a false positive. The high-risk pregnancy specialist told her that most NIPT results are pretty accurate. He also said that, at 13 weeks, it was too soon for amniocentesis, but that he would recommend it if the next appointment showed anything. Because Davis understood that amniocentesis is invasive and carried a risk of causing a miscarriage, she worried about having the procedure done.

58. At each appointment she was told that she would need to wait for answers. Although her ultrasounds continued to show no abnormalities, she was told that she still needed to continue to see the high risk specialist. Davis paid approximately three thousand dollars out of pocket for these additional doctors' appointments. She also paid approximately $100 out of pocket for the portion of the Natera test that was not covered by her insurance.

59. When she was around 22 weeks pregnant, Davis' high-risk doctor determined that her child likely did not have a chromosomal disorder based on continued ultrasounds. Davis later gave birth to a healthy baby.

60. Plaintiff Davis would not have utilized and contributed out of pocket payments for a Natera NIPT test if she had known that the test is inaccurate and unreliable.

61. In addition to the other harm described herein, Plaintiff suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

VI. CLASS ACTION ALLEGATIONS

62. Plaintiffs brings this suit as a class action on behalf of herself and all other persons similarly situated, pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), as representative of:

Class: All purchasers of Natera's NIPT testing services, including consumers who paid out-of-pocket, through health insurance, or through any other collateral source.

Ohio Subclass: All Purchasers of Natera's NIPT testing services in Ohio, including consumers who paid out-of-pocket, through health insurance, or through any other collateral source.

63. The Class and the state Subclass are referred to collectively herein as the "Class." Excluded from the Class are Defendant, its affiliates, employees, officers and directors, and the Judge(s) assigned to this case. Plaintiff reserves the right to modify, change or expand the Class and Subclass definitions based on discovery and further investigation.

64. This action is brought as a class action and may properly be so maintained pursuant to the provisions of Rule 23 of the Federal Rules of Civil Procedure.

65. **Numerosity** – The members of the Class are so numerous that their individual joinder is impracticable. While the exact number of individual Class members is unknown at this time, Plaintiff believes the information is in the possession of Natera, and that Class membership is determinable by objective criteria using Defendant's own records.

66. **Existence and Predominance of Common Question of Fact and Law –** There are questions of law and fact common to the Class. These questions predominate over any questions affecting only individual class members and include, but are not limited to:

A. Whether Defendant's NIPT test is accurate and reliable;

B. Whether Defendant has a duty to disclose the complete truth regarding the accuracy and reliability of its NIPT test;

C. Whether Defendant concealed material information about the accuracy and reliability of its NIPT test results;

D. Whether Defendant's conduct violates the laws set forth in the causes of action;

E. Whether Plaintiff and the Class have been harmed as a result of Defendant's conduct alleged herein;

F. Whether Defendant has been unjustly enriched as a result of the conduct alleged herein;

67. **Typicality** – Plaintiff's claims are typical of the claims of the Class. Plaintiff and the Class were subjected to the same common pattern of conduct by Defendant, and Plaintiff, like the other members of the Class, sustained damages arising from Defendant'sviolations of the law, as alleged herein.

68. **Adequacy –** Plaintiff will fairly and adequately represent and protect the interests of the Class and has retained competent counsel who are highly experienced in complex class actions and who intend to vigorously prosecute this action. There are no material conflicts between Plaintiff and the members of the Class.

69. **Superiority –** A class action is superior to other available means for the fair and efficient adjudication of this dispute. The injury suffered by each individual Class member is relatively small in comparison to the burden and expense of prosecuting these claims individually. Individualized litigation also would risk inconsistent or contradictory judgments and increase the delay and expense to all parties and the courts. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

VII. CAUSES OF ACTION

COUNT I

Fraudulent Concealment

70. Plaintiff incorporates and realleges the foregoing allegations of facts.

71. Plaintiff brings this claim on behalf of herself and the Class under California law, or alternatively, Ohio law.

72. Natera marketed and sold Panorama NIPT tests that it knew to be unreliable and failed to take sufficient steps to ensure the reliability of such tests. Yet it encouraged consumers and doctors to rely on such tests to make vital decisions about their pregnancy and pregnancy related treatments. Defendant knew that Plaintiff, consumers, and their treating physicians would reasonably expect the NIPT tests to be reliable, given the nature and importance of prenatal testing.

