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

MELISSA KLEIN and VALERIE GRIFFETH, individually and on behalf of all others similarly situated, Plaintiffs, v. NATERA, INC., Defendant.	**CASE NO.** **CLASS ACTION COMPLAINT FOR:** **1. VIOLATIONS OF NEW YORK CONSUMER PROTECTION GBL § 349, et seq.** **2. VIOLATIONS OF NEW YORK CONSUMER PROTECTION GBL § 350** **3. VIOLATIONS OF ILLINOIS' CONSUMER FRAUD AND**

DECEPTIVE BUSINESS PRACTICES ACT, 815 ILL. COMP. STAT. 505/2; AND UNIFORM DECEPTIVE TRADE PRACTICES ACT, 815 ILL. COMP. STAT. 510/2

4. **FRAUD**
5. **FRAUD BY CONCEALMENT**
6. **UNJUST ENRICHMENT/RESTITUTION**

DEMAND FOR JURY TRIAL

Plaintiffs Melissa Klein, and Valerie Griffeth ("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. In addition to making misrepresentations as detailed herein, there are circumstances in which non-disclosure or concealment may constitute actionable fraud, and the facts set forth below demonstrate that in marketing to Plaintiffs and Class members, Defendant made partial representations while suppressing material facts. 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.

10. Defendant markets its PGT-A testing product directly to individual consumers.

11. Defendant also markets its PGT-A testing product to clinics and clinicians.

12. Individual consumers going through the IVF process must decide whether to purchase PGT-A testing prior to the testing being performed.

13. If PGT-A testing is purchased by individual consumers as an add-on to the IVF process from Defendant, the IVF clinic performs a biopsy and sends a small number of cells from the embryo to one of Defendant's laboratories who performs the PGT-A testing and provides results to the customer and their clinic.

14. 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.

15. 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 as an add-on to their IVF treatment.

16. PGT-A testing does not occur as part of the IVF process until after it is purchased from Defendant by the Plaintiffs and Class members.

17. 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 or disclosed.

18. 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.

19. 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.

20. 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]

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

22. 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.

23. 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.

24. 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.

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

26. 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, increase the success of IVF, or increase the chances of a healthy baby. Despite that, Defendant has

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[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.

to aggressively promote PGT-A to vulnerable and unsuspecting consumers.

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

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

29. 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.

30. 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

31. Plaintiff Melissa Klein is a resident of Staten Island, New York and received fertility treatment fertility in Staten Island, New York.

32. Plaintiff Valerie Griffeth is a resident of Chicago, Illinois and received fertility treatment fertility in Chicago, Illinois.

33. Defendant Natera, Inc. is a company incorporated in Delaware with a principal executive office at 13011 McCallen Pass, Building A, Suite 100, Austin, Texas 78753.

34. According to its SEC filings, Defendant considers itself a "diagnostics company with proprietary molecular and bioinformatics technology" and since 2009, has "launched a comprehensive suite of products to improve patient care outcomes."[3]

35. One laboratory is located at 201 Industrial Road, Suite 410, San Carlos, California.

36. The San Carlos laboratory holds a Clinical and Public Health Laboratory License

[3] Natera Inc., SEC Form 10-K. April 24, 2025. https://www.sec.gov/Archives/edgar/data/1604821/000155837025005447/ntra-20241231xars.pdf.

which lists the owners as the Vanguard Group, Inc. and Blackrock Fund Advisors.

37. The San Carlos laboratory holds a certificate of accreditation with Clinical Laboratory Improvement Amendments ("CLIA") under the name Natera, Inc.

38. The second laboratory is located at 13011 McAllen Pass, Building A, Suite 100, Austin, Texas.

39. The Austin laboratory holds a Clinical and Public Health Laboratory License which lists the owner as Natera, Inc.

40. The Austin laboratory holds a certificate of accreditation with Clinical Laboratory Improvement Amendments ("CLIA") under the name NSTX, Inc.

41. Defendant markets, advertises, and promotes the sale of its PGT-A testing product in California and throughout the United States.

JURISDICTION AND VENUE

42. 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.

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

44. 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.

45. 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.

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

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

47. 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.

48. 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.

49. 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.

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

51. 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.

52. If the PGT-A testing product is purchased from Defendant, then 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.

53. 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.

54. The biopsy is sent to one of Defendant's laboratories for PGT-A testing to be performed.

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

56. Test results are then provided by Defendant to the IVF clinic and to the patient.

57. If Plaintiffs and Class members were aware of the true efficacy and accuracy rates of PGT-A testing, they would have forgone such testing.

58. Defendant is aware of the lengths to which individuals undergoing IVF go to create embryos, the emotional and financial investment in assuring the viability of embryos, and the expectation that any genetic testing product they are selling be accurate and non-misleading.

59. 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.

60. 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.

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

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

63. 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.

64. Defendant promotes its PGT-A product as an add-on to the IVF process and

strongly encourages consumers undergoing IVF to purchase its PGT-A testing to determine which embryos are suitable to transfer.

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

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

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

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

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

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

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

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

73. In selling PGT-A to consumers, Defendant represents that its PGT-A testing product produces results that: (a) are 99% accurate; (b) increase the chance of embryo implantation, (c) decrease the chance of miscarriage, (d) reduce the time to pregnancy, (e) increase the rate of pregnancy, (f) increase the rate of live birth, (g) improve the chance of a healthy pregnancy, (h) increase IVF success, and (i) improve pregnancy rates for all ages, especially those of advanced maternal age which Defendant identifies as above 35.

74. 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. Defendant further made these misrepresentations while suppressing material facts as set forth in detail below.

B. History of PGT-A Testing

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

76. 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.[4]

77. 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.

78. 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.

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

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

81. This method, described as PGS 1.0, became increasingly popular despite that researchers in 2005 were still unable to demonstrate outcome benefits.[5]

82. 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 age with variable risks for embryonic aneuploidy, and weighed these effects against the results

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

[5] 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.

obtained after IVF without PGS.[6]

83. 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.[7]

84. In 2009, Defendant originated its PGT-A product which it markets as "Spectrum."[8]

85. In 2011, researchers conducted a meta-analysis of randomized control trials on the effect of PGS on the probability of live birth after IVF.[9]

86. 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.[10]

87. 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.[11]

88. The authors cautioned that new approaches in the application of PGS should be carefully evaluated before introduction into clinical practice.[12]

89. In a 2013 paired randomized clinical trial on 116 patients, scientists sought to evaluate if cleavage[13] or blastocyst stage embryo biopsy affects reproductive competence.[14]

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[6] 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).

[7] *Id*.

[8] 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).

[9] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).

