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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

SHANNON PETERSEN and ERIN VEDRODE, individually and on behalf of all others similarly situated, Plaintiffs, v. NATERA, INC., Defendant.	Case No. 3:24-cv-07062 **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs Shannon Petersen and Erin Vedrode ("Plaintiffs"), individually and on behalf of all others similarly situated, through their undersigned attorneys, allege as follows based upon personal knowledge as to the individual allegations pertaining to each of them, and the investigation of their counsel, against Defendant Natera, Inc. ("Natera" or "Defendant").

NATURE OF THE ACTION

1. Plaintiffs bring this class action lawsuit to recover economic losses suffered by Plaintiffs and Class members (defined below) as a result of the false, deceptive, unfair, and misleading advertising, marketing, and promotion of Defendant's preimplantation genetic testing for aneuploidy ("PGT-A" or "PGT-A testing"). Plaintiffs and Class members each spent thousands of dollars for PGT-A based on Defendant's material misrepresentations and omissions.

2. Plaintiffs file this lawsuit to remedy Defendant's unfair and deceptive business practices arising from its marketing and sale of PGT-A testing as a proven, accurate, and reliable method to decrease the chance of miscarriage and increase the chance of giving birth to a healthy baby when science does not support this. Defendant's misleading statements and omissions as described in detail below are false and misleading to any reasonable consumer because PGT-A is unproven, inaccurate, and unreliable.

INTRODUCTION

3. According to the World Health Organization in April 2023, one in six people worldwide experience infertility. One-third of the people in the United States have sought or know someone who has sought fertility treatments or assisted reproductive technology ("ART") to assist them in becoming pregnant.

4. According to the United States Centers for Disease Control ("CDC"), as of 2021, approximately 2.3% of all infants born in the United States each year are conceived using ART, and that percentage is growing.

5. According to The American Society of Reproductive Medicine ("ASRM") in 2022, the number of babies in America born from *in vitro* fertilization ("IVF") increased from 89,208 in 2021 to 91,771 in 2022, indicating that 2.5% of all births in the United States are a result of successful ART cycles. The total number of IVF cycles performed increased by over 6% from 2021, from 368,502 in 2021 to 389,993 in 2022.

6. The demand for IVF is growing, thus providing economic opportunity for investors wishing to take advantage of this increasing market.

7. There are now approximately 450 fertility clinics in the United States performing IVF and a huge majority of these procedures are not covered by insurance, as many states do not mandate insurance for IVF.

8. The IVF process begins with medication taken by women to stimulate the follicles to create several mature eggs for collection. Once the eggs are retrieved from the ovaries, they

are then fertilized by the fertility clinic with sperm to create embryos. If the embryos reach the blastocyst stage, they are then ready for implantation to see if they will result in a pregnancy.

9. PGT-A testing is marketed and sold by Defendant as an add-on to the IVF process and purports to screen embryos for chromosomal abnormalities. With respect to PGT-A conducted by Defendant, IVF clinics perform a biopsy and send a small number of cells from the embryo to Defendant who performs the PGT-A testing and provides results to the customer and their clinic. The results purport to determine which embryos are "euploid" or best suited for implantation and which embryos are "aneuploid" or abnormal and not suited for implantation.

10. PGT-A testing is marketed and sold by Defendant to people pursuing IVF as increasing the chance of embryo implantation, decreasing the chance of miscarriage, reducing the time to pregnancy, increasing the rate of pregnancy, increasing live birth rates, improving the chance of a healthy pregnancy, and improving pregnancy rates for all ages, especially those of advanced maternal age which Defendant identifies as over 35 years old. Defendant also markets PGT-A as being 99% accurate. Based on these material representations and the material omissions that underlay them as detailed below, Plaintiffs and Class members choose to purchase PGT-A testing from Defendants.

11. The above representations by Defendant are false and/or misleading and deceptive based upon the omission of material information. Studies show that when looking at clinic pregnancy, miscarriage, or live-birth rates, there is no difference between cycles utilizing PGT-A and cycles not utilizing PGT-A. Studies also show the accuracy rating for PGT-A is significantly lower than advertised.

12. Defendant's false and misleading statements have severe consequences, including causing ascertainable economic losses in the thousands of dollars suffered by Plaintiffs and Class members.

13. Insurance companies have independently determined that there is insufficient basis to support the use of PGT-A. Thus, PGT-A testing is rarely covered by insurance and is

primarily sold to consumers as an additional out-of-pocket expense in addition to the expensive cost of IVF.

14. For example, the largest health insurance company in America, United Healthcare, has noted that PGT-A is unproven and not medically necessary due to "insufficient evidence of efficacy." United Healthcare further states with respect to PGT-A that "[t]here is insufficient evidence to support the use of PGT for aneuploidy screening at this time."[1]

15. Likewise, another large health insurance company, Aetna, states that PGT-A testing is "experimental, investigational, or unproven."[2]

16. As detailed below, these conclusions by United Healthcare, Aetna, and other insurance companies are in line with conclusions reached by major professional health organizations in the area of women's health.

17. Embryos that are assigned an "abnormal" or "aneuploid" testing result (*i.e.*, embryos that are designated as having an abnormal number of chromosomes) by Defendant are typically not transferred and are often discarded due to customers being told that "abnormal" embryos as determined by Defendants' PGT-A testing are unsuitable for transfer.

18. Despite scientific research and studies showing insufficient evidence of efficacy, the use of PGT-A has spiked in recent years due to Defendant's marketing and advertising. For example, from 2014 to 2021, the use of PGT-A testing increased from being utilized in 13% of IVF cycles to approximately 40% of IVF cycles.

19. The PGT-A testing industry now generates an estimated revenue of between $300 million to $400 million dollars per year.

20. Defendant has known for years that there is insufficient evidence of efficacy of PGT-A, and that PGT-A does not improve pregnancy rates, reduce the chance of miscarriage,

[1] United Healthcare Commercial and Individual Exchange Medical Policy, Preimplantation Genetic Testing and Related Services, effective date June 1, 2024.
[2] *See* https://www.aetna.com/cpb/medical/data/300_399/0358.html.

increase the success of IVF, or increase the chances of a healthy baby. Despite that, Defendant has continued to aggressively promote PGT-A to vulnerable and unsuspecting consumers.

21. Defendant has known for years that its PGT-A testing is not 99% accurate.

22. Defendant has acted to mislead customers with its false and deceptive marketing and advertising statements, and material omissions, in exchange for the opportunity to reap millions of dollars in profit each year from selling PGT-A testing.

23. Plaintiffs and Class members have relied on Defendant's false and deceptive marketing and advertising statements, and material omissions in purchasing PGT-A testing, and have suffered economic losses as a direct result.

24. Plaintiffs and Class members would not have purchased PGT-A testing from Defendant had they known the truth as detailed below, and seek all available damages, equitable relief, and other remedies from Defendant as alleged herein.

PARTIES

25. Plaintiff Shannon Petersen is a resident of Petaluma, California and received fertility treatment in Greenbrae, California.

26. Plaintiff Erin Vedrode is a resident of Saginaw, Michigan and received fertility treatment fertility in Ann Arbor, Michigan.

27. Defendant Natera, Inc. is incorporated in Delaware and headquartered at 201 Industrial Road, Suite 410, San Carlos, California 94070.

28. PGT-A testing is performed by Defendant Natera, Inc. at its laboratory in San Carlos, California.

29. Defendant markets, advertises, and promotes PGT-A in California and throughout the United States.

JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. Section 1332(d)(3)(B) and (D) because: (i) there are 100 or more Class members; (ii) there is an aggregate amount in controversy exceeding $5,000,000, exclusive

of interest and costs; and (iii) some Plaintiffs and Class members and Defendant are residents of different states.

31. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

32. The injuries, damages and/or harm upon which this action is based occurred or arose out of activities engaged in by Defendant within, affecting, and emanating from, the State of California. Defendant regularly conducts and/or solicits business in, engages in other persistent courses of conduct in, and/or derives substantial revenue from services provided to persons in the State of California. Defendant has engaged, and continues to engage, in substantial and continuous business practices in the State of California and across the country.

33. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the State of California, including within this District.

34. The **Divisional Assignment.** Pursuant to Civ. L.R. 3-2(c), this action should be assigned to the San Francisco Division, as the first-listed Named Plaintiff resides in Sonoma County.

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

35. IVF is a process of fertilization in which an egg is combined with sperm in vitro ("in glass").

36. To prepare for egg retrieval, certain drugs and hormone therapies are taken orally and by injection over several weeks to stabilize the uterine lining, stimulate the ovaries into producing follicles, and stop the ovary follicles from releasing eggs. The injections often result in bruising, swelling, and discomfort. The drugs and hormones often also trigger side effects including fatigue, nausea, headaches, allergic reactions, and blood clots, as well as negative emotions and mood swings.

37. After eggs are determined to be ready for retrieval, an ovulation trigger injection is performed. The patient then proceeds to an operating room for egg retrieval, where she is sedated or placed under general anesthesia and undergoes insertion of a needle through the vaginal wall and into each follicle in the ovary to drain the follicles of their fluid. The fluid in the follicle is then extracted into a test tube and studied under a microscope to look for eggs.

38. Residual pain from the egg retrieval procedure can last for several days. Some patients suffer significant side effects such as ovarian hyperstimulation syndrome that causes the ovaries to painfully swell and can lead to hospitalization.

39. The extracted eggs are then fertilized with sperm in a laboratory to create embryos.

40. If PGT-A testing is not performed on the embryos, after the fertilized egg (zygote) undergoes embryo culture for 2-6 days, it may then be transferred by catheter into the uterus with the intention of establishing a successful pregnancy.

41. If PGT-A testing is performed, a biopsy is taken from the trophectoderm component of the embryo (meaning the outer layer of the blastocyst) after the embryo reaches the blastocyst stage of development.

42. During the biopsy, the embryologist creates a hole in the embryo's zona pellucida which allows for the removal of five to ten cells from the trophectoderm component of the embryo.

43. For those who purchase PGT-A testing from Defendant, the removed cells are then sent to Defendant's laboratory in San Carlos, California for PGT-A testing.

44. Meanwhile, the embryos are frozen and stored with the IVF clinic while PGT-A testing is performed by Defendant.

45. Embryos are fragile and vulnerable to damage from biopsy and the freezing and thawing process necessary for PGT-A testing to be performed.[3]

[3] Aluko, A., et al., *Multiple cryopreservation – warming cycles, coupled with blastocyst biopsy, negatively affect IVF outcomes.* Reproductive Biomedicine Online. Vol. 42, Issue 3. March 2021.

46. For this reason, experts caution that performing additional biopsies for PGT-A testing, which requires thawing and refreezing the embryo, can cause additional damage to the embryo and negatively affect IVF outcomes.[4] It can also result in a reduced chance of pregnancy.[5]

47. As a result, if Plaintiffs and Class members were aware of the true efficacy and accuracy rates of PGT-A testing, they would forego such testing.

48. Defendant is aware of the lengths to which individuals undergoing IVF go to create embryos, their emotional and financial investment in assuring the viability of their embryos, and their expectations that any genetic testing should not be sold in a misleading and deceptive manner.

49. In some cases, additional procedures with additional costs may be purchased by those undergoing IVF, including (a) intracytoplasmic sperm injection ("ICSI") to increase the chance for fertilization; (b) assisted hatching of embryos to potentially increase the chance of embryo attachment ("implantation"); and (c) cryopreservation (freezing) of eggs or embryos.

50. Embryos are precious and irreplaceable. Human eggs, also known as oocytes, are a limited resource. A woman has about one million eggs at birth and this supply diminishes at a rate of about 1,000 eggs per month as part of the natural aging process.

51. The loss of oocytes from the ovaries continues in the absence of menstrual cycles, and even during pregnancy, nursing, or taking of oral contraceptives.

52. Egg quality, too, diminishes with time, with miscarriages and chromosomal abnormalities occurring more frequently for older women than for younger women.

53. Defendant's PGT-A testing sold to Plaintiffs and Class members has substantial ramifications including, without limitation, the costs that are paid for such testing, and the additional costs of related procedures.

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[4] *Id.*

[5] Bradley, Cara. *Impact of multiple blastocyst biopsy and vitrification – warming procedures on pregnancy outcomes.* Fertility and Sterility. Vol. 108, Issue 6. December 2021.

54. Defendant promotes PGT-A as an add-on to the IVF process and strongly encourages individuals to purchase PGT-A to determine which embryos are suitable to transfer.

55. PGT-A testing can and does result in the unnecessary loss of embryos.

56. PGT-A testing can and does result in embryos that could result in live births not being transferred.

57. PGT-A testing can and does result in embryos that could result in live births being discarded.

58. PGT-A testing can and does result in additional egg retrievals.

59. PGT-A testing can and does provide false positives and false negatives.

60. PGT-A testing can and does result in important decisions being made during IVF based upon inaccurate information.

61. PGT-A testing can and does result in embryos being unable to be transferred.

62. Inaccurate PGT-A testing can and does result in healthy babies being born from embryos deemed "abnormal" and "unsuitable for transfer."

63. In selling PGT-A to consumers, Defendant represents that PGT-A testing is (a) 99% accurate; (b) increases the chance of embryo implantation, (c) decreases the chance of miscarriage, (d) reduces the time to pregnancy, (e) increases the rate of pregnancy, (f) increases the rate of live birth, (g) improves the chance of a healthy pregnancy, (h) increases IVF success, and (i) improves pregnancy rates for all ages, especially those of advanced maternal age which Defendant identifies as above 35.

64. These representations are false and misleading, and Plaintiffs and Class members would not have purchased PGT-A testing from Defendant had they known the truth about PGT-testing, which Defendant misrepresented and materially omitted.