73. Natera, however, made misleading partial representations and did not fully and truthfully disclose to its customers and their physicians that its NIPT tests cannot accurately and reliably detect rare disorders such as DiGeorge syndrome. Such information was not readily discoverable by Plaintiff, consumers, or their doctors. A reasonable consumer and physician would not expect that NIPT tests—which Defendant repeatedly claimed and heavily promoted to be highly accurate—would in fact frequently result in false positives.

74. At all relevant times, Defendant had a duty to disclose all facts material to Plaintiff and Class members' regarding the use and reliance upon NIPT test results because it had superior knowledge and access to relevant information regarding its own testing, made misleading partial representations regarding the accuracy and reliability of NIPT testing, and because it was in a special relationship with Plaintiff and Class members. Natera, however, failed to disclose all material information regarding its NIPT test to Plaintiff and the Class, as well as to their treating physicians, and concealed such material information with the intent that Plaintiff, Class members, and their physicians would rely on such misleading and incomplete information.

75. Plaintiff and Class members have reasonably relied on the misleading incomplete representations and omissions made by Defendant, including but not limited to, by paying (out-of

pocket and/or through health insurance) for Natera's Panorama NIPT testing services and relying on the test results to make decisions about their pregnancy and treatment.

76. Plaintiff and the Class were actually misled and deceived and suffered damages as a result. Natera's fraudulent conduct was also intentional, willful, wanton, oppressive, reprehensible, and malicious and caused Plaintiff and Class members to suffer emotional distress, stress, and anxiety. Consequently, Plaintiff and Class members are entitled to an award of punitive damages.

COUNT II

Breach of Implied Warranty

77. Plaintiff incorporates and realleges the foregoing allegations of facts.

78. Plaintiff brings this claim on behalf of herself and the Class under California law, or alternatively, Ohio law.

79. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

80. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions Panorama screens for is as low as 2-5%.

81. Plaintiff, Class members, and their doctors relied on Natera's claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions regarding their pregnancy and treatment.

82. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff and Class members have been damaged in an amount to be proven at trial.

COUNT III

Unjust Enrichment

83. Plaintiff incorporates and realleges the foregoing allegations of fact.

84. This count is pled in the alternative to Plaintiff's fraud and warranty claims.

85. Plaintiff brings this claim on behalf of herself and the Class under California law, or alternatively, Ohio law.

86. Plaintiff and Class members lack an adequate remedy at law.

87. As the intended and expected result of its conscious wrongdoing, Natera has profited and benefitted from Plaintiff and Class members' purchases of Panorama NIPT tests.

88. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a result of its misconduct alleged herein, Plaintiff and the Class were not receiving accurate test results an ordinary consumer would expect. Plaintiff and Class members reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-altering decisions regarding their pregnancy and their course of treatment.

89. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct and by its withholding of benefits and unearned monies from Plaintiff and the Class rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a constructive trust so that Plaintiff and Class members can obtain restitution.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the members of the Class, respectfully request that this Court:

1. Determine that the claims alleged herein may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and issue an order certifying the Class and Subclass as defined above and appoint Plaintiff as representative of the Class and Subclass and her counsel as Class Counsel;

2. Award all actual, general, special, incidental, statutory, punitive, and consequential damages to which Plaintiff and Class members are entitled;

3. Award pre-judgment and post-judgment interest on such monetary relief;

4. Award reasonable attorneys' fees and costs as provided by law; and

5. Grant such further and other relief that this Court deems appropriate.

IX. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all claims so triable.

Dated: February 17, 2022

/s/ *Adam E. Polk*

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