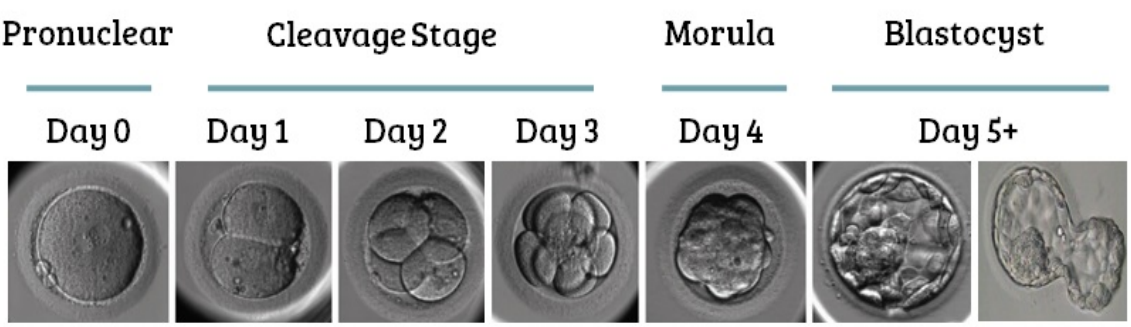
[10] *Id.*

[11] *Id*.

[12] *Id.*

[13] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.

[14] 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.



90. 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.

91. The authors concluded that cleavage-stage biopsy markedly reduced embryonic reproductive potential.[15]

92. 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.[16]

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

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

95. 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.

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

97. 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.

98. 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.

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[15] *Id.*
[16] *Id.*

99. 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.

100. 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.

101. 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.

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

103. 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.

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

105. In a 2016 study, researchers tested embryos that had previously been tested and deemed aneuploid.[17] Six out of eleven embryos upon retesting were determined to be either definitively normal or mosaic with the potential to be normal, thus offering a chance for pregnancy if transferred.[18]

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[17] 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.
[18] *Id*.

106. 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%.[19]

107. 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.[20]

108. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[21]

109. 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.[22]

110. 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.[23] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

111. 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.[24]

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[19] *Id.*
[20] *Id*.
[21] *Id*.
[22] 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.
[23] 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).
[24] 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.

112. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[25]

113. 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.

114. 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.

115. 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.

116. 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."

117. 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.

118. 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.

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

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

121. 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

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[25] *Id.*

publications related to testing and concluded that all five assumptions made in 1996 are scientifically unsupportable and the hypotheses of PGS were discredited.[26]

122. 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.[27]

123. 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.

124. 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.

125. 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.[28] 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.[29]

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

[27] *Id*.

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

[29] *Id.*

126. 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.[30]

127. 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."[31] 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.

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

129. 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.

130. 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."[32]

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

132. Instead, Defendant issued a press release on August 2, 2018 which "announced the

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[30] 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.

[31] *Id.*

[32] 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.

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."[33] 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.)

133. In 2019, Santiago Munne, conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[34]

134. 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.[35]

135. 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."[36]

136. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[37]

137. 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

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[33]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).

[34] 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.

[35] *Id.*

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

[37]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).

the losses of potential implantations are evident. Dr. Paulson called for scientific scrutiny of the available PGT-A data.[38]

138. The American College of Obstetricians and Gynecologists' (ACOG) Committee Opinion released in March 2020 raised similar concerns. Notably, ACOG noted that the three randomized control studies on the clinical effectiveness of PGT-A that reported higher pregnancy rates in younger patients with no previous failed IVF attempts were small studies with substantial limitations.[39]

139. ACOG also determined that a randomized control study which found women aged 38 to 41 had higher birth rates and lower miscarriage rates after PGT-A was problematic because 32% of the patients in the PGT-A group did not have an embryo to transfer.[40]

140. ACOG cited to ASRM's 2018 determination that "there is insufficient evidence to recommend the routine use of preimplantation genetic testing-aneuploidy in all infertile women" and concluded that the ideal genetic platform to analyze all chromosomes had not yet been established.[41]

141. ACOG also stated that worldwide randomized controlled trials are needed to determine which patient cohorts, if any, may benefit from PGT-A and that, in concordance with ASRM, there is insufficient evidence to recommend routine use of PGT-A in all infertile women.[42]

142. In conclusion, ACOG determined future research is necessary to establish the overall clinical utility for PGT-A, the subset of patients that may benefit from PGT-A, the clinical significance of mosaicism, and the residual risk for aneuploidy in PGT-A screened embryos.[43]

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

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[38] *Id*.
[39] Committee on Genetics of the American College of Obstetricians and Gynecologists. *ACOG Committee Opinion – Preimplantation Genetic Testing*. Number 799. March 2020.
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id*.

144. 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.[44]

145. 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 truthful and complete information about PGT-A in an accessible and comprehensible manner may lead to disparities in the use of PGT-A because patient educational materials have exceeded the average literacy skills of U.S. residents.[45]

146. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[46] The authors of the 2020 study found that PGT-A resulted in a lower chance of live birth in all age groups compared to transfer of embryos without PGT-A.[47]

147. 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 live-birth rate as compared with conventional IVF.[48]

148. 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."[49]

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[44] 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).
[45] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: Challenges in clinical practice*, Human Genomics, article 69 (2022).
[46] 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).
[47] *Id*.
[48] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[49] *Id.*

149. 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."[50]

150. The authors of the study concluded, among other things:

a. No benefit for PGT-A regardless of age on cumulative live-birth rate;[51] and

b. No benefit for PGT-A for ongoing pregnancy and live birth rates after first frozen embryo transfer.[52]

151. 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;

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.[53]

152. 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.