B. History of PGT-A Testing

65. Preimplantation genetic testing was pioneered by Yuri Verlinsky and his colleagues beginning in the late 1980s.

66. In 1996, the hypothesis was first proposed that preimplantation genetic screening ("PGS") that eliminated aneuploid embryos prior to transfer would improve implantation rates of remaining embryos in IVF, increase pregnancy and live birth rates, and reduce miscarriages.[6]

67. In reaching this hypothesis, the authors made at least five assumptions: (a) most IVF cycles fail because of aneuploid embryos; (b) their elimination prior to embryo transfer will improve IVF outcomes; (c) a single trophectoderm biopsy ("TEB") at blastocyst stage is representative of the whole trophectoderm ("TE"); (d) TE ploidy reliably represents the inner cell mass ("ICM"); and (e) ploidy does not self-correct downstream from blastocyst stage.

68. Based upon these assumptions, PGS began to be marketed as an add-on to IVF treatments, with promises of improved outcomes and reduced miscarriage rates.

69. In fact, as of 2024, there have been no randomized, properly structured, non-commercial trials to support the basis of its marketing.

70. Initially, PGS was proposed by polar body biopsy, and eventually, technology was implemented to a more invasive cleavage state embryo biopsy.

71. This method, described as PGS 1.0, became increasingly popular despite that researchers in 2005 were still unable to demonstrate outcome benefits.[7]

72. In 2008, a randomized clinical trial sought to study one of the above-stated hypotheses: whether the effect of PGS on live births rates differs in women of advanced maternal

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[6] Verlinsky, Y. and Kuliev, A., *Preimplantation diagnosis of common aneuploidies in infertile couples of advanced maternal age*. Hum. Reprod. 1996, 11:2076-7.

[7] Staessen C, Platteau P, Van Assche E, Miciels A, Tournaye H, Camus M, Devroey P, Liebaers I, van Steirteghem A. *Comparison of blastocyst transfer with and without preimplantation genetic diagnosis for aneuploidy screening in women of advanced maternal age: a prospective randomized controlled trial*. Hum Reprod. 2005;19:2849–58. 16. Platteau P, Staessen C, Michiels A, Van Steirteghem A, Liebaers I, Devroey P. *Preimplantation genetic diagnosis for eneuploidy screening in women older than 37 years. Fertil Steril*. 2005;84:319–24. 17. Platteau P, Staessen C, Michiels A, Van Steirteghem A, Liebaers I, Devroey P. *Preimplantation genetic diagnosis for aneuploidy screening in patients with unexplained recurrent miscarriages*. Fertil Steril. 2005;83:393–7.

age with variable risks for embryonic aneuploidy, and weighed these effects against the results obtained after IVF without PGS.[8]

73. The authors of this study concluded that PGS had no clinical benefit over standard IVF in women of advanced maternal age regardless of their risk for embryonic aneuploidy.[9]

74. In 2009, Defendant originated its PGT-A product which it markets as "Spectrum."[10]

75. In 2011, researchers conducted a meta-analysis of randomized control trials on the effect of PGS on the probability of live birth after IVF.[11]

76. The authors of this meta-analysis found that there is no evidence of a beneficial effect of PGS as currently applied on the live birth rate after IVF.[12]

77. In addition, the authors determined that PGS significantly *lowers* the live birth rate for women of advanced maternal age. The authors noted that technical drawbacks underlied the inefficiency of PGS.[13]

78. The authors cautioned that new approaches in the application of PGS should be carefully evaluated before introduction into clinical practice.[14]

79. In a 2013 paired randomized clinical trial on 116 patients, scientists sought to evaluate if cleavage[15] or blastocyst stage embryo biopsy affects reproductive competence.[16]

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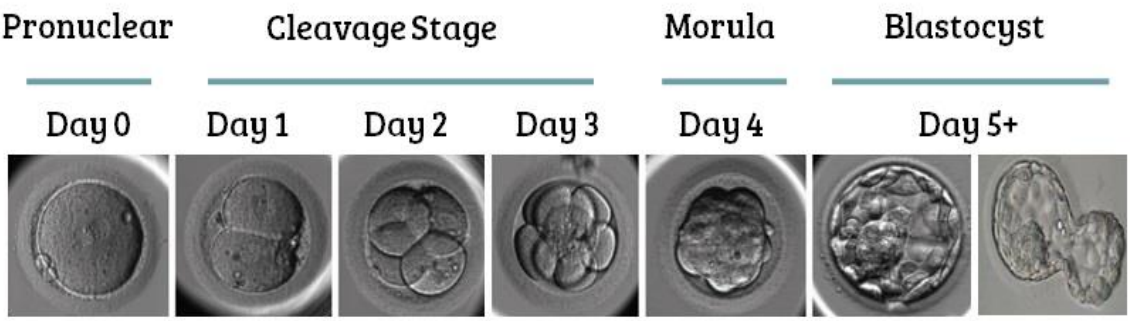
[8] Twisk, M., Mastenbroek, S., et al., *No beneficial effect of preimplantation genetic screening in women of advanced maternal age with a high risk for embryonic aneuploidy*. Human Reproduction, Vol,23, No. 12 pp. 2813-2817 (2008).
[9] *Id.*
[10] Natera Company Fact Sheet located at https://www.natera.com/wp-content/uploads/2020/12/NAT_FS_2019_11_21_NAT-801958_DWNLD.pdf (last visited October 8, 2024).
[11] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.
[16] Scott, R., et al., *Cleavage-stage biopsy significantly impairs human embryonic implantation potential while blastocyst biopsy does not: a randomized and paired clinical trial*, Fertility and Sterility Vol. 100, No. 3, September 2013 0015-0282.



80. Until this time, most biopsies for PGS were performed at the cleavage stage of embryogenesis, whereas less than one percent (1%) were being performed on blastocyst stage.

81. The authors concluded that cleavage-stage biopsy markedly reduced embryonic reproductive potential.[17]

82. They further concluded that until laboratories demonstrated safety by applying a similar powerful study design, there remained insufficient evidence that biopsy at the blastocyst stage could be safely performed without impacting the reproductive potential of human embryos.[18]

83. Soon thereafter, however, the PGS testing labs began trophectoderm biopsy at the blastocyst stage without conducting further appropriate studies.

84. To perform PGT-A, DNA must be obtained from embryos for analysis.

85. The approach most widely adopted in practice today to obtain DNA is by performing a biopsy from a blastocyst 5 to 6 days after conception.

86. The blastocyst is made up of embryonic cells and extraembryonic cells.

87. The embryonic cells form the inner cell mass ("ICM") of the blastocyst, which will lead to the development of the fetus, and the extraembryonic cells form the trophectoderm of the blastocyst which will form the placenta.

[17] *Id.*
[18] *Id.*

88. The biopsy is taken from the trophectoderm which is made up of extraembryonic cell lineage cells. This extraembryonic cell DNA is then analyzed to determine if the embryo contains a normal or abnormal number of chromosomes.

89. For PGS testing results, the number of chromosomes detected from the biopsied cells, taken from the trophectoderm, are interpreted to be representative of the entire embryo including the inner cell mass.

90. Laboratories performing preimplantation genetic testing proclaim that if testing results show a normal number of chromosomes in the biopsy, then the embryo should be considered euploidy (the word comes from the Greek word *eu*, which means true or even), which means it has a higher chance of successful implantation and live birth. In contrast, if testing shows an abnormal number of chromosomes in the biopsy, then the embryo should be considered aneuploid.

91. The trophectoderm biopsy at blastocyst stage, referred to as PGS 2.0, was considered by PGS proponents as more accurate than PGS 1.0, and quickly replaced the earlier method.

92. There were, however, no properly conducted studies to assess PGS 2.0 accuracy and whether the new method increased implantation and reduced miscarriage rates.

93. When embryo biopsy moved from cleavage to blastocyst stage, and selected chromosome investigations went to full chromosomal analyses with a newly developed diagnostic platform for conducting PGS 2.0, the assumption was that PGS would finally show its effectiveness. This, however, did not happen.

94. Thus, genetic laboratories questioned whether other platforms could more accurately determine embryo ploidy.

95. In a 2016 study, researchers tested embryos that had previously been tested and deemed aneuploid.[19] Six out of eleven embryos upon retesting were determined to be either

[19] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of human embryos*, Reproductive Biology and Endocrinology (2016) 14:54.

definitively normal or mosaic with the potential to be normal, thus offering a chance for pregnancy if transferred.[20]

96. The authors of this 2016 study concluded that while the study was small, it suggested a potential false positive rate of almost 55% and an intra-embryo discrepancy of almost 50%.[21]

97. Further, of the eleven embryos originally deemed abnormal, eight patients decided to undergo a transfer, and five of those eight transfers resulted in the delivery of healthy newborns.[22]

98. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[23]

99. In another 2016 study, researchers analyzed assisted reproductive technology in the United States from 2011 to 2012 and found that overall PGS was associated with a decreased live birth rate when compared to IVF without PGS.[24]

100. In yet another study in 2016, researchers re-biopsied 37 embryos determined to be "abnormal" and found that 33% of embryos originally reported to be "aneuploid" were found to be "euploid" upon repeat assessment.[25] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

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[20] *Id*.
[21] *Id.*
[22] *Id*.
[23] *Id*.
[24] Kushnir, VA, et al., *Effectiveness of in vitro fertilization with preimplantation genetic screening: a reanalysis of Unites States assisted reproductive technology data 2011-2012*. Fert Steril, 2016; 106(1): 75-9.
[25] Tortoriello D., et al., *Reanalysis of human blastocysts with different molecular genetic screening platforms reveals significant discordance in ploidy status*. Fert Steril, 2016; 106(1).

101. Furthermore, in 2016, researchers in a mouse study found that mosaic embryos were able to self-correct and that aneuploid cells were progressively depleted from the blastocyst stage on.[26]

102. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[27]

103. By this time, proponents of PGS were aware of the above scientific literature that a problem existed with the results of PGS and that there was a problem with strictly defining embryos as either euploid or aneuploid, with the known resulting consequences of delivering aneuploid test results to patients.

104. Defendant, however, did not incorporate this knowledge into its marketing and advertising to inform its customers about the problems and issues inherent in PGS testing.

105. Despite the mounting research as of 2016, the Preimplantation Genetic Diagnosis International Society ("PGDIS") published practice guidance for PGS on its website for the first time in July 2016.

106. At the same time, PGDIS announced a name change from PGS to PGT-A. Notably, this change replaced the term "screening" with the term "testing."

107. PGDIS is heavily influenced by and comprised of influential members of the genetic testing industry and has its headquarters located at a genetic testing laboratory.

108. PGDIS was cofounded by Yuri Verlinsky, who created a genetic testing company, Reproductive Genetic Innovations, Inc. ("RGI"), and Santiago Munne, who also co-founded the genetic testing companies, Reprogenetics and Recombine and worked as the Chief Scientific Officer of CooperGenomics in 2016 and 2017.

109. In fact, PGDIS has its headquarters at the same location as RGI, another genetic testing laboratory that markets and sells PGT-A.

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[26] Bolton, H., et al., *Mouse model of chromosome mosaicism reveals lineage-specific depletion of aneuploid cells and normal development potential*. *Nat Commun* 7, 11165 (2016). https://doi.org/10.1038/ncomms11165.

[27] *Id.*

110. The PGDIS guidelines contained no references to valid scientific literature and were published without being subject to peer review.

111. Research conducted the following year in 2017 shed even more light on the issues with PGS testing, now known as PGT-A. Specifically, the authors conducted a review of 455 publications related to testing and concluded that all five assumptions made in 1996 are scientifically unsupportable and the hypotheses of PGS were discredited.[28]

112. The authors of the 2017 review urged testing for the purpose of research and acknowledged that not one properly analyzed study had been able to demonstrate clinical outcome benefits and, indeed, increasing evidence suggested that at least in unfavorable patient populations (*i.e.*, older patients) who were considered the best candidates for the test, testing may instead reduce pregnancy and live birth chances.[29]

113. Instead of undertaking randomized and properly structured studies, Defendant continued to falsely promote and tout the benefits of PGS testing and PGT-A testing to IVF patients without appropriate validation or scientific support.

114. Thereafter, PGT-A testing proponents pivoted yet again, and suggested that aneuploid embryos would now be divided into two diagnostic categories, mosaic and aneuploid. However, the thresholds of classification for euploid, mosaic, and aneuploid embryos were not based on appropriate peer reviewed scientific research.

115. In another study in 2017, a researcher sought to analyze the clinical reliability of PGT-A results and the resulting loss of what may be viable embryos.[30] The author estimated that the proportion of normal embryos that are discarded based upon faulty results may be as high as 40%. The author noted that this would lead to an overall decrease in the cumulative pregnancy rate achievable.[31]

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[28] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21

[29] *Id.*

[30] Paulson, R., *Preimplantation genetic screening: what is the clinical efficiency?* Fert. Ster. Vo. 108 No. 2, August 2017.

[31] *Id.*

116. In 2018, an abstract titled *The Emperor Still Looks Naked* was published in Reproductive Biomedicine criticizing PGS/PGT-A as a novel technology that has seen widespread implementation without scientific support.[32]

117. The author commented, "I have been appalled at the implementation into clinical practice of novel technology without the appropriate underpinning science. Saddest of all is the peddling, not infrequently for substantial pecuniary gain, of these unproven techniques to vulnerable people – older age women, or those with repeated IVF failure or recurrent miscarriage – as miracle treatments that will change their blighted lives."[33] The author called for registered, randomized, properly structured, non-commercial trials before clinical application of a technology that can lead to such devastating consequences like viable embryo destruction.

118. Subsequently, no such study was conducted, and no such study was sponsored or proposed by Defendant.

119. Instead, Defendant continued its marketing efforts to obtain greater market share in the PGT-A industry and continued not to disclose the truth about PGT-A to its vulnerable customers.

120. In 2018, the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART") issued a committee opinion on PGS/PGT-A, concluding that "the value of PGS/PGT-A as a screening test for IVF patients has yet to be determined."[34]

121. Defendant, however, materially omitted to inform its customers and potential customers of this important pronouncement by the leading professional organization for reproductive medicine.

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[32] Braude P. *The Emperor Still Looks Naked*. Reprod Biomed Online. 2018 Aug;37(2):133-135. doi: 10.1016/j.rbmo.2018.06.018. PMID: 30075840.

[33] *Id.*

[34] Penzias, A., et al., *The use of preimplantation genetic testing for aneuploidy (PGT-A): A committee opinion.* Fertility and Sterility, Vol. 109, No. 3, March 2018.

122. Instead, Defendant issued a press release which "announced the publication of a study demonstrating the value of the company's Spectrum® preimplantation genetic screening for aneuploidy (PGT-A) to improve in vitro fertilization (IVF) results for all women, including those of advanced maternal age."[35] The press release was titled, "Study Shows Natera's Spectrum Preimplantation Genetic Testing for Aneuploidy Improves IVF Outcomes for All Women, Regardless of Maternal Age" and touted that "Spectrum's patented SNP-based technology with Parental Support provides a highly comprehensive 24-chromosome PGT-A *with an accuracy greater than 99 percent* per chromosome call." (emphasis added.)

123. In 2019, Santiago Munne, conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[36]

124. Mr. Munne and his fellow researchers found that PGT-A did not improve overall pregnancy outcomes, did not improve live birth rates, and did not reduce miscarriage rates.[37]

125. Commentary published following this study included the following: "Considering all presented evidence, it is difficult to understand what further argument can be made for the continuous routing clinical utilization of PGT-A to improve IVF outcomes."[38]

126. Defendant, however, continued to promote PGT-A including by making the specific affirmative misrepresentation that PGT-A improves pregnancy rates for all ages[39] and the other representations stated above, including that it increases the chance of implantation, decreases the chance of miscarriage, increases IVF success, and increases the rate of pregnancy and live birth, all while omitting to inform customers concerning the truth about PGT-A.

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[35] https://www.natera.com/company/news/study-shows-nateras-spectrum-preimplantation-genetic-testing-for-aneuploidy-improves-ivf-outcomes-for-all-women-regardless-of-maternal-age-2/(last visited October 8, 2024).

[36] Munne, S., et al., *Preimplantation genetic testing for aneuploidy versus morphology as selection criteria for single frozen-thawed embryo transfer in good-prognosis patients: a multicenter randomized clinical trial*. Fertility and Sterility, Vol. 112, No. 6, December 2019.

[37] *Id.*

[38] Orvieto, R., *Preimplantation genetic testing for aneuploidy (PGT-A- finally revealed*. Journal of Assisted Reproduction and Genetics (2020) 37-669-672.

[39] https://www.natera.com/resource-library/spectrum/what-is-pgt-a-and-how-does-it-support-ivf/ (last visited October 8, 2024).

127. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[40]

128. Dr. Paulson noted that the marketing of PGT-A as accurate, having minimal errors, and applicable to IVF patients generally was not supported with evidence-based science and that the losses of potential implantations are evident. Dr. Paulson called for scientific scrutiny of the available PGT-A data.[41]

129. In addition, an assessment was done of IVF and PGT patient education materials, which also raised concerns.

130. The United States Centers for Disease Control and Prevention ("CDC") requires that patient education materials be written at or below a fifth-grade reading level, but researchers found that among the educational materials examined, none met the CDC standard.[42]

131. These findings suggested that patient educational materials concerning PGT-A may not always be comprehensible or clear to all patients. Lack of appropriate educational materials that present information about PGT-A in an accessible, unbiased, and comprehensible manner have the potential to lead to disparities in the use of PGT-A because patient educational materials have exceeded the average literacy skills of U.S. residents.[43]

132. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[44] The authors of the 2020 study found

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[40] Paulson, R. *Hidden in plain sight: the overstated benefits and underestimated losses of potential implantations associated with advertised PGT-A success rates.* Human Reproduction, Vol. 35, Issue 3, p. 490-493 (March 2020).

[41] *Id*.

[42] Early, M., et al., *Literary assessment of preimplantation genetic patient education materials exceed national reading levels*, Journal of Assisted Reproduction and Genetics, Vol.37, p. 1913-1922, (2020).

[43] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: Challenges in clinical practice*, Human Genomics, article 69 (2022).

[44] Doody, K. *Live Birth Rate Following PGT Results in Lower Live Birth Rate Compared to Untested Embryos Transferred at Day 5/6.* Fertility and Sterility. Vol. 114, Issue 3, Supplement E419 (September 2020).

that PGT-A resulted in a lower chance of live birth in all age groups compared to transfer of embryos without PGT-A.[45]

133. In November 2021, the preeminent New England Journal of Medicine published the results of a randomized controlled trial to assess whether PGT-A improves the cumulative life-birth rate as compared with conventional IVF.[46]

134. The authors concluded that "conventional IVF treatment was noninferior to PGT-A and resulted in a higher cumulative live-birth rate in women with a good prognosis for a live birth."[47]

135. The authors also noted that "the results of trophectoderm biopsy may not totally represent the genetic composition of the inner cell mass of the blastocyst that is the precursor to the embryo, and subsequent cell division may also eliminate a genetically abnormal cell line."[48]

136. The authors of the study concluded:

a. Trophectoderm biopsy may be harmful;[49]

b. No benefit for PGT-A regardless of age on cumulative live-birth rate;[50] and

c. No benefit for PGT-A for ongoing pregnancy and live birth rates after first frozen embryo transfer.[51]

137. Also in 2021, researchers reviewed the literature on PGT-A as a precursor to the possibility of advancing technology to a non-invasive test for aneuploidy. In their analysis, the authors recognized:

a. That it is possible for normal embryos to be misdiagnosed as mosaic thus unsuitable for transfer, that ultimately will self-correct and lead to a live birth;

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[45] *Id.*
[46] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[47] *Id.*
[48] *Id.* at 2054.
[49] *Id.* at 2056.
[50] *Id.*
[51] *Id.*

b. Studies do not support the use of PGT-A for all couples who undergo IVF, even in women on the older end of the age spectrum (35-40), who theoretically have the most to gain;

c. Improved live birth rates with PGT-A have not been consistently reported; and

d. Whether PGT-A improves live birth outcomes has yet to be proven.[52]

138. Despite these findings, Defendant continued to advertise and misrepresent non-existent benefits of PGT-A that are not supported by science to vulnerable consumers, while at the same time omitting material information concerning the efficacy of PGT-A.

139. Another study in 2021 also reconfirmed a known observation that term placentas, which are what the trophectoderm becomes, are inherently mosaic, characterized by a substantial number of chromosomal abnormalities, even if the fetus is completely euploid.[53]

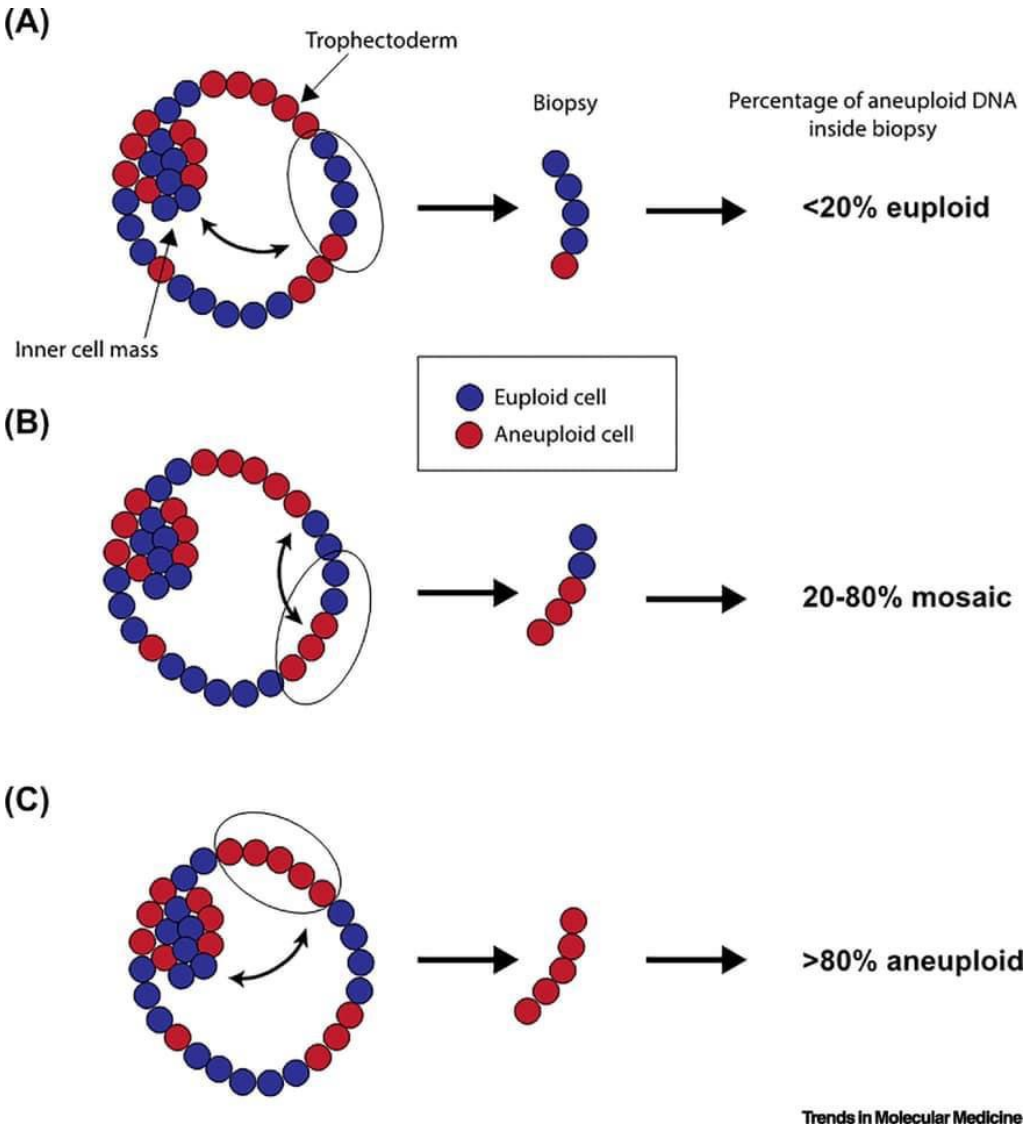
140. The results of the 2021 study conflict with and further undermine Defendant's position in promulgating PGT-A that a trophectoderm biopsy at blastocyst stage can adequately predict the entire embryo and what will develop from the inner cell mass.

141. For this reason, where the trophectoderm biopsy is taken from may alter the results of PGT-A such that the test does not accurately predict the entire trophectoderm or the inner cell mass, as shown in the following illustration:[54]

[52] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.

[53] Coorens, et al., *Inherent mosaicism and extensive mutation of human placentas*. Nature 592, 80-85 (2021).

[54] Gleicher, N., et al., *Preimplantation Genetic Testing for Aneuploid – a Castle built on sand.* Trends in Molecular Medicine, Opinion I Special Issue: Reproductive and Sexual Health, Vol. 27, Issue 8, pp 731-742 (August 2021).



142. In March 2022, an opinion based upon a review of the recent scientific literature was published in Human Reproduction, urging that PGT-A be restricted to only research protocols.[55]

143. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[56] The authors noted that an

[55] Gleicher, N., et al., *We have reached a dead end for preimplantation genetic testing for aneuploidy*, Human Reproduction, Vol. 37, No. 12, pp. 273002734 (2022).

[56] Kucherov, A., et al., *PGT-A is associated with reduced cumulative live birth rate in first reported IVF stimulation cycles age ≤; an analysis of 133,494 autologous cycles reported by SART CORS*, Journal of Assisted Reproduction and Genetics (2023) 40:137-149.

improvement in cumulative live birth rates with PGT-A utilization, calculated per cycle start, cannot be assumed because simply testing embryos for aneuploidy does not increase the number of euploid embryos, nor does it decrease the number of aneuploid embryos.[57]

144. The authors concluded that there is no clear improvement to cumulative live birth rates with PGT-A. In fact, "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative live birth rates per cycle start."[58]

145. The authors further recognized calls for reevaluation or even repeal of widespread PGT-A usage and concluded with an advocation for "responsible innovation supported by high-quality data, which is not the case for PGT-A."[59]

146. Defendants, however, continued to advertise and market PGT-A based upon live birth rates per embryo transfer thereby excluding from analysis any IVF cycles without transferrable embryos. As a result, Defendants artificially and materially inflated and misrepresented the utility of PGT-A on increasing the chance of pregnancy, increasing live birth rates across all age groups, and increasing the chance of implantation.