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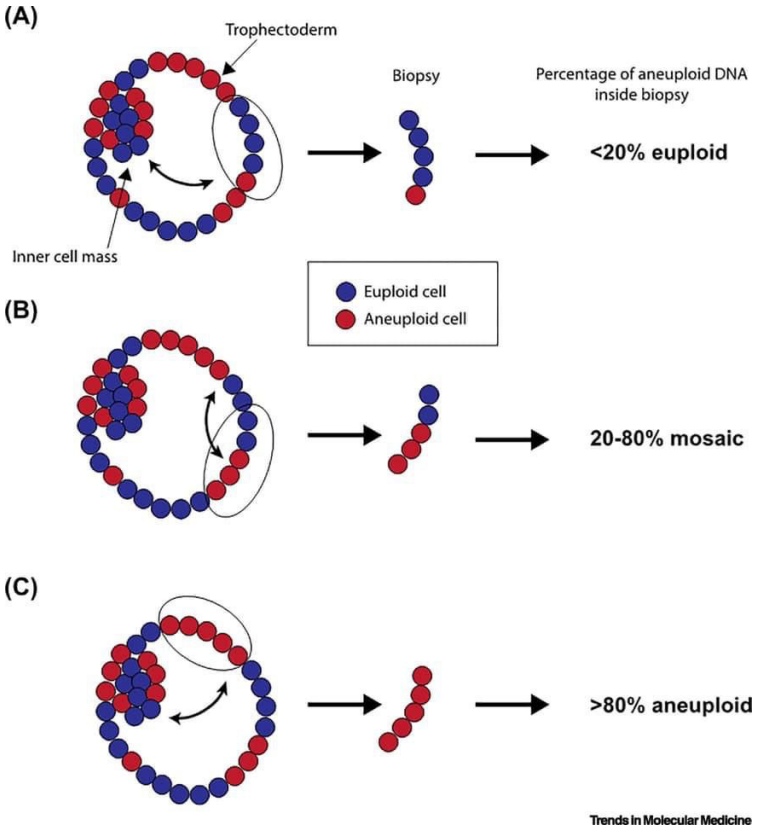
[50] *Id*. at 2054.
[51] *Id.*
[52] *Id*.
[53] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.

153. 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.[54]

154. 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.

155. 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:[55]



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

[55] 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).

156. 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.[56]

157. However, since at least as early as April 2022, Defendant continued to promote PGT-A by making the specific affirmative misrepresentation that PGT-A improves pregnancy rates for all ages 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.[57]

158. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[58] The authors noted that an 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.[59]

159. 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."[60]

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[56] 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).

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

[58] 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.

[59] *Id*.

[60] *Id*.

160. 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."[61]

161. 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.

162. 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;
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.[62]

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

163. 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.[63]

164. The researchers noted that the euploid rate suggested that chaotic abnormal results on PGT-A have "reduced predictive value."[64]

165. 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%.[65]

166. 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.[66]

167. 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.[67]

168. The European Society of Human Reproduction and Embryology ("ESHRE") add-ons working group released its good practice recommendations on add-ons in reproductive

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[63] 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.
[64] *Id.*
[65] 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.
[66] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).
[67] *Id*.

medicine in September of 2023 in which it was determined that PGT-A was not currently recommended for routine clinical use.[68]

169. 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.

170. 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."[69]

171. 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.

172. For example, Defendant's marketing has included the following on its website from 2021 to present:

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

[70]

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

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

[69] 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.

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

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.[71]

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

175. Defendant has not conducted such studies.

176. Notably, Defendant's researchers stated that a limitation of their 2018 study on their own PGT-A product to demonstrate the value of the company's Spectrum® preimplantation genetic screening for aneuploidy (PGT-A) was that it was not randomized.[72]

177. In addition, the researchers stated that "the data presented in this study are not sufficient to demonstrate the absolute impact of SNP-based PGT-A on IVF outcomes".[73]

178. Thus, Defendant's own study did not support or prove the representations it makes to sell its PGT-A testing product.

179. 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, and while suppressing material facts.

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[71] *Id.*

[72] 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.

[73] *Id.*

180. 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).[74]

181. Defendant omitted this material fact in its advertising and marketing materials, including those received, reviewed, and relied upon by Plaintiffs and Class Members.

182. 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.[75]

183. 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 among other issues.[76]

184. 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.[77]

185. 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.[78]

186. 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

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[74] 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.

[75] *Id.*

[76] 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.

[77] *Id*.

[78] 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).

pregnancy."[79]

187. 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.[80]

188. 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.[81]

189. 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 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".[82]

190. In addition, a review of 552 pregnancies of mosaic embryo transfers found that only

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[79] *Id.*
[80] *Id.*
[81] https://www.hfea.gov.uk/treatments/treatment-add-ons/pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited September 26, 2024).
[82] 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.

7 of the 552 pregnancies revealed the mosaicism that had been detected in the PGT-A testing.[83]

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

192. 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.[84]

193. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[85]

194. In May 2024 and then in September 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.[86]

195. ASRM noted that despite early single-center studies reporting higher birth rates after PGT-A in the primary embryo transfer of favorable-prognosis patients, two recent, multicenter, randomized control trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[87]

196. According to ASRM, there have been few well-designed studies providing high-quality evidence regarding IVF pregnancy outcomes in select populations with PGT-A.[88]

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[83] 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

[84] 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.

[85] 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.

[86] 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.

[87] *Id.*

[88] *Id.*

197. This position was supported by Dr. Viville and Dr. Aboulghar who reviewed the studies supporting PGT-A testing and determined that all of the studies were based upon criterion which implied the exclusion of a large number of attempts.[89]

198. The doctors noted the several studies, on the other hand, concluded that overall pregnancy outcomes per one cycle were similar between PGT-A and conventional IVF and that PGT-A is actually associated with lower live birth rates.[90]

199. ASRM also indicated that the value of PGT-A to lower the risk of miscarriage is unclear.[91]

200. ASRM concluded that the studies had important limitations and questions remained about appropriate patient selection and testing platforms.[92]

201. Defendant omitted these material facts in its advertising materials.

202. 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.[93]

203. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[94]

204. Still, Defendant continues to promote widespread use and sale of its PGT-A product.

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[89] Viville, S. and Aboulghar, M., *PGT-A: what's it for, what's wrong?* Journal of Assisted Reproduction and Genetics. Vol. 42, pp. 63-69 (2025).

[90] *Id. citing* Viotti M, Victor AR, Barnes FL, Zouves CG, Besser AG, Grifo JA, et al. *Using outcome data from one thousand mosaic embryo transfers to formulate an embryo ranking system for clinical use.* Fertility Sterilility. 2021;115:1212–24; Viotti M, Greco E, Grifo JA, Madjunkov M, Librach C, Cetinkaya M, et al. *Chromosomal, gestational, and neonatal outcomes of embryos classified as a mosaic by preimplantation genetic testing for aneuploidy.* Fertility Sterilility. 2023;120:957–66; Cornelisse S, Zagers M, Kostova E, Fleischer K, van Wely M, Mastenbroek S. Preimplantation genetic testing for aneuploidies (abnormal number of chromosomes) in in vitro fertilisation. Cochrane Database Syst Rev. 2020;9:CD005291.

[91] I*d.*

[92] *Id.*

[93] *Id.*

[94] *Id.*

205. Following the 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.[95]

206. 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.[96]

207. 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.