147. Another article published in Human Genomics called for regulatory oversight, recognizing that PGT-A had regrettably become a routine add-on for IVF to improve clinical outcomes, and noted the following:

a. There are significant knowledge gaps in PGT-A;

b. PGT-A is a screening tool, not a diagnostic test;

c. Mosaicism is much higher in the blastocyst stage from PGT-A than recognized by industry;

d. Mosaic embryos may not accurately represent future fetal viability;

e. PGT-A has not been validated;

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[57] *Id.*
[58] *Id.*
[59] *Id.*

f. High false positive rates are extremely concerning;

g. Use in particular age groups is uncertain;

h. Routine use of PGT-A should not be recommended;

i. Evidence-based data are needed to evaluate the risks and benefits for patients; and

j. Industry self-regulation has shown to be insufficient.[60]

148. As further proof of the concern raised by the authors in Human Genomics regarding the high false positive rates, a re-biopsy and repeat of PGT-A testing on fifty-eight embryos that were originally determined to be chaotically abnormal concluded that twenty-two of the embryos had a euploid result.[61]

149. The researchers noted that the euploid rate suggested that chaotic abnormal results on PGT-A have "reduced predictive value."[62]

150. These findings were further supported a year later when researchers re-biopsied sixty-four embryos reported as "chaotic", which they defined as an embryo with a PGT-A result of more than six chromosome aneuploidies and found concordance of only 67%.[63]

151. Then in April 2023, Dr. Robert Casper determined that when the research data utilized all IVF cycles, and not just the ones where there was a transferrable embryo following PGT-A, there was actually a threefold increase in live birth rates for the group that did not have PGT-A testing performed, and a reduction in live birth rates for the group where PGT-A was utilized.[64]

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[60] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: challenges in clinical practice*, Human Genomics (2022)16.69.

[61] Rabkina, L., et al., *Concordance of Chromosomes Within Re-Biopsy Samples of Embryos Following Initial Chaotic Results.* Fertility and Sterility, Vol. 118, Issue 4. October 2022.

[62] *Id.*

[63] Lim, Joshua, et al., *Corcordance of Repeat Biopsy Results Among Embryos with 6 or More Aneuploidies*. Fertility and Sterility. Vol. 120, Issue 4. October 2023.

[64] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).

152. Based upon his findings, Dr. Casper raised concerns that PGT-A caused irreparable harm to patients with diminished ovary reserve who lost their only chance to have a baby from their cycle of IVF.[65]

153. The European Society of Human Reproduction and Embryology ("ESHRE") add-ons working group released its good practice recommendations on add-ons in reproductive medicine in September of 2023 in which it was determined that PGT-A was not currently recommended for routine clinical use.[66]

154. In support of this recommendation, ESHRE noted that random control test studies did not report benefits on live birth rates and caused disposal of viable embryos.

155. Then in October 2023, it was recognized in the scientific literature that "there is currently insufficient evidence to prove the effectiveness of PGT-A in patients with unexplained recurrent implantation failure."[67]

156. Patients with unexplained recurrent implantation failure are precisely the type of vulnerable and unsuspecting consumers that Defendant is targeting and marketing to with its misleading statements that PGT-A reduces miscarriage rates and increases the chances of a live birth.

157. For example, Defendant's marketing includes the following:[68]

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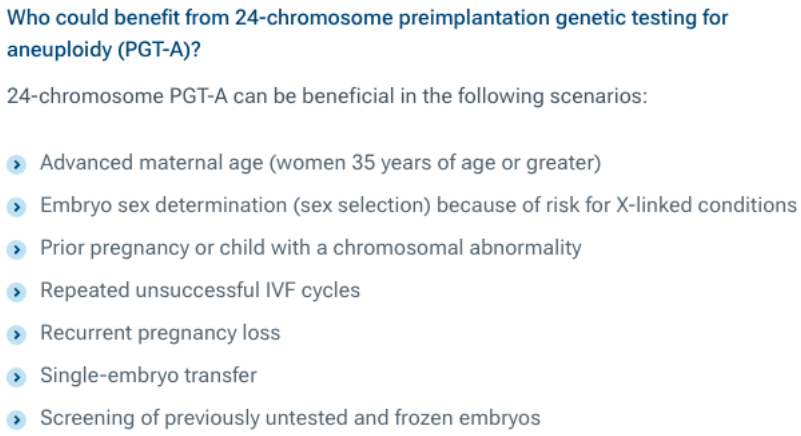
[65] *Id.*

[66] Lundin, K., et al., *Good Practice Recommendations on Add-Ons in Reproductive Medicine*. Human Reproduction. Vol, 38, Issue 11. November 2023.

[67] Lui, Y., et al., *Preimplantation Genetic Testing for Aneuploidy Could Not Improve Cumulative Live Birth Rate Among 705 Couples with Unexplained Recurrent Implantation Failure*, The Application of Clinical Genetics 2024:17 1-13.

[68] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/faq/#pg-menu-tabs (last visited October 8, 2024).



Who could benefit from 24-chromosome preimplantation genetic testing for aneuploidy (PGT-A)?

24-chromosome PGT-A can be beneficial in the following scenarios:

- Advanced maternal age (women 35 years of age or greater)
- Embryo sex determination (sex selection) because of risk for X-linked conditions
- Prior pregnancy or child with a chromosomal abnormality
- Repeated unsuccessful IVF cycles
- Recurrent pregnancy loss
- Single-embryo transfer
- Screening of previously untested and frozen embryos

158. The authors of the October 2023 retrospective cohort study noted:

a. The ineffectiveness of PGT-A may be due to the high mosaicism and unavoidable false-positive results from trophectoderm biopsies, "which led to much waste of viable embryos";

b. The effectiveness of PGT-A in ≥38-year-old group is significantly undermined by low egg retrieval, high aneuploidy and mosaicism rate, resulting in a lot of women with no embryos to transfer;

c. Trials targeting older women found no improvement in the cumulative live birth rate after PGT-A.[69]

159. Again, researchers determined that high quality randomized clinical trials are needed to find patients with indications that would benefit from PGT-A.

160. Defendant has not conducted such studies. Notably, its researchers stated that a limitation of their 2018 study "demonstrating the value of the company's Spectrum® preimplantation genetic screening for aneuploidy (PGT-A)" was that it was not randomized.[70]

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[69] *Id.*

[70] Simon, A., et.al., *Pregnancy outcomes from more than 1,800 in vitro fertilization cycles with the use of 24-chromosome single-nucleotide polymorphism-based preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 110, Issue 1. July 2018.

161. Instead, Defendant has continued to falsely and misleadingly market and advertise the purported benefits of PGT-A as described herein without a valid and proven scientific basis to do so.

162. In November 2023, ASRM again stated emphatically and clearly that *the "value of preimplantation genetic testing for aneuploidy (PGT-A) as a universal screening test for all patients undergoing in vitro fertilization (IVF) has not been established*." (emphasis added).[71]

163. Defendant has omitted to include this material fact in its advertising and marketing materials.

164. ASRM further noted that two randomized controlled trials have been conducted which showed no benefit of PGT-A in improving live birth rates, particularly in women less than 38 years of age.[72]

165. An article published in March of 2024 noted that it was imperative to acknowledge the inherent risks associated with PGT-A, including the potential for misdiagnosis and the risk of embryo damage during biopsy.[73]

166. In support of the importance of acknowledging the risks associated with PGT-A, the authors cited to the Human Fertilisation & Embryology Authority ("HFEA"), which is the United Kingdom's government's independent regulator of fertility treatment and research involving human embryos.[74]

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[71] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

[72] *Id.*

[73] Gudapati, S. Advancements and Applications of Preimplantation Genetic Testing in In Vitro Fertilization: A Comprehensive Review. Cureus 16(3): e57357, doi: 10.7759/cureus.57357. March 2024.

[74] *Id*.

167. The HFEA states that there is limited evidence to show that PGT-A improves the chances of having a baby for women over 37, individuals with a history of or chromosomal problems, and those with several miscarriages or failed IVF attempts.[75]

168. For this reason, the HFEA cautions that "Until larger trials have been run and we have more evidence, there's no guarantee that PGT-A can improve your chances of a successful pregnancy."[76]

169. Further, the HFEA cautions that PGT-A can cause damage to the embryo thereby preventing it from developing once transferred to the womb, and that PGT-A has the possibility of misdiagnosis.[77]

170. In looking at the evidence for PGT-A, the HFEA also noted the following:

a. There is no evidence from randomized controlled trials that PGT-A carried out at the blastocyst stage on day 5 or 6 is effective at improving your chances of having a baby for most patients undergoing IVF.

b. PGT-A may decrease the chance of having a baby as it often reduces the number of embryos available for transfer.

c. Although current PGT-A techniques are mostly very accurate, the test may give the wrong result.

d. If a test result is not accurate, healthy embryos may be discarded.

e. Embryos can continue to develop successfully after a few cells have been removed, however, removing cells from the embryo may damage it and prevent it from successfully developing.[78]

171. Further research conducted in 2024 supported HFEA's position that PGT-A testing may give the wrong result. A re-biopsy and PGT-A testing of 69 embryos previously

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[75] https://www.hfea.gov.uk/treatments/explore-all-treatments/frequently-asked-questions-about-pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited September 26, 2024).

[76] *Id.*

[77] *Id.*

[78] https://www.hfea.gov.uk/treatments/treatment-add-ons/pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited September 26, 2024).

determined as abnormal with a result of more than five abnormal chromosomes revealed that 24.6 percent of those embryos were in fact euploid or "normal".[79]

172. In addition, a review of 552 pregnancies of mosaic embryo transfers found that only 7 of the 552 pregnancies revealed the mosaicism that had been detected in the PGT-A testing.[80]

173. This agreed with prior studies where prenatal testing determined that the pregnancy did not have the same mosaic result as the PGT-A testing.

174. In 2021, research revealed no instances of mosaicism in pregnancies or newborns born from 282 embryos deemed "low-grade mosaic", and 131 embryos deemed "medium-grade mosaic" by PGT-A testing.[81]

175. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[82]

176. In May 2024, ASRM and SART issued another committee opinion to replace their prior committee opinion of the same name published in 2018 and discussed above. ASRM and SART reiterated that the value of PGT-A as a universal screening test for all patients undergoing IVF had not been demonstrated.[83]

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[79] Bago, A., et al., *Chaotic blastocysts in preimplantation genetic testing for aneuploidies: prevalence, characterization and re-biopsy results.* Human Reproduction, Vol. 39, Issue Supplement_1. July 2024.

[80] Spinella, F, et al., *Chromosomal, gestational, and neonatal outcomes of mosaic embryos: analysis of 3074 cases from the international registry of mosaic embryo*, *Human Reproduction*, Volume 39, Issue Supplement_1. July 2024

[81] Capalbo, A., et al., *Mosaic human preimplantation embryos and their developmental potential in a prospective, non-selection clinical trial.* Am. J. Hum. Genet. Vol. 108, Issue 2. December 2021.

[82] Viotti, M, et al., *Chromosomal, gestational, and neonatal outcomes of embryos classified as a mosaic by preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 120, Issue 5. November 2023.

[83] Practice Committee of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology, *The use of preimplantation genetic testing for aneuploidy: a committee opinion.* Fertility and Sterility. Vol. 122, Issue 3. September 2024.

177. ASRM further noted that two recent, multicenter, randomized control trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[84]

178. Defendant omitted to include these material facts in its advertising materials.

179. ASRM stated that the value of PGT-A to lower the risk of clinical miscarriage was unclear and raised concerns about the studies and trials performed. ASRM cautioned that large, prospective, well-controlled studies in a more inclusive patient population are needed.[85]

180. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[86]

181. Still, Defendant continues to promote widespread use of PGT-A.

182. Following the May 2024 committee opinion by ASRM and SART, researchers re-examined the PGT-A results of embryos that were determined to be abnormal by PGT-A testing and again found a low rate of concordance between the initial PGT-A testing result and PGT-A testing result of the re-biopsy.[87]

183. Specifically, the researchers found that the re-biopsy was concordant with only 47.7% of the PGT-A testing results. They also found that 15.8% of the re-biopsies revealed a partially concordant result and 36.8% revealed totally discordant results.[88]

184. Despite the lack of supporting research and scientific basis as well as the recommendations of ASRM and SART, Defendant has continued to aggressively market and promote PGT-A as having benefits and properties that it does not have and has omitted the disclosure of material and relevant information to consumers.

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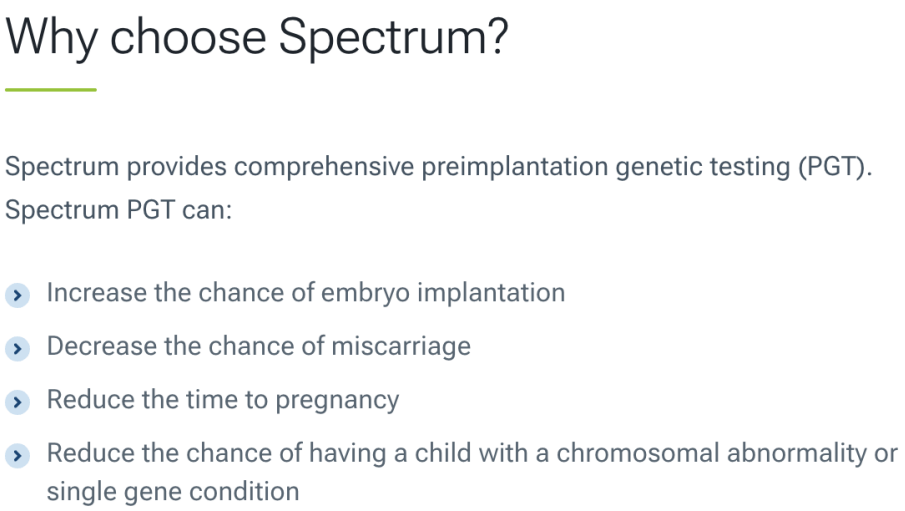
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] Tikhonov, A., et al., *Re-Examination of PGT-A Detected Genetic Pathology in Compartments of Human Blastocysts: A Series of 23 Cases*. Journal of Clinical Medicine. 2024; 13(11):3289. https://doi.org/10.3390/jcm13113289.
[88] *Id.*

185. Despite the lack of supporting research and scientific basis as well as the recommendations of ASRM and SART, Defendant has continued to aggressively market and promote PGT-A as having benefits and properties that it does not have and has omitted the disclosure of material and relevant information to consumers:[89]



186. Plaintiffs and Class members have relied on Defendant's material misstatements and omissions to their detriment by purchasing an expensive test that they would not have purchased if the facts had been disclosed at the time of sale.

C. Defendants Have Utilized False And Misleading Statements To Increase Sales Of PGT-A

187. As a result of Defendant's aggressive advertising and marketing, PGT-A testing is now purchased by consumers as an add-on in an estimated 40% of IVF cycles in the United States.

188. Despite the increase in PGT-A testing use, live birth rates among individuals undergoing IVF have declined.

[89] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).

189. Defendant's false and misleading statements concerning its PGT-A, include, without limitation, the following:

a. PGT-A testing increases IVF success;

b. PGT-A testing is 99% accurate;

c. PGT-A testing increases the chance of implantation;

d. PGT-A testing decreases the chance of miscarriage;

e. PGT-A testing reduces the time to pregnancy;

f. PGT-A testing increases the rate of pregnancy;

g. PGT-A testing increases the rate of live birth;

h. PGT-A testing improves the chance of a healthy pregnancy; and

i. PGT-A testing improves pregnancy rates for all ages, especially those of advanced maternal age.

190. Further, in making the above statements, Defendant has concealed and omitted material information from consumers, including, without limitation:

a. By failing to disclose an accurate assessment of the state of scientific study and knowledge concerning PGT-A, of which Defendant is aware;

b. By failing to disclose that the value of PGT-A as a screening test for IVF patients has not been demonstrated by science;

c. By failing to have the above statements supported by properly designed research studies;

d. By failing to tell consumers that PGT-A is experimental;

e. By failing to tell consumers that PGT-A is unproven;

f. By failing to tell consumers that PGT-A results have a substantial degree of inaccuracy; and

g. By failing to tell consumers that PGT-A has a substantial degree of unreliability.

191. Defendant's false and misleading advertising and marketing statements, which include the following, have played a key role in driving up the use of PGT-A testing in the United States.

1. Defendant Falsely States That Its PGT-A Testing Is 99% Accurate

192. Defendant claims that Spectrum's PGT-A results are greater than 99% accurate.[90]

> Spectrum preimplantation genetic testing evaluates the number of chromosomes in embryos to detect extra or missing chromosomes and screens for inherited genetic disorders. Spectrum's patented SNP-based technology with Parental Support provides a highly comprehensive 24-chromosome PGT-A with an accuracy greater than 99 percent per chromosome call, helping provide the best chance of transferring an embryo with the correct number of chromosomes. Identifying the

193. Also in its patient brochure, Defendant misleadingly states that its PGT-A testing as greater than 99% accurate.

> Natera's methodology uses patented technology to improve detection of single gene conditions. Originated in 2009, Spectrum informs embryo selection by combining PGT-M and PGT-A testing with a typical accuracy of greater than 99%.

[91]

194. Not only does Defendant fail to provide support for this assertion but it is belied by the scientific literature which has found concordance rates of reanalysis with original PGT-A

[90] https://www.natera.com/company/news/study-shows-nateras-spectrum-preimplantation-genetic-testing-for-aneuploidy-improves-ivf-outcomes-for-all-women-regardless-of-maternal-age-2/ (last visited October 8, 2024).

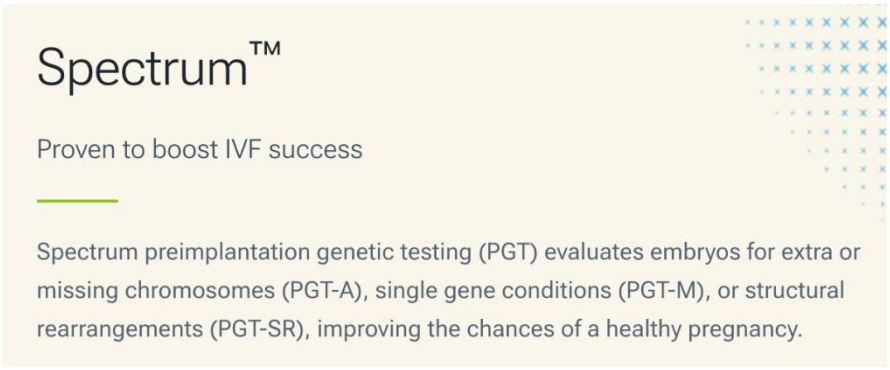
[91] https://www.natera.com/resource-library/spectrum/spectrum-pgt-a-patient-brochure/ (last visited October 8, 2024).

results as 93.8% for euploid results, 81.4% for aneuploid results and 42.6% for mosaic aneuploid results.[92]

195. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[93]

2. Defendant Falsely States That Its PGT-A Increases The Success of IVF in All Age Groups

196. The PGT-A section of Defendant's website proclaims that PGT-A performed by Natera's "Spectrum™ is "Proven to boost IVF success."[94]



197. Defendant, however, knows this statement is false and misleading, and omits material information from consumers, as there is no valid and scientifically supportable evidence to show that PGT-A improves the success of IVF, and in light of all the studies described above.

198. Defendant also previously promoted its Spectrum PGT-A testing as increasing pregnancy rates.[95]

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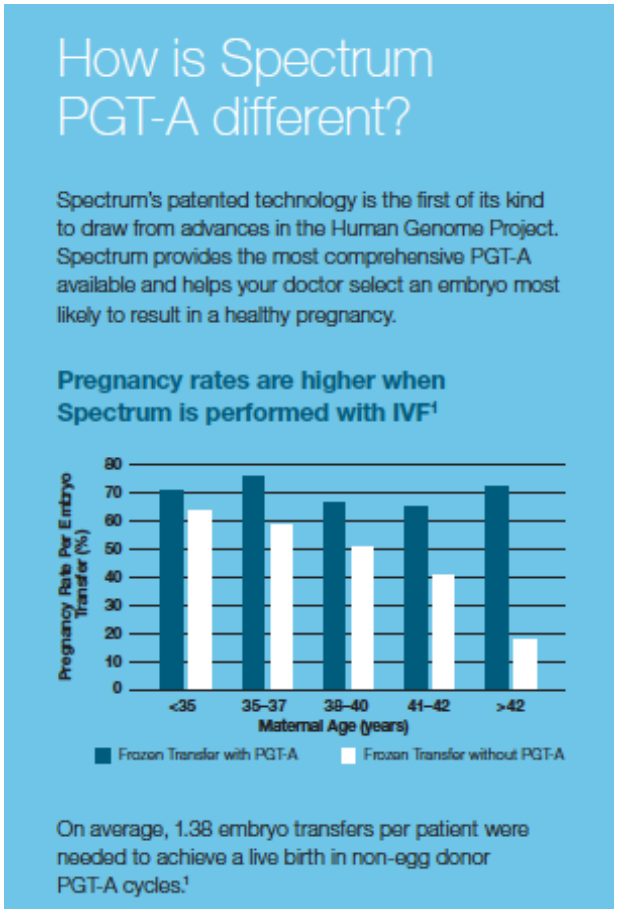
[92] Marin, D., et al., *Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance data.* Prenatal Diagnosis. Vol. 4, Issue 5. Pp. 545-553. April 2021.

[93] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocriniology (2016) 14:54.

[94] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).

[95] Spectrum PGT-A Patient Brochure https://www.natera.com/resource-library/spectrum/spectrum-pgt-a-patient-brochure/ (last visited July 7, 2023).



199. As an additional example of a false and misleading statement, and material omission of the scientific knowledge detailed above of which Defendant is certainly aware, Defendant suggests with its graph that women under 35 years of age who used PGT-A were far more successful in achieving live birth than women who did not utilize PGT-A (~62% to 71%).

200. Published scientific results, however, have reported no benefit of PGT-A to live birth rates for women under 35 and unchanged ongoing embryo implantation rates of ~50% for PGT-A and non-PGT-A.[96]

[96] Paulson, R. *Hidden in plain sight: the overstated benefits and underestimated losses of potential implantations associated with advertised PGT-A success rates.* Human Reproduction, Vol. 35, Issue 3, p. 490-493 (March 2020).

201. Defendant's false and misleading claim also contradicts scientific research that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[97]

202. Further, scientists have found that "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative birth rate per cycle start."[98]

203. Researchers looking across age groups have further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[99]

204. Defendant's false and misleading statements promoting the use of PGT-A are also in direct contradiction to the ASRM which has concluded that PGT-A has showed no improvement in live birth rates.[100]

205. In fact, research in 2016 had already shown that PGT-A *decreased* live birth rates when compared to IVF without testing.[101]

3. Defendant Falsely States That Its PGT-A Decreases The Chance Of Miscarriage

206. Defendants also falsely claim in its advertising materials and statements to consumers that its PGT-A decreases the chance of miscarriage.[102]

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[97] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.

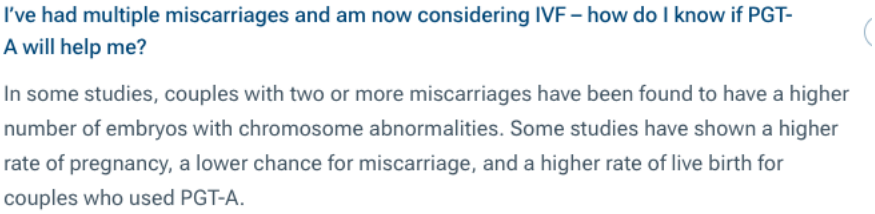
[98] Kucherov, A., et al., *PGT-A is associated with reduced cumulative live birth rate in first reported IVF stimulation cycles age ≤; an analysis of 133,494 autologous cycles reported by SART CORS*, Journal of Assisted Reproduction and Genetics (2023) 40:137-149.

[99] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.

[100] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

[101] Kushnir, VA, et al., *Effectiveness of in vitro fertilization with preimplantation genetic screening: a reanalysis of Unites States assisted reproductive technology data 2011-2012*. Fert Steril, 2016; 106(1): 75-9.

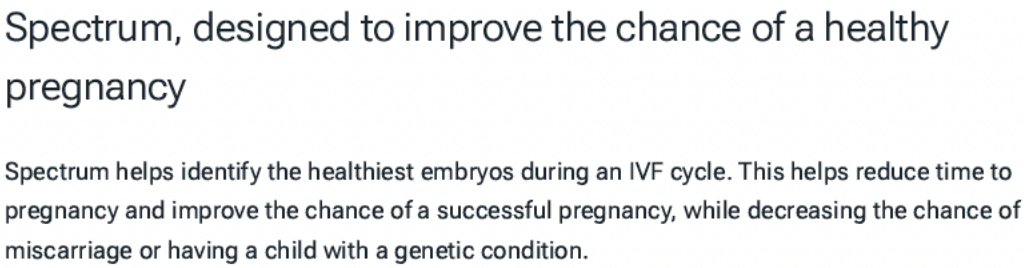
[102] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/faq/ (last visited October 8, 2024).



I've had multiple miscarriages and am now considering IVF – how do I know if PGT-A will help me?

In some studies, couples with two or more miscarriages have been found to have a higher number of embryos with chromosome abnormalities. Some studies have shown a higher rate of pregnancy, a lower chance for miscarriage, and a higher rate of live birth for couples who used PGT-A.

207. Defendant's website also includes the same statements regarding a decrease in the chance of miscarriage in the clinician information section.[103]



Spectrum, designed to improve the chance of a healthy pregnancy

Spectrum helps identify the healthiest embryos during an IVF cycle. This helps reduce time to pregnancy and improve the chance of a successful pregnancy, while decreasing the chance of miscarriage or having a child with a genetic condition.

208. Defendant knows these statements and material omissions in light of the scientific research set forth above are false and misleading to consumers as there is no clear evidence resulting from valid scientific studies to show that PGT-A decreases the chance of miscarriage.

4. Defendant Falsely States That Its PGT-A Leads To A Higher Chance Of Pregnancy

209. In its patient brochure, Defendant states directly to consumers that PGT-A leads to a higher chance of a healthy pregnancy.[104]

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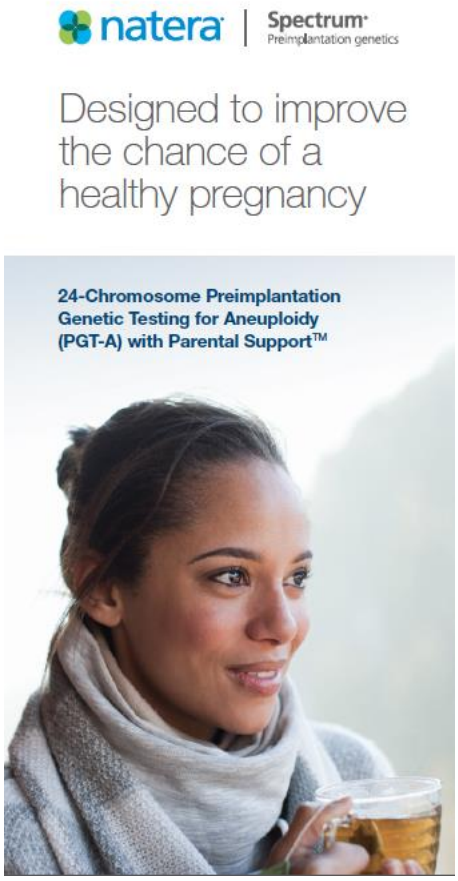
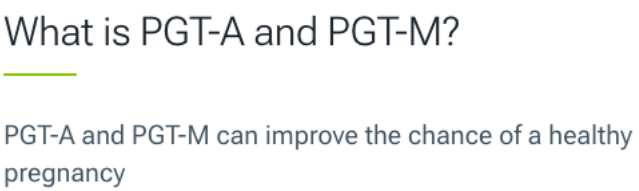
[103] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/clinicians/(last visited October 8, 2024).

[104] https://www.natera.com/resource-library/spectrum/spectrum-pgt-a-patient-brochure/ (last visted October 8, 2024).