208. Despite the lack of supporting research and scientific basis as well as the recommendations of ASRM and SART, Defendant continued to aggressively market and promote PGT-A as having benefits and properties that it does not have while suppressing material facts and omitting material and relevant information from consumers:[97]

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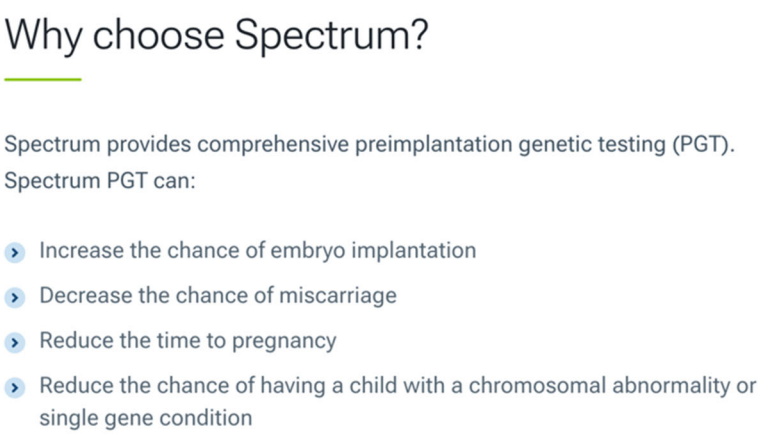
[95] Tikhonov, A., et al., *Re-Examination of PGT-A Detected Genetic Pathology in Compartments of Human Blastocysts: A Series of 23 Cases*. Journal of Clinical Medicine. 2024; 13(11):3289. https://doi.org/10.3390/jcm13113289.

[96] *Id.*

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



209. As of December 2025, Defendant no longer offers its Spectrum PGT-A testing.[98]

210. According to Defendant, "after many years of offering Spectrum™ preimplantation genetic testing, it has discontinued Spectrum™ PGT."[99]

211. Prior to the discontinuation of the sale of its PGT-A testing, Plaintiffs and Class members 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

212. 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.

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

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

a. PGT-A testing increases IVF success;

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[98] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/faq/ (last visited May 4, 2026).
[99] *Id.*

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.

215. In making these claims to sell, promote and market its PGT-A testing product, Defendant has provided no valid studies or support for its claims.

216. Further, Defendant has suppressed material facts and 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.

217. 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

218. Since at least as early as August 2, 2018, Defendant has claimed that Spectrum's PGT-A results are greater than 99% accurate. [100]

> 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

219. Also in its consent form, Defendant misleadingly states that its PGT-A testing is 99% accurate.

220. 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 results as 93.8% for euploid results, 81.4% for aneuploid results and 42.6% for mosaic aneuploid results.[101]

221. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[102]

222. The only non-selection study performed on next-generation sequencing PGT-A was on a testing assay which differs from the one utilized by Defendant and specifically stated that validation needs to be performed on each assay.[103]

223. Defendant's assay has never been properly validated to determine its accuracy, but this fact has been suppressed by Defendant and not disclosed to Plaintiffs and Class members.

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[100] 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).

[101] 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.

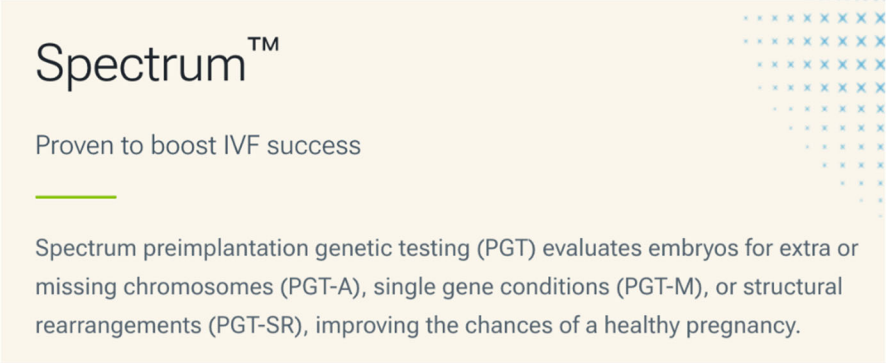
[102] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocriniology (2016) 14:54.

[103] Tiegs, A.W., et al., *A multicenter, prospective, blinded, nonselection study evaluating the predictive value of an aneuploid diagnosis using a targeted next-generation sequencing–based preimplantation genetic testing for aneuploidy assay and impact of biopsy.* Fertility and Sterility, Vol. 115, Issue 3. March 2021.

224. Rather, Defendant improperly relies on research which specifically states that it does not apply to other assays.[104]

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

225. From 2020 to present, the PGT-A section of Defendant's website has proclaimed that PGT-A performed by Natera's "Spectrum™ is proven to boost or improve IVF success."[105]



226. Defendant has conducted no studies to prove its Spectrum boosts IVF success and so it boasts unproven claims. Again, Defendant has suppressed this material fact from Plaintiffs and Class members while at the same time making the misrepresentations set forth herein.

227. Defendant makes knowingly false statements 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. [106]

228. In the brochure provided to consumers, including the Plaintiffs, from as early as January 2021 to late 2024, Defendant promoted its Spectrum PGT-A testing as increasing

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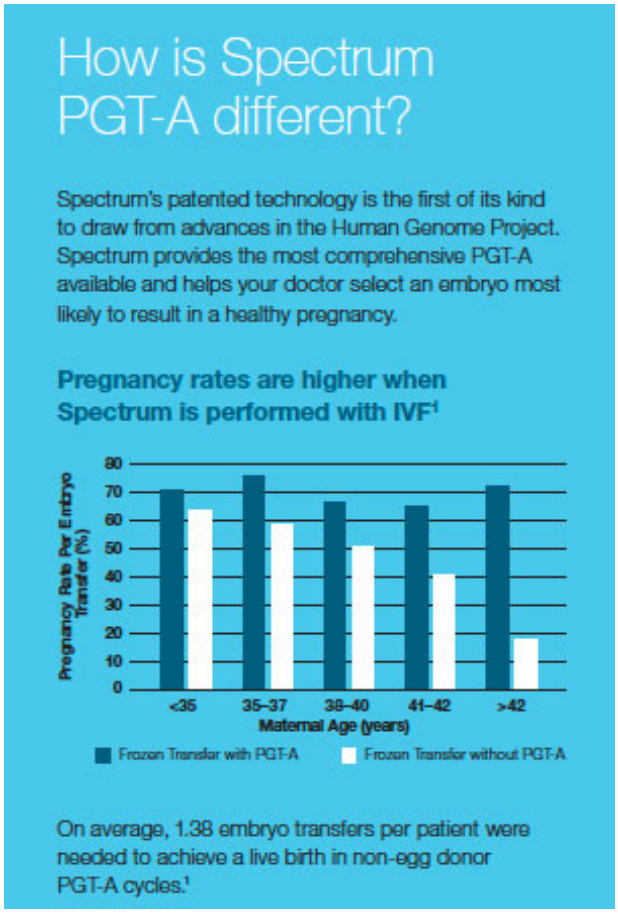
[104] *Id.*

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

[106] 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).

pregnancy rates.[107] *A copy of the brochure provided prior to 2025 is attached hereto as Exhibit "A".*



229. However, Defendant's own research, which served as the basis for Defendant's chart above and claims that pregnancy rates are higher with its PGT-A testing, specifically noted that "the data presented in this study are not sufficient to demonstrate the absolute impact of SNP-based PGT-A on IVF outcomes".[108]

230. Thus, it does not support or prove Defendant's claim of an increase in pregnancy or live birth rate.

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

[108] Simon, Alexander, 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, No. 1. July 2018.

231. 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%).

232. 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.[109]

233. Defendant's false and misleading claim is contradicted by scientific research that concluded that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[110]

234. 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."[111]

235. Researchers looking across age groups have further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[112]

236. 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.[113]

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[109] 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).

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

[111] 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.

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

[113] 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.

237. In fact, research in 2016 had already shown that PGT-A *decreased* live birth rates when compared to IVF without testing.[114]

238. Notably, the brochure now provided to IVF patients, which was altered sometime in 2025 by Defendant, no longer includes the misleading graph in paragraph 229.[115]

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

239. Since January 2021, Defendant has falsely claimed in its advertising materials and statements to consumers that its PGT-A decreases the chance of miscarriage.[116]

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.

240. Also, since January 2021, Defendant's website has included the same statements regarding a decrease in the chance of miscarriage in the clinician information section.[117]

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.

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[114] 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.

[115] https://www.natera.com/resource-library/spectrum/spectrum-pgt-a-patient-brochure/ (last visited August 25, 2025).

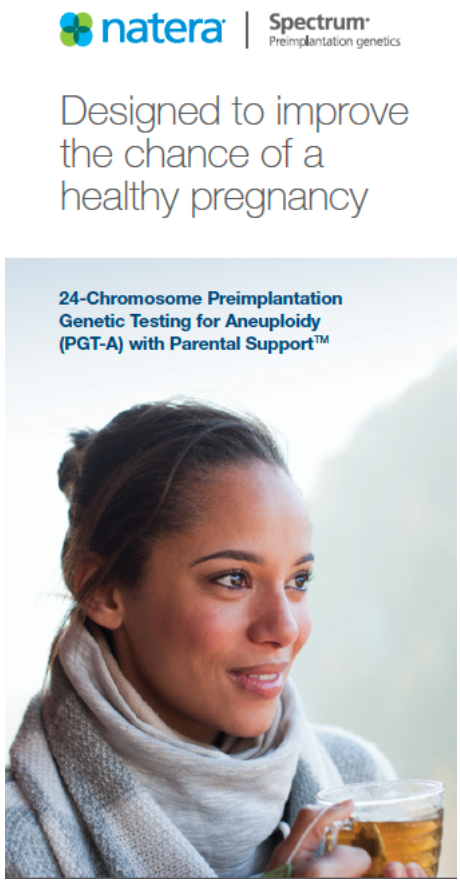
[116] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/faq/ (last visited October 8, 2024).

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

241. 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.

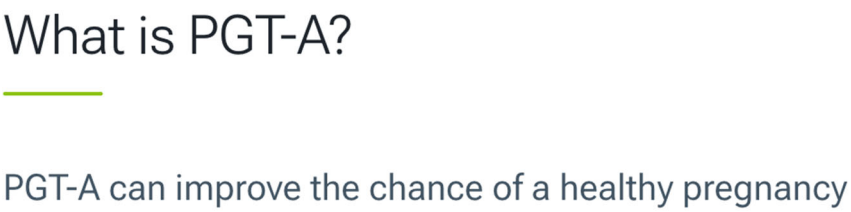
4. Defendant Falsely States That Its PGT-A Leads To A Higher Chance Of Pregnancy

242. In the patient brochure provided to patients from 2021 to 2024, Defendant states directly to consumers that PGT-A leads to a higher chance of a healthy pregnancy.[118] *See also* Exhibit "A".



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

243. A similar claim has been on Defendant's website since 2020.[119]

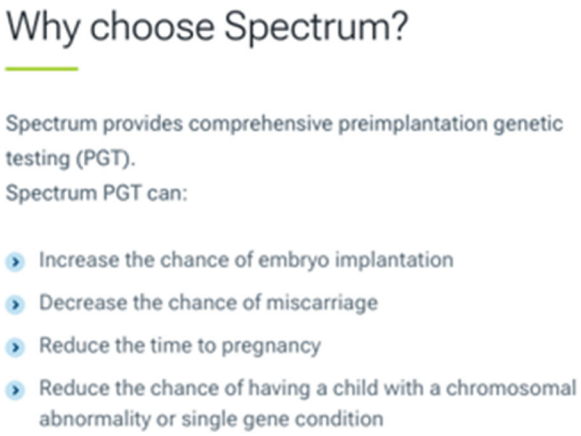


244. Defendant makes this claim even though no valid scientific research supports the accuracy of this claim. This is a material fact that was suppressed by Defendant.

245. 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.[120]

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

246. Defendant's website since 2021 has stated that its PGT-A testing potentially reduces the time to pregnancy.[121]



[119] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited August 25, 2025).

[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.

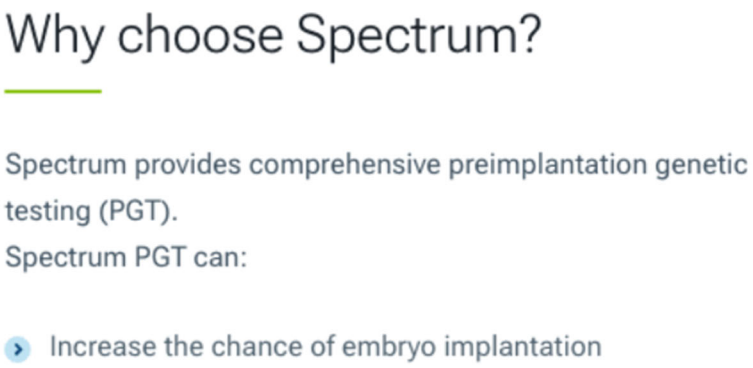
[121] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (last visited October 8, 2024).

247. Defendant makes this claim even though no valid scientific research supports the accuracy of this claim, which again shows that Defendant suppressed a material fact.