210. The same statement is also made on Defendant's website.[105]



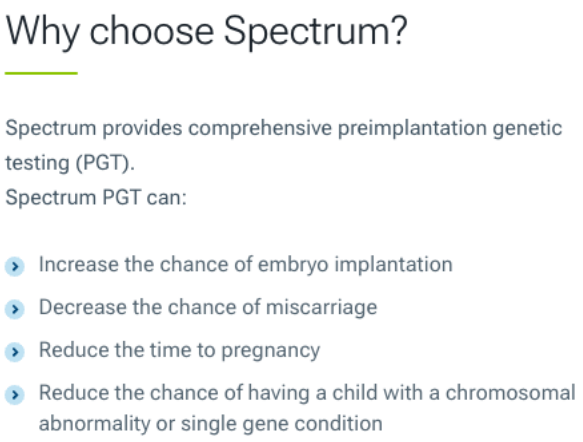
211. No valid scientific research, however, has concluded this to be accurate. In fact, ASRM has repeatedly noted that trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[106]

[105] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).

[106] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

5. Defendant Falsely States That Its PGT-A Reduces The Time To Pregnancy

212. Defendant's website also states that PGT-A potentially reduces the time to pregnancy.[107]



213. No valid scientific research supports this misleading statement, and in fact, research shows that utilizing PGT-A does not decrease time to pregnancy.[108]

6. Defendant Falsely States That Its PGT-A Increases The Chance Of Implantation And Pregnancy

214. Defendant misleads consumers by stating that PGT-A can increase the chance of implantation and pregnancy.[109]

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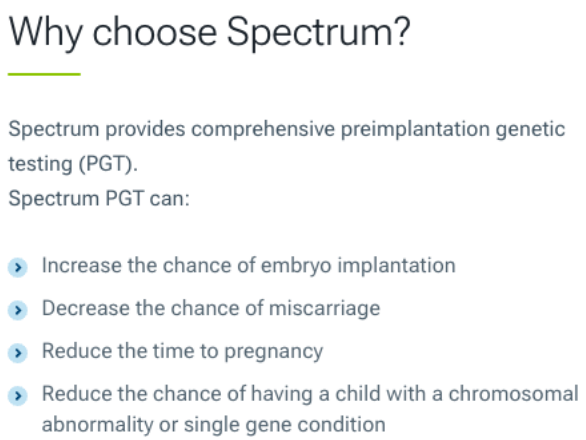
[107] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).

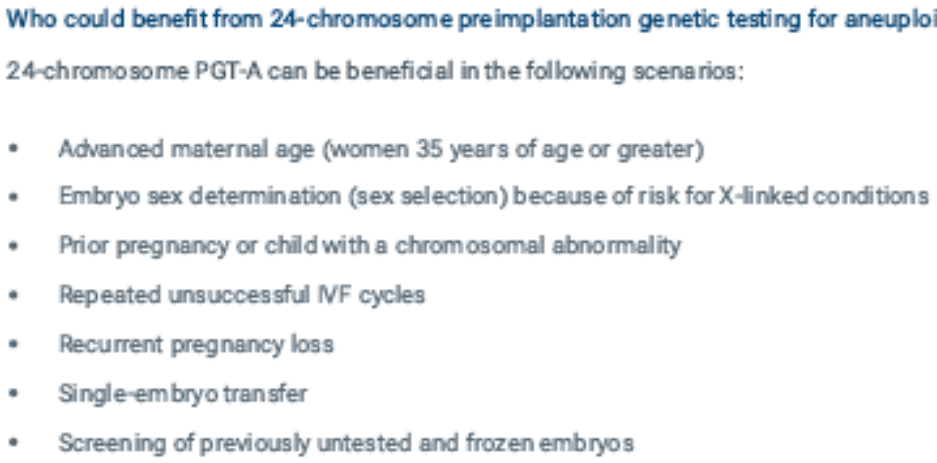
[108] Palmer, M., et al., *Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy*. Fertility and Sterility. Vol. 114, Issue 3. September 2020.

[109] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).



215. As previously discussed above, the available science does not show this. To the contrary, pregnancy outcomes were similar between conventional IVF and PGT-A, but this material fact is omitted to consumers by Defendants.[110]

216. Despite this, Defendant continues to promote PGT-A testing to IVF consumers:



[110]Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

7. Defendant Falsely States That Its PGT-A Reduces the Time to Pregnancy

217. Defendant is aware that they are advertising, marketing, and selling their product to vulnerable consumers pursuing IVF.

218. Despite knowing this, in prioritizing sales of PGT-A over consumers, Defendant has utilized the emotional, physical, and financial impact of IVF to mislead consumers.

219. On its website, Defendant states that its PGT-A testing can reduce the time to pregnancy.[111]

220. Defendant also markets its PGT-A testing to clinicians as reducing the time pregnancy.[112]

> Spectrum, designed to improve the chance of a healthy pregnancy
>
> Spectrum helps identify the healthiest embryos during an IVF cycle. This helps reduce time to pregnancy and improve the chance of a successful pregnancy, while decreasing the chance of miscarriage or having a child with a genetic condition.

221. There is no valid scientific research to support this false and misleading statement, and in fact, research shows that utilizing PGT-A does not decrease time to pregnancy.[113]

222. Research has shown that there is a threefold increase in live birth rates for those that did not have PGT-A testing performed and a reduction in live birth rates for the group where PGT-A was utilized.[114]

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[111] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).
[112] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/clinicians/ (last visited October 8, 2024).
[113] Palmer, M., et al., *Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy*. Fertility and Sterility. Vol. 114, Issue 3. September 2020.
[114] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).

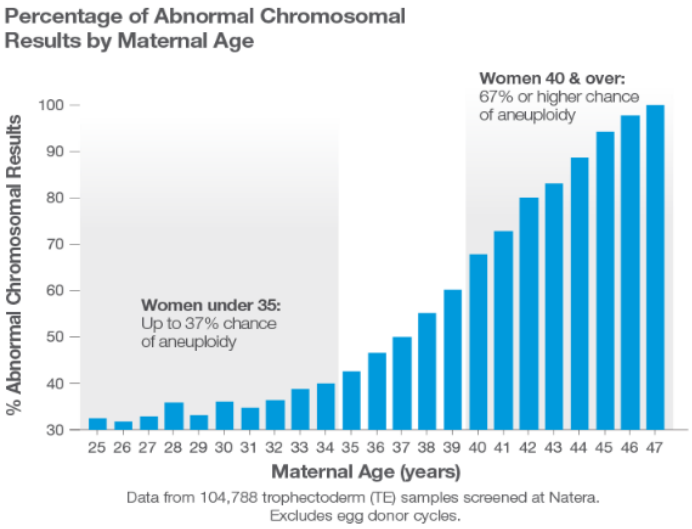
8. Defendant Falsely States That Its PGT-A Improves Pregnancy Rates for All Ages Undergoing IVF, Especially Individuals of Advanced Maternal Age

223. Defendant states on its website that PGT-A is a test for all ages of individuals undergoing IVF, which is a false and misleading statement, and material omission of the known scientific knowledge detailed above.[115]

Spectrum™ PGT-A from Natera has been studied to learn whether it helped people achieve their goal of a healthy pregnancy. Study results showed that PGT-A improves pregnancy rates for parents of all ages.[7] Spectrum uses advanced genetic technology to screen all 24 chromosomes in a cell (22 chromosome pairs and the sex chromosomes X and Y).

224. Defendant further states that PGT-A is especially useful for egg providers of advanced maternal age, which Defendant indicates is over 35 years old.[116]

Clinical studies suggest that PGT-A is especially useful if the egg provider is over 35 years old.[7] The following graph illustrates how the rate of chromosomal anomalies increases with the age of the biological mother.[7] These embryos were tested with Spectrum™, a PGT-A from Natera.



More than half of embryos provided by a biological female older than 37 had a chromosomal anomaly.[7] For this reason, PGT-A is more likely to be recommended when the egg provider is older.

[115] https://www.natera.com/resource-library/spectrum/what-is-pgt-a-and-how-does-it-support-ivf/ (last visited October 8, 2024).
[116] *Id.*

225. Defendant's false and misleading claims contradict evidence and scientific research. Researchers looking across age groups have found no benefit for PGT-A regardless of age on cumulative live-birth rate.[117]

226. In addition, research has concluded that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[118]

227. Furthermore, scientists have found that "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative birth rate per cycle start."[119]

228. Defendant's false and misleading statements promoting the use of PGT-A for all couples is also in direct contradiction to the ASRM which has concluded that PGT-A has showed no improvement in live birth rates.[120]

D. Defendant's Additional Material Omissions

229. There is no valid, independent, and properly conducted scientific research supporting that conducting a biopsy of an embryo does not harm implantation. However, biopsying an embryo is a prerequisite for PGT-A testing and this material fact is not disclosed by Defendant to consumers.

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[117] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.

[118] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.

[119] Kucherov, A., et al., *PGT-A is associated with reduced cumulative live birth rate in first reported IVF stimulation cycles age ≤; an analysis of 133,494 autologous cycles reported by SART CORS*, Journal of Assisted Reproduction and Genetics (2023) 40:137-149.

[120] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

230. Further, Defendant omits to inform consumers of the fact that damage to embryos caused by biopsy may be the reason for unsuccessful IVF outcomes following PGT-A.[121] Defendant claims that embryo biopsy and PGT-A are nearly harmless.

231. As detailed above, Defendant aggressively markets PGT-A via misleading and unsupported statements while omitting material information from consumers prior to their payment for PGT-A.

232. Defendant has failed to inform consumers concerning the numerous scientific studies and opinions of professional organizations detailed above.

233. Defendant informs consumers that a PGT-A biopsy is taken from the trophectoderm but does not inform consumers that science shows that the inner cell mass is more effective in self-correcting than the trophectoderm. Chromosomal abnormal embryos may self-correct downstream, which renders earlier biopsy results irrelevant, but Defendant omits this from consumers.

234. The trophectoderm – from which the placenta develops – has been known to contain aneuploid cells even in chromosomally normal pregnancies, while the fetus, arising from the inner cell mass, remains chromosomally normal. Defendant omits this from consumers.

235. Because of the complexity introduced by mosaicism when testing an extremely small sample of cells that may or may not represent the whole embryo, there is a substantial probability that an embryo may be misdiagnosed, and the test results inaccurate, but Defendant omits this from consumers.

236. Further, with respect to self-correction that occurs in human embryos, Defendant fails to inform consumers that biopsy at the blastocyst stage may not accurately reflect the final chromosomal outcome of embryos.

[121] Alteri, Alessandra. *Obstetrick neonatal and child health outcomes following embryo biopsy for preimplantation genetic testing. Human Reproduction Update*, Vol,29, Issue 3. pp. 291-306 (2023).

237. Defendant also omits to inform consumers concerning the false positives and false negatives that occur with PGT-A, and the actual rates of false positives and false negatives shown through scientific study.

238. Scientific research has found concordance rates of reanalysis with original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results, and 42.6% for mosaic aneuploid results.[122]

239. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[123]

E. PGT-A Has Enriched Defendant

240. The average cost of PGT-A is approximately $5,000 per IVF cycle and is an "add-on" expense to IVF usually not covered by insurance.

241. The global preimplantation genetic testing market was estimated to be worth $0.7 billion in 2023 and is poised to reach $1.2 billion by 2028.

242. The PGT-A segment is expected to dominate the global preimplantation genetic testing market within the next several years.

243. The use of PGT-A now encompasses an estimated 40% of IVF cycles in the United States.

244. Despite all the scientific literature concerning PGT-A set forth above, Defendant has continued to advertise and market PGT-A to consumers as 99% accurate, increasing the chance of embryo implantation, decreasing the chance of miscarriage, reducing the time to pregnancy, increasing the rate of pregnancy, increasing live birth rates, improving the chance of a healthy pregnancy, and improving pregnancy rates for all ages, especially those of advanced maternal age which Defendant identifies as over 35 years old. Each of these claims are false and

[122] Marin, D., et al., *Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance data.* Prenatal Diagnosis. Vol. 4, Issue 5. Pp. 545-553. April 2021.

[123] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocriniology (2016) 14:54.

misleading, unsupported by scientific evidence, and made while Defendant omitted and withheld material information.

F. Plaintiffs' Experiences With Defendant's PGT-A

245. Plaintiffs and Class members were harmed by paying for an unproven and unreliable test sold utilizing false statements and omissions.

246. Plaintiffs and Class members were injured at the time of sale and would not have purchased PGT-A from Defendant had they been told the truth at the time of sale concerning the body of scientific knowledge about PGT-A and each of the misstatements and omissions detailed above. Each separate misstatement and omission by Defendant separately and independently gives rise to the causes of action alleged below.

247. Plaintiffs and Class members suffered direct economic losses as a result of their purchase of PGT-A testing from Defendant, including but not limited to the out-of-pocket payments that each paid to Defendant for their PGT-A testing as well as additional costs associated with their PGT-A testing.

1. Plaintiff Shannon Petersen's Purchase of PGT-A Testing

248. Shannon Petersen purchased PGT-A testing from Defendant based upon Defendant's false and misleading statements, including that PGT-A testing is greater than 99% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, reduces the time to pregnancy, and increases the chance of implantation and pregnancy.

249. Plaintiff Petersen purchased Defendant's PGT-A testing, in or around November 2022, based upon Defendant's misrepresentations and omissions of material information as detailed above.

250. Plaintiff Petersen relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $700 plus additional costs for her PGT-A testing, which she would not have purchased absent Defendant's false and misleading misrepresentations and omissions.

2. Plaintiff Erin Vedrode's Purchase of PGT-A Testing

251. Plaintiff Vedrode underwent IVF and purchased PGT-A testing from Defendant based upon Defendant's statements that PGT-A testing is greater than 99% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, reduces the time to pregnancy, and increases the chance of implantation and pregnancy.

252. Plaintiff Vedrode further purchased Defendant's PGT-A testing, in or around November 2022, based upon Defendant's misrepresentations and omissions of material information as detailed above.

253. Plaintiff Vedrode relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $2,250.00 plus additional costs for her PGT-A testing which she would not have purchased absent Defendant's false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

254. Plaintiffs bring this lawsuit individually and, pursuant to Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, for economic losses, injunctive relief, and declaratory relief on behalf of all persons in the United States who have purchased PGT-A testing from Defendants (the "Nationwide Class").

255. In addition, Plaintiff Petersen brings this lawsuit on behalf of a class of all residents of the State of California who purchased PGT-A testing from Defendants (the "California Class").

256. In addition, Plaintiff Vedrode brings this lawsuit on behalf of a class of all residents of the State of Michigan who purchased PGT-A testing from Defendants (the "Michigan Class").

257. The Nationwide Class and each state-wide Class defined above are referred to collectively herein as the "Class."

258. Excluded from each Class are Defendants, its affiliates, employees, officers, and directors, and the Judge(s) assigned to this case.

259. Plaintiffs reserve the right to modify, change, or amend the Class definitions set forth above based on discovery and further investigation.

260. **Numerosity**. Each defined Class is so numerous that the joinder of all Class members is impracticable and the disposition of their claims in a class action rather than in individual actions will benefit the parties and the courts. Plaintiffs do not presently know the exact size of each Class, but this information is in Defendant's possession and will be obtained in discovery.

261. **Common Questions Predominate**. This action involves common questions of law and fact to each Class because each member's claim derives from Defendant's false, deceptive, and misleading statements and omissions as alleged above. Common questions of law and fact include but are not limited to:

- Defendant's misstatements and omissions to Class members regarding PGT-A;
- Whether a reasonable consumer would consider the misstatements and omissions to be material;
- Whether a reasonable consumer would be misled by Defendant's advertising and marketing regarding PGT-A;
- Whether a reasonable consumer would rely upon Defendant's misstatements and omissions concerning PGT-A;
- Defendant's knowledge of its misstatements and omissions;
- The date of Defendant's knowledge;

- Whether each of the alleged advertising misstatements described in detail above was false or misleading;
- Whether Defendants conduct violates each of the laws set forth in the causes of action below;
- Whether Plaintiffs and the Class were harmed at the point of sale by Defendant's conduct;

- Whether Defendants violated express and/or implied promises or warranties concerning the sale of PGT-A; and
- Whether Defendants were unjustly enriched as a result of its conduct.

These common questions of law and fact predominate over individual questions, as proof of a common or single set of facts will establish the right of each member of the Class to recover.

262. **Typicality**. Plaintiffs' claims are typical of the claims of other Class members they seek to represent because, among other things, all such claims arise out of the same unlawful course of conduct by Defendants as alleged herein. Plaintiffs and Class members each purchased PGT-A based on Defendant's misrepresentations and omissions and they all suffered economic damages as a result.

263. **Adequacy of Representation**. Plaintiffs will fairly and adequately protect the interests of all Class members. Plaintiffs have no interests in conflict with the interests of Class members. Plaintiffs have retained highly competent and experienced class action attorneys to represent their interests and those of the Class. By prevailing on their own claims, Plaintiffs will establish Defendant's liability to all Class members. Plaintiffs and their counsel have the necessary financial resources to adequately and vigorously litigate this class action and Plaintiffs and their counsel are aware of their fiduciary responsibilities to the Class members and will diligently discharge those duties.

264. **Superiority**. There is no plain, speedy, or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by Class members will tend to establish inconsistent standards of conduct for Defendant and result in the impairment of Class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Furthermore, an important public interest will be served by addressing the matter as a class action.

265. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

266. **Injunctive Relief**. Class certification is also appropriate under Rule 23(b)(2) of the Federal Rules of Civil Procedure because Defendants acted and refused to act on grounds generally applicable to the class, making appropriate final injunctive relief with respect to the Class as a whole.

CAUSES OF ACTION

242. All Nationwide Class members have a nexus with California such that California law should apply to all of them. In the alternative, if the Court finds that California law, including all of the California law causes of action alleged below, does not apply to Plaintiffs and all Class members residing outside of California for any reason, then Plaintiffs and Class members residing outside of California assert their claims under the laws of their respective states of residence.

COUNT I
Violations of California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq*. (Unfair and Fraudulent Prongs) (On behalf of Shannon Petersen and the Class)

243. Plaintiffs incorporate by reference all preceding allegations.

244. California Business & Professions Code § 17200 ("UCL") prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

245. The acts and practices of Defendant as alleged herein constitute "unfair" business acts and practices under the UCL in that Defendant's conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Defendant's conduct outweighs any conceivable benefit of such conduct.

246. Defendant has in the course of its business, and in the course of trade or commerce, undertaken and engaged in unfair business acts and practices under the UCL by making misleading statements and omitting material information regarding the accuracy and reliability of PGT-A, and making the additional false and misleading statements and omissions alleged herein.

247. These acts also constitute "fraudulent" business acts and practices under the UCL in that Defendant's conduct is false, misleading, and has a tendency to deceive Class members and the general public.

248. Plaintiff and the Class members have suffered injury in fact and have lost money as a result of Defendant's fraudulent business acts or practices.

249. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiff and Class members in that Defendants have systematically perpetrated the unfair conduct upon members of the public by engaging in the conduct described herein.

250. Pursuant to Business and Professions Code §§ 17200 and 17203, Plaintiff and Class members seek an order providing restitution and disgorgement of all profits relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

251. Because of their reliance on Defendant's misleading statements and omissions concerning Defendant's PGT-A testing, Plaintiff and Class members suffered an ascertainable loss of money, property, and/or value, and were harmed and suffered actual damages.

252. Plaintiff and Class members are reasonable consumers who, based on Defendant's public misleading statements and omissions as alleged herein, did not expect that Defendant's PGT-A would not be consistent with those statements.

253. Defendant's conduct in concealing and failing to disclose the inaccuracy and unreliability of PGT-A testing is unfair in violation of the UCL, because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

254. Defendant acted in an immoral, unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner.

255. The gravity of harm resulting from Defendant's unfair conduct outweighs any potential utility. The practice of falsely and deceptively marketing PGT-A as accurate and reliable

to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

256. Plaintiff and the Class suffered injury in fact, including direct economic losses, as a direct result of Defendant's unfair acts. Absent Defendant's conduct, Plaintiff would not have bought PGT-A from Defendants.

257. Through its unfair conduct, Defendant acquired money that Plaintiffs and the Class members once had ownership of.

258. Plaintiffs and the Class members accordingly seek appropriate relief under the UCL, including (a) restitution in full, and (b) such orders or judgments as may be necessary to enjoin Defendant from continuing its unfair practices.

COUNT II
Violations of California Unfair Competition Law,
Cal. Bus. & Prof. Code §§ 17200, *et seq*. (Unlawful Prong)
(On behalf of Shannon Petersen and the Class)

259. Plaintiff incorporates by reference all preceding allegations.

260. The UCL prohibits any "unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200 ("UCL"). By engaging in business practices which are also illegal, Defendant violated the UCL.

261. Defendant's "unlawful" acts and practices include breach of the implied warranty of merchantability, breach of the implied warranty of usability, fraud-based omissions, and unjust enrichment.

262. More specifically, Defendant breached applicable warranties in connection with the marketing and sale of Defendant's PGT-A to consumers. Defendants marketed and sold PGT-A testing to Plaintiff and the Class knowing that PGT-A was unproven, inaccurate, and unreliable.

263. Plaintiff and the Class members conferred tangible and material economic benefits upon Defendant by purchasing PGT-A. Plaintiff and the Class members would not have purchased PGT-A from Defendant had they known that it was unproven, inaccurate, and unreliable.

264. Defendant reaped unjust profits, revenue, and benefits by virtue of their UCL violations. Plaintiff and Class members seek restitutionary disgorgement of these unjust profits and revenues.

COUNT III
Violations of California Consumer Legal Remedies Act,
Cal. Civ. Code § 1750, *et seq*.
(On behalf of Shannon Petersen and the Class)

265. Plaintiff incorporates by reference all preceding allegations.

266. Plaintiff Petersen is a consumer as defined by Civil Code §§ 1761(d) and 1770 and have engaged in "transaction[s]" as defined by Civil Code §§ 1761(e) and 1770.

267. Defendant is a "person" as defined by Civil Code §§ 1761(c) and 1770 and has provided "services" as defined by Civil Code §§ 1761(b) and 1770.

268. Defendant's acts and practices as detailed herein, violated Civil Code § 1770 by the following:

a. (2) Misrepresenting the source, sponsorship, approval, or certification of goods or services;

b. (5) Representing that services have approval, characteristics, uses, benefits, or qualities that they do not have;

c. (7) Representing that services are of a particular standard, quality, or grade; and

d. (9) Advertising services with intent not to sell them as advertised.

269. Defendant's acts and practices violated the Consumers Legal Remedies Act because they failed to disclose information that was material to Plaintiff and Class members' relevant transactions, for example:

a. By failing to provide an accurate assessment of the state of scientific study and knowledge concerning PGT-A;

b. By failing to disclose that the value of PGT-A as a screening test for IVF patients has not been demonstrated by science;

c. By failing to have the above-described statements supported by properly designed research studies;

d. By failing to tell consumers that PGT-A is experimental;

e. By failing to tell consumers that PGT-A is unproven;

f. By failing to tell consumers that PGT-A results have a substantial degree of inaccuracy; and

g. By failing to tell consumers that PGT-A has a substantial degree of unreliability.

270. Defendant had ample means and opportunities to alert Plaintiff and Class members that PGT-A was not supported by science as claimed by Defendant's advertising, marketing, and promotional materials.

271. Despite these opportunities, Defendant failed to disclose information that was material to Plaintiff and Class members. Had such disclosures been made, Plaintiff and Class members would not have purchased PGT-A and relied on the results.

272. Defendant had a duty to accurately disclose the validity of PGT-A, the unsupported claims that they were making to consumers, and to accurately disclose the current state of science regarding PGT-A. Defendant had a duty not to mislead consumers through its advertising, marketing, and promotion of PGT-A.

273. Defendant had superior knowledge of the relevant facts and science as compared to Plaintiff and Class members, yet actively concealed and misled consumers concerning the truth about PGT-A.

274. As a direct and proximate result of Defendant's deceptive acts and practices in violation of the Consumers Legal Remedies Act, Plaintiff and the Class members have suffered actual damages.

275. Plaintiff and the Class members would not have purchased PGT-A had they been told the truth by Defendant. In the meantime, Defendant generated more revenue than they otherwise would have, unjustly enriching themselves.

276. Plaintiff and the Class members were harmed, and Defendant's misleading statements and omissions were a substantial factor in causing this harm in the form of economic losses.

277. Plaintiffs accordingly are entitled to statutory relief, equitable relief, reasonable attorneys' fees and costs, declaratory relief, and a permanent injunction enjoining Defendant from continuing its continued unlawful, fraudulent, and deceptive activity.

278. Pursuant to Civil Code § 1782(a), on July 12, 2024, Plaintiff, individually and on behalf of the Class, sent a letter Defendant to notify it of its CLRA violations and afford it the opportunity to correct its business practices and rectify the harm it caused. The correspondence was mailed via first class certified mail with return receipt requested. Defendant failed to correct the acts and practices detailed herein within 30 days. Therefore, Plaintiff and the Class Members seek money damages under CLRA.

COUNT IV
Violations of the Michigan Consumer Protection Act,
MCL § 445.901, *et seq*.
(On behalf of Erin Vedrode and the Michigan Class)

279. Plaintiffs incorporate by reference all preceding allegations.

280. Plaintiff Vedrode and Defendant are "person[s]" within the meaning of MCL § 445.902(d).

281. Defendant is engaged in "trade" and "commerce" within the meaning of MCL § 445.902(g) as they market, promote, and sell PGT-A testing for sale to consumers within the State.

282. Defendant's representations were material to a reasonable consumer and likely to affect consumer decisions and conduct.

283. Defendant used and employed deceptive and unfair methods of competition and unfair or deceptive acts, practices, and or representations in the conduct of trade or commerce.

284. Defendant's acts and practices offend public policy as established by statute. Defendant's acts and practices violate the Federal Trade Commission Act, which provides that

"unfair or deceptive acts or practices in or affecting commerce . . . are . . . declared unlawful." 15 U.S.C. Sec. 45(a)(1). An act or practice is "unfair" if it "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

285. Defendant's acts and practices are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

286. Defendant violated MCL § 445.903(1)(a), (b), (s), and (cc), among others.

287. Defendant's conduct is substantially injurious to consumers. Such conduct has, and continues to cause, substantial economic injury to consumers because consumers would not have paid for Defendant's PGT-A testing but for Defendant's false and misleading representations, omissions, and promotion.

288. Consumers have thus paid unnecessarily for testing and such injury is not outweighed by any countervailing benefits to consumers or competition.

289. No benefit to consumers or competition results from Defendant's conduct. Since consumers reasonably rely on Defendant's representations and omissions, consumers could not have reasonably avoided such injury.

290. The foregoing unfair and deceptive practices directly, foreseeably, and proximately caused Plaintiff and the Michigan Class to suffer an ascertainable loss when they paid for PGT-A testing based on Defendant's false and misleading material statements and omissions.

291. Plaintiff and the Michigan Class are entitled to recover damages and other appropriate relief pursuant to MCL § 445.911.