248. In fact, research shows that utilizing PGT-A does not decrease time to pregnancy.[122]

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

249. Defendant has misled consumers since at least April 2021 by stating that PGT-A can increase the chance of implantation and pregnancy.[123]



250. As previously discussed above, the available science does not support this claim. To the contrary, pregnancy outcomes were similar between conventional IVF and PGT-A, but this material fact is omitted to consumers by Defendants.[124]

251. Despite this, Defendant has continued to promote PGT-A testing to IVF consumers as follows since as early as May of 2021:[125]

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

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

[124] 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.

[125] https://www.natera.com/womens-health/spectrum-preimplantation-genetics/faq/#pg-menu-tabs (last visited August 25, 2025).

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

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

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

253. 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.

254. On its website since April 2021, Defendant states that its PGT-A testing can reduce the time to pregnancy.[126]

> Reduce the time to pregnancy

255. Since June 2021, Defendant also markets its PGT-A testing to clinicians as reducing the time pregnancy.[127]

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.

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

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

256. 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.[128]

257. 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.[129]

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

258. Since April 2022, Defendant has stated 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.[130]

> 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).

259. Defendant further states that PGT-A is especially useful for egg providers of advanced maternal age, which Defendant indicates is over 35 years old.[131]

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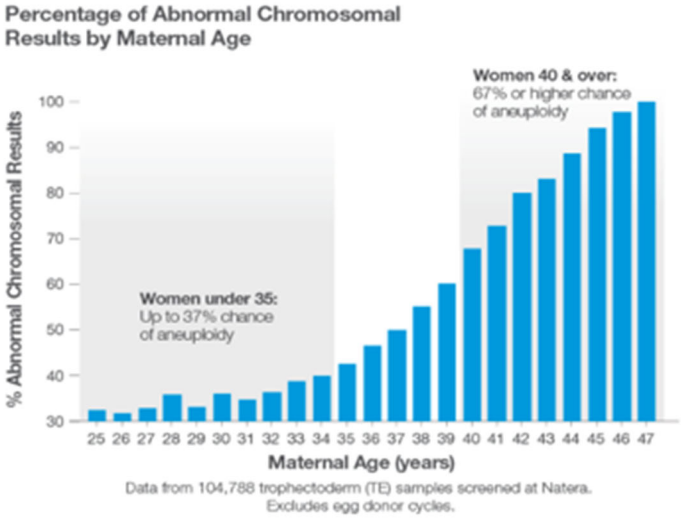
[128] Palmer, M., et al., *Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy*. Fertility and Sterility. Vol. 114, Issue 3. September 2020.

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

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

[131] *Id.*

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.

260. Defendant's false and misleading claims contradict evidence and scientific research. Researchers have found no benefit for PGT-A regardless of age on cumulative live-birth rate.[132]

261. In addition, research has concluded that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[133]

262. 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."[134]

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[132] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[133] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.
[134] 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.

263. 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.[135]

264. ASRM also noted that the only two randomized controlled trials that have been conducted on PGT-A showed no benefit in improving live birth rates particularly in women under 38 years of age,[136] but Defendant suppressed and did not disclose this material fact.

D. Defendant's Additional Material Omissions

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

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

267. 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 suppresses and omits this from consumers.

268. 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.

269. 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

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[135] 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.

[136] *Id.*

probability that an embryo may be misdiagnosed, and the test results inaccurate, but Defendant omits this from consumers.

270. 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.

271. 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.

272. 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.[137]

273. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[138]

E. PGT-A Has Enriched Defendant

274. 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.

275. 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.

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

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

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[137] 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.

[138] 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.

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

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

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

280. 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.

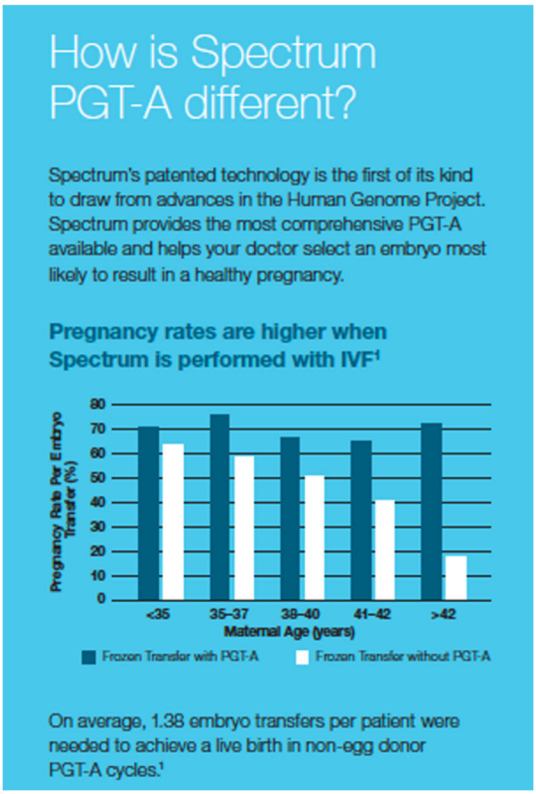
281. Plaintiffs and Class members suffered direct economic losses because of their purchase of PGT-A testing from Defendant, including but not limited to the out-of-pocket payments that each paid to Defendant for their PGT-A testing as well as additional costs associated with their PGT-A testing.

1. Plaintiff Melissa Klein's Purchase of PGT-A Testing

282. Plaintiff Klein underwent IVF and purchased PGT-A testing from Defendant based upon Defendant's statements and omissions of material information 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.

283. Prior to purchasing PGT-A testing from Defendant, and specifically, on or about February 1, 2023, Plaintiff Klein was provided with Defendant's patient brochure which at the time stated that Spectrum provided the most comprehensive PGT-A available and was designed to improve the chance of a healthy pregnancy and increase pregnancy rates.[139]

284. The brochure also included a chart in which Defendant claimed that its Spectrum PGT-A testing increased pregnancy rates.[140] *See also* Exhibit "A".



285. Defendant's patient brochure was the same from 2019 to 2024. It changed sometime in 2025 to remove the chart. The other claims remained the same.

286. On or about February 1, 2023, Plaintiff Klein viewed Defendant's website which stated that Defendant's Spectrum increases the success of IVF, increases the chance of embryo

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[139] Defendant's patient brochure was the same from 2019 to 2024. It changed sometime in 2025 to remove the chart discussed in paragraph 229.

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

implantation, decreases the chance of miscarriage, reduces the time to pregnancy, increases the rate of pregnancy, and is the most comprehensive preimplantation genetic testing available.[141]

287. On February 8, 2023, in order to purchase PGT-A testing from Defendant, Plaintiff Klein signed Defendant's consent form, which stated that Defendant's PGT-A testing has a 98 to 99% accuracy rate and increases the chance for a successful pregnancy and live birth.

288. Following the viewing of the website, the brochure and the consent form, which collectively led to Plaintiff Klein's purchase of PGT-A testing from Defendant, biopsies were collected from her embryos on or about February 19, 2023, and provided to Defendant on or about February 20, 2023.

289. Test results were delivered by Defendant in February 2023.

290. Plaintiff Klein relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $2,850.00 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 Valerie Griffeth's Purchase of PGT-A Testing

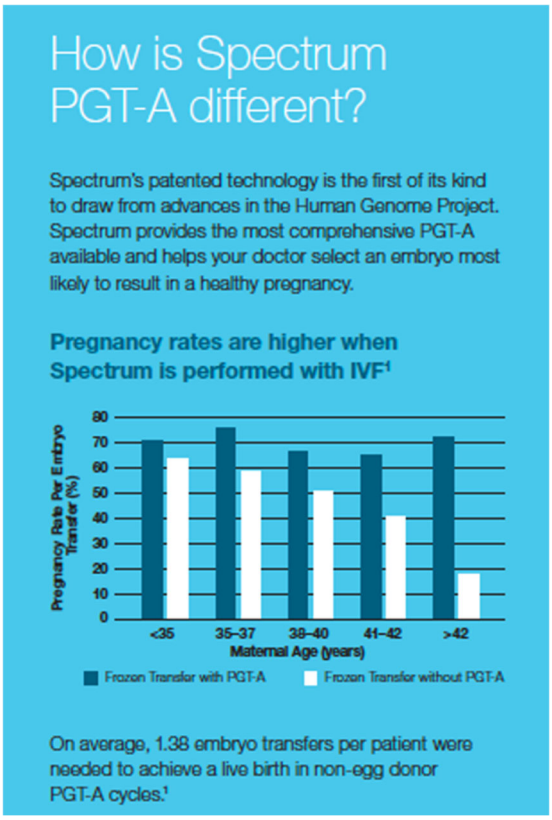
291. Plaintiff Griffeth underwent IVF and purchased PGT-A testing from Defendant based upon Defendant's statements and omissions of material information that PGT-A testing is greater than 99% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy,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

292. Prior to purchasing PGT-A testing from Defendant, and specifically, on or about May 5, 2023, Plaintiff Griffeth was provided with frequently asked questions about Defendant's PGT-A and Defendant's patient brochure which at the time stated that Spectrum provided the most

[141] https://web.archive.org/web/20230329121919/https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (version of the site on February 1, 2023).

comprehensive PGT-A available, and was designed to improve the chance of a healthy pregnancy and increase pregnancy rates.[142]

293. The brochure also included a chart in which Defendant claimed that its Spectrum PGT-A testing increased pregnancy rates.[143] *See also* Exhibit "A".



294. Defendant's patient brochure was the same from 2019 to 2024. It changed sometime in 2025 to remove the chart. The other claims remained the same.

295. On or about May 5, 2023, Plaintiff Griffeth viewed Defendant's website which stated that Defendant's Spectrum increases the success of IVF, increases the chance of embryo

[142] Defendant's patient brochure was the same from 2019 to 2024. It changed sometime in 2025 to remove the chart discussed in paragraph 229.

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

implantation, decreases the chance of miscarriage, reduces the time to pregnancy, increases the rate of pregnancy, and is the most comprehensive preimplantation genetic testing available.[144]

296. In May 2023, in order to purchase PGT-A testing from Defendant, Plaintiff Griffeth signed Defendant's consent form, which stated that Defendant's PGT-A testing has a 98 to 99% accuracy rate and increases the chance for a successful pregnancy and live birth.

297. Following the viewing of the website, the brochure and the consent form, which collectively led to Plaintiff Griffeth's purchase of PGT-A testing from Defendant, a biopsy was collected from their embryo on or about July 18, 2023 and provided to Defendant on or about July 22, 2023.

298. Test results were delivered by Defendant on or about August 2, 2023.

299. Plaintiff Griffeth relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $474 plus additional costs for their PGT-A testing which they would not have purchased absent Defendant's false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

300. 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").

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

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

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[144] https://web.archive.org/web/20230329121919/https://www.natera.com/womens-health/spectrum-preimplantation-genetics/ (version of the site on February 1, 2023).

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

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

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

306. **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.

307. **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.

308. 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.

309. **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.

310. **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.

311. **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.

312. 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.

313. **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

314. 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 New York Consumer Protection GBL § 349, *et seq*.
(On behalf of Melissa Klein and the New York Class)

315. Plaintiffs incorporate by reference all preceding allegations.

316. New York General Business Law Section 349 ("GBL § 349") declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state…".

317. Defendants' conduct alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiffs and the the New York Class members seek monetary damages and the entry of preliminary and permanent injunctive relief

against Defendants, enjoining them from inaccurately, misleadingly, or deceptively describing, marketing, and promoting PGT-A testing to consumers as alleged herein.

318. Defendants have marketed, promoted, and sold PGT-A to consumers in New York and received substantial revenue in New York for doing so.

319. Defendants' improper consumer-oriented conduct includes, but is not limited to, the following false and/or deceptive assurances:

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.

320. Defendants' improper consumer-oriented conduct is misleading in a material way and induced Plaintiff and the New York Class to purchase PGT-A from Defendants when they otherwise would not have. Defendants made their misleading representations and omissions willfully, wantonly, and with reckless disregard for the truth.

321. Defendants further breached their duties to Plaintiff as follows, without limitation:

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 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.

322. Plaintiff and the New York Class Members and all consumers nationwide have been injured because they paid for PGT-A sold by Defendants (and related costs) that they reasonably believed was accurate and reliable based on Defendants' misrepresentations and omissions as alleged herein. Accordingly, Plaintiff and the New York Class members incurred economic losses purchasing PGT-A that did not perform as advertised and did not have the qualities that were represented.

323. Defendants' advertising, marketing, and promotion of PGT-A induced Plaintiff and the New York Class to buy Defendants' PGT-A.

324. Defendants' deceptive and misleading practices constitute a deceptive act and practice in the conduct of business in violation of New York General Business Law § 349(a), and Plaintiff and the New York Class have been damaged by these practices.

325. As a result of Defendants' recurring, "unlawful" deceptive acts and practices, Plaintiff and the New York Class members are entitled to monetary, compensatory, treble, statutory, and punitive damages, injunctive relief, restitution, and disgorgement of all moneys obtained by means of Defendants' unlawful conduct, interest, and attorneys' fees and costs.

COUNT II
Violations of New York Consumer Protection GBL § 350
(On behalf of Melissa Klein and the New York Class)

326. Plaintiffs incorporate by reference all preceding allegations.

327. N.Y. Gen. Bus. Law § 350 provides, in part, as follows: "False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful."

328. N.Y. Gen. Bus. Law § 350a(1) provides, in part, as follows:

329. The term 'false advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, ***but also the extent to which the advertising fails to reveal facts material in the light of such representations*** with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual . . .

Id. (emphasis added).

330. Defendants' marketing and advertising contain untrue and materially misleading statements and omissions concerning the accuracy, reliability, and science supporting its PGT-A.

331. Plaintiff and the New York Class have been injured as they relied upon Defendants' misleading and deceptive advertising and marketing of PGT-A.

332. Defendants' advertising, marketing, and promotion induced Plaintiff and the New York Class members to PGT-A.

333. Defendants made untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

334. Defendants' conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

335. Defendants made the material misrepresentations described in this Complaint in Defendants' advertising, marketing, and other promotional materials.

336. Defendants' material misrepresentations were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing PGT-A continue to be exposed to Defendants' material misrepresentations and omissions which remain to this day on their advertising, marketing, and promotional materials.

337. As a result of Defendants' recurring, "unlawful" deceptive acts and practices, Plaintiff and the New York Class members are entitled to monetary, compensatory, treble, statutory, and punitive damages, injunctive relief, restitution, and disgorgement of all moneys obtained by means of Defendants' unlawful conduct, interest, and attorneys' fees and costs.

COUNT III

Violations of Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2; and Uniform Deceptive Trade Practices Act, 815 Ill. Comp. Stat. 510/2 (On behalf of Plaintiff Griffeth and the Class Members)

338. Plaintiffs incorporate by reference by reference all preceding allegations.

339. Plaintiff Griffeth brings this count individually and on behalf of the Illinois Class.

340. Plaintiff Griffeth is a "consumer" within the meaning of 815 Ill. Comp. Stat. 505/1.

341. Defendant is a "person" within the meaning of 815 Ill. Comp. Stat. 505/1.

342. Defendant is engaged in "trade" and "commerce" within the meaning of 815 Ill. Comp. Stat. 505/1 as they promote and sell PGT-A testing for sale to consumers within the State.

343. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq*. (the "Consumer Fraud Act"), protect both consumers and companies by promoting fair competition in commercial markets for goods and services.

344. The Consumer Fraud Act prohibits any "unfair or deceptive [business] acts or practices," including the use of any "deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment . . . in the conduct of any trade or commerce." 815 ILCS 505/2.

345. As described herein, Defendant engaged in deceptive business practices, as defined in the Consumer Fraud Act. For example, Defendant represented 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.

346. Defendant's representations were, in fact, false and misleading. Defendant's PGT-A tests were neither reliable nor accurate. Defendant's PGT-A tests were not 99% accurate, did not increase the chances of implantation, did not decrease the chances of miscarriage, did not reduce the time to pregnancy, did not increase the rate of pregnancy, did not increase the rate of live birth, did not improve the chance of a healthy pregnancy, and did not improve pregnancy rates for all ages, especially those of advanced maternal age.

347. The making of the representations and omissions with the intent that consumers rely on them constitutes a deceptive act or practice in or affecting commerce in violation of Section 2 of the Consumer Fraud Act, 815 ILCS 505/2.

348. Defendant also violated the "unfair" prong of Section 2 of the Consumer Fraud Act by causing substantial injury to consumers. Defendant advertised and marketed their PGT-A testing as reliable and accurate, when it was neither and when science deems it to be unproven. Plaintiff and the Class relied on these representations and purchased PGT-A for thousands of dollars that was neither reliable nor accurate.

349. Defendant's unfair and deceptive acts and practices occurred in the course of its business practices: the marketing and sale of PGT-A testing.

350. In the selling of PGT-A testing within the State, Defendant employs and uses fraud, misrepresentation, concealment, and omission of material facts within the State with the intention that consumers rely upon this fraud, misrepresentation, concealment and omission of fact. 815 Ill. Comp. Stat 505/2Defendant's unfair and deceptive acts and practices directly and proximately

caused Plaintiff and the Class actual economic damages in the form of the amounts paid by Plaintiff and each Class member for PGT-A testing and other associated costs.

351. Defendant's conduct is substantially injurious to consumers. Such conduct has caused, and continues to cause, actual damages to consumers because consumers would not have paid for Defendant's PGT-A but for relying on Defendant's false and deceptive promotion as detailed throughout this Complaint.

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

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

354. The foregoing unfair and deceptive practices directly, foreseeably, and proximately caused Plaintiff and the Illinois Class (and the Nationwide Class if the Consumer Fraud Act is deemed to apply to individuals outside of Illinois), to suffer ascertainable damages when they paid for PGT-A testing based on false and misleading material statements and omissions.

355. Plaintiff sent notice of this and her other claims on July 15, 2024.

356. Plaintiff and the Illinois Class (and the Nationwide Class if the Consumer Fraud Act is deemed to apply to individuals outside of Illinois) are entitled to recover damages and other appropriate relief, as alleged below.

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

357. Plaintiffs incorporate by reference all preceding allegations.

358. 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.

359. While making the above representations, Defendant also suppressed and omitted material facts from Plaintiffs and the Class members.

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

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

362. 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.

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

364. Defendant's advertising, marketing, and promotion of PGT-A fraudulently suppressed and 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.

365. 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.

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

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

367. Plaintiffs incorporate by reference all preceding allegations.

368. 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.

369. 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.

370. 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.

371. 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.

372. 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.

373. 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.

374. 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.

375. 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.

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

377. 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.

378. 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.

379. 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.

380. 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 damages in an amount sufficient to deter such conduct, to be determined according to proof at trial.

COUNT VI
Unjust Enrichment / Restitution
(On behalf of Plaintiffs and Class Members)

381. Plaintiffs incorporate by reference all preceding allegations.

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

383. 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.

384. As a result, Defendant have been unjustly enriched at Plaintiffs and Class Members' expense by retaining the benefits derived from the sale of PGT-A testing, despite not providing Plaintiff with fair compensation.

385. Plaintiffs and Class Members conferred a benefit on Defendant in the form of payment for PGT-A testing and associated costs.

386. Defendant knowingly accepted and retained this benefit under circumstances that make it unjust for Defendant to retain the benefit without compensating Plaintiffs and Class members.

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

388. 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.

389. As a result, Defendant should be required to make restitution to Plaintiffs and Class members in an amount according to proof at trial.

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 damages, statutory damages, and restitution as provided by law or equity;

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 and/or available statutory 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.

l. Plaintiffs reserve the right to seek all remedies available at law or equity, including any remedies that may become available upon motion and/or further order of the Court.

DEMAND FOR JURY TRIAL

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

DATED: June 2, 2026

/s/ Karen