COUNT V
Breach of the Implied Warranty of Merchantability
(On behalf of Plaintiffs and the Class)

292. Plaintiffs incorporate by reference all preceding allegations.

293. By operation of law, Defendant, as the provider and seller of its PGT-A testing, impliedly warranted to Plaintiffs and the Class members that Defendant's PGT-A was of merchantable quality and fit for its ordinary and intended use.

294. Such implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2-314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-31, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, *et seq.*; S.D. Codified Laws §§ 57A-2-314, *et seq.*; Tenn. Code Ann. §§ 47-2-314, *et seq.*; Tex. Bus. & Com. Code §§ 2.314, *et seq.*; Utah Code Ann. §§ 70A-2-314, *et seq.*; Va. Code Ann. §§ 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq.*; Wash. Rev. Code §§ 62A.2-314, *et seq.*; W. Va. Code §§ 46-2-314, *et seq.*; Wis. Stat. Ann. §§ 402.314, *et seq.*; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq.*

295. Defendant breached the implied warranty of merchantability in connection with the sale of PGT-A. While Defendant advertises, markets, and promotes that its PGT-A testing is substantiated, accurate and reliable, it is not, rendering it unsuitable for use.

296. Had Plaintiffs and the Class members known that Defendant's PGT-A was unproven, inaccurate, and unreliable, they would not have purchased it.

297. To the extent privity may be required, Plaintiffs and the Class members can establish privity with Defendant because Plaintiffs purchased PGT-A from Defendants.

298. As a direct and proximate result of Defendant's breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT VI
Breach of the Implied Warranty of Usability
(On behalf of Plaintiffs and the Class)

299. Plaintiffs incorporate by reference all preceding allegations.

300. By operation of law, Defendant, as the seller and provider of PGT-A testing, warranted to Plaintiffs and the Class members through its statements that PGT-A was usable for its ordinary and intended use.

301. Such implied warranty arises under U.C.C. § 2-314(3) as adopted in each state.

302. Such implied warranty of usability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann.

Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2-314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-31, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, *et seq.*; S.D. Codified Laws §§ 57A-2-314, *et seq.*; Tenn. Code Ann. §§ 47-2-314, *et seq.*; Tex. Bus. & Com. Code §§ 2.314, *et seq.*; Utah Code Ann. §§ 70A-2-314, *et seq.*; Va. Code Ann. §§ 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq.*; Wash. Rev. Code §§ 62A.2-314, *et seq.*; W. Va. Code §§ 46-2-314, *et seq.*; Wis. Stat. Ann. §§ 402.314, *et seq.*; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq.*

303. Defendant by its advertising, marketing, and sale of PGT-A to Plaintiffs and the Class, impliedly warrant that its product is usable.

304. Defendant breached the implied warranty of usability in connection with its sale of PGT-A testing, as it contained defects and suffered from issues that were not readily apparent to consumers.

305. Defendant knew or should have known that PGT-A is unproven and does not produce accurate or reliable results to such an extent that it is unusable.

306. To the extent privity may be required, Plaintiffs and the Class can establish privity with Defendants as they purchased PGT-A from Defendants.

307. Had Plaintiffs and Class members known that they would not be able to use the results of Defendant's PGT-A, they would not have purchased it or would have paid significantly less for it.

308. As a direct and proximate result of Defendant's breach of the implied warranty of usability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT VII
Breach of Express Warranty
(On behalf of Plaintiffs and the Class)

309. Plaintiffs incorporate by reference all preceding allegations.

310. By advertising and selling PGT-A testing, Defendant made promises and affirmations of fact about PGT-A testing through its marketing and advertising statements, patient brochure, Consent Form, test results, and as further set forth above.

311. These promises and affirmations constitute an express warranty U.C.C. § 2-313 and became the basis for the purchase of PGT-A testing by Plaintiff and Class members from Defendant.

312. Defendant purports, through its marketing and advertising, patient brochure, consent forms, statements, and test results that its PGT-A testing is accurate and reliable, among other things as detailed here.

313. Despite Defendant's express warranties about accuracy and reliability, its PGT-A testing is not accurate or reliable.

314. Defendant's PGT-A testing is therefore not what Defendant represented it to be.

315. Accordingly, Defendant breached express warranties about PGT-A because its PGT-A testing does not conform to Defendant's affirmations and promises that the testing is accurate and reliable.

316. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT VIII
Fraud
(On behalf of Plaintiffs and Class Members)

317. Plaintiffs incorporate by reference all preceding allegations.

318. Defendant created and implemented a scheme to market its PGT-A to increase sales through false and misleading statements and material omissions, including, for example, that:

a. PGT-A testing increases IVF success;

b. PGT-A testing is 99% accurate;

c. PGT-A testing increases the chance of implantation;

d. PGT-A testing decreases the chance of miscarriage;

e. PGT-A testing reduces the time to pregnancy;

f. PGT-A testing increases the rate of pregnancy;

g. PGT-A testing increases the rate of live birth;

h. PGT-A testing improves the chance of a healthy pregnancy; and

i. PGT-A testing improves pregnancy rates for all ages, especially those of advanced maternal age.

319. Defendant's conduct was fraudulent and deceptive because its misrepresentations and omissions were likely to, and did, deceive consumers, including Plaintiffs and the Class.

320. Defendant knew or should have known that its misrepresentations and omissions were false and misleading and intended for consumers to rely on.

321. Plaintiff and the Class members have been injured because they paid for PGT-A and suffered economic losses based upon the material misrepresentations and omissions of Defendants.

322. Defendant's false statements and omissions induced Plaintiffs and Class members to purchase Defendant's PGT-A.

323. Defendant's advertising, marketing, and promotion of PGT-A fraudulently concealed the truth about PGT-A as alleged herein. Accordingly, Plaintiffs and the Class could not have known that they were subject to deceptive and misleading marketing and promotion.

324. Absent Defendant's conduct, Plaintiffs and Class members would not have purchased PGT-A from Defendant and are entitled to a full refund of the purchase price and additional economic losses. In the alternative, Plaintiffs and Class members are entitled to the difference in value between the unproven and unreliable test Plaintiffs and Class members purchased and the test Defendant advertised.

325. As a result of Defendant's false and deceptive conduct, Plaintiffs and Class members are entitled to monetary, compensatory, treble, and punitive damages, injunctive relief, restitution, and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

COUNT IX
Fraud by Concealment
(On behalf of Plaintiffs and Class Members)

326. Plaintiffs incorporate by reference all preceding allegations.

327. Defendant intentionally suppressed and concealed material facts about its PGT-A testing as alleged herein. Defendant knew about the problems and issues with PGT-A, that it was unproven, inaccurate, and unreliable, as well as the status of scientific knowledge concerning PGT-A but failed to disclose these material facts to Plaintiffs and Class members.

328. Plaintiffs and Class members had no reasonable means of knowing that Defendant's representations concerning PGT-A were materially incomplete, false, or misleading, or that Defendant had failed to disclose relevant material facts about PGT-A. Plaintiffs and Class members did not and reasonably could not have discovered Defendant's deceit before they purchased PGT-A.

329. Had Plaintiffs and Class members known the truth, and of the material facts that Defendant omitted to disclose to them, they would not have purchased PGT-A from Defendant and incurred economic costs.

330. Defendant had a duty to disclose the truth because the facts that Defendant choose not to disclose are material and Defendant possessed knowledge of these facts that unsuspecting and vulnerable consumers did not have.

331. Defendant was aware of the scientific study and research concerning PGT-A as Defendant reviewed the research and publications concerning PGT-A, including from major medical associations such as ASRM.

332. Defendant had a duty to disclose the truth about PGT-A because, through Defendant's advertising, marketing, website statements, patient brochures, consent form, and

other written statements made to consumers, Defendant made partial representations regarding PGT-A including purported representations concerning its reliability and accuracy, but failed to disclose facts that would have materially qualified those partial representations.

333. Having volunteered purportedly scientific and research-based information relating to PGT-A to Plaintiffs and Class members, Defendant had a duty to disclose the whole truth about PGT-A and its unproven, inaccurate, and unreliable nature.

334. Each Plaintiff and Class member was exposed to Defendant's representations prior to and immediately after purchase. Each Plaintiff and Class member saw the same generalized representations as detailed herein, that were repeated by Defendant throughout its promotional materials. None of the informational sources that Plaintiffs and Class members were provided by Defendant, including advertisements, websites, brochures, or promotional materials indicated or disclosed the full truth about PGT-A testing as detailed herein.

335. Defendant concealed the truth to sell more PGT-A testing and to avoid the public finding out the truth about PGT-A.

336. The facts that Defendant suppressed and omitted were material, and Plaintiffs and Class members were unaware of them at the time of purchase. Had the facts been disclosed, Plaintiffs and Class members would not have purchased PGT-A and incurred the associated economic costs by which they were damaged.

337. When deciding whether to purchase PGT-A, Plaintiffs and Class members reasonably relied to their detriment on Defendant's material misrepresentations and omissions as detailed herein.

338. Plaintiffs and Class members sustained damages in the form of economic costs as a direct and proximate result of Defendant's deceit and fraudulent concealment.

339. Defendant's fraudulent concealment was malicious, oppressive, deliberate, intended to defraud Plaintiffs and Class members, and intended to enrich Defendant, and has been in reckless disregard of Plaintiffs' and Class members' rights, interests, and well-being.

Defendant's conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct, to be determined according to proof at trial.

COUNT X
Unjust Enrichment
(On behalf of Plaintiffs and Class Members)

340. Plaintiffs incorporate by reference all preceding allegations.

341. Plaintiffs plead this claim in the alternative to their other claims to the extent there is no adequate remedy at law.

342. Defendant created and implemented a scheme to market for PGT-A testing to increase sales through numerous false and misleading statements and material omissions as set forth above.

343. As a result, Defendant have been unjustly enriched.

344. Defendant received a measurable benefit at the expense of Plaintiffs and Class members in the form of payment for PGT-A testing and associated costs.

345. Defendant accepted monetary benefits from Plaintiffs and Class members at the detriment of Plaintiffs and Class members.

346. These benefits were the result of Defendant acting in its pecuniary interest at the expense of its consumers.

347. There is no justification for Defendant's enrichment. It would be inequitable, unconscionable, and unjust for Defendant to be permitted to retain benefits because the benefits were procured as a result of its wrongful conduct.

348. Plaintiffs and Class members are entitled to full restitution of the benefits that Defendant unjustly received and/or any amounts necessary to return Plaintiffs and Class members to the position they occupied prior to purchasing PGT-A from Defendant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Classes defined above, respectfully request that the Court:

a. Determine that Defendant is liable for the violations set forth above;

b. Award Plaintiffs and the Classes defined above all compensatory, statutory, restitution, and punitive damages as provided by law;

c. Grant appropriate equitable relief, including, without limitation, an order requiring Defendants to adequately disclose the true nature of PGT-A testing;

d. Certify each Class as defined herein, designating Plaintiffs as Class representatives, and appointing the undersigned counsel as Class Counsel;

e. Declare that Defendants are financially responsible for notifying the Class members of the pendency of this action;

f. Require that Defendants disgorge amounts wrongfully obtained for PGT-A testing and award injunctive relief as permitted by law or equity, including enjoining Defendants from engaging in misleading and deceptive practices going forward;

g. Schedule a trial by jury in this action on all claims so triable;

h. Award Plaintiffs' reasonable attorneys' fees, costs, and expenses, as provided by law;

i. Award Plaintiffs and Class members trebled, statutory, and/or punitive damages as authorized by law;

j. Award pre-judgment and post-judgment interest on any amounts awarded, as provided by law; and

k. Grant such further relief that the Court deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs request a trial by jury of all issues triable as of right.

Dated: October 8, 2024

Respectfully submitted,

/s/Sophia M. Rios

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Attorneys for Plaintiffs

CIVIL COVER SHEET

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

SHANNON PETERSEN and ERIN VEDRODE, individually and on behalf of all others similarly situated

(b) County of Residence of First Listed Plaintiff Sonoma
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Berger Montague, 8241 La Mesa Blvd, Suite A, La Mesa, CA 91942, 619-489-0300

DEFENDANTS

NATERA, INC.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment Of Veteran's Benefits
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☒ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury – Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
- ☐ 448 Education

PRISONER PETITIONS

HABEAS CORPUS
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

OTHER
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee–Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC § 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent—Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 USC § 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation–Transfer
- ☐ 8 Multidistrict Litigation–Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Section 1332(d)(3); Cal. Bus. & Prof. Code §§ 17200, et seq.

Brief description of cause:
Violations of consumer protection statutes and breach of warranties regarding false advertising

VII. REQUESTED IN COMPLAINT:

✓ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, Fed. R. Civ. P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S), IF ANY *(See instructions):*

JUDGE

DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only) ☒ **SAN FRANCISCO/OAKLAND** ☐ **SAN JOSE** ☐ **EUREKA-MCKINLEYVILLE**

DATE 10/08/2024

SIGNATURE OF ATTORNEY OF RECORD /s/Sophia M. Rios

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-CAND 44

Authority For Civil Cover Sheet. The JS-CAND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)."

II. Jurisdiction. The basis of jurisdiction is set forth under Federal Rule of Civil Procedure 8(a), which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

(1) United States plaintiff. Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.

(2) United States defendant. When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

(3) Federal question. This refers to suits under 28 USC § 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

(4) Diversity of citizenship. This refers to suits under 28 USC § 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS-CAND 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.

(1) Original Proceedings. Cases originating in the United States district courts.

(2) Removed from State Court. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.

(3) Remanded from Appellate Court. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

(4) Reinstated or Reopened. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

(5) Transferred from Another District. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

(6) Multidistrict Litigation Transfer. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.

(8) Multidistrict Litigation Direct File. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

Please note that there is no Origin Code 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC § 553. Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Federal Rule of Civil Procedure 23.

Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

IX. Divisional Assignment. If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated."

Date and Attorney Signature. Date and sign the civil cover sheet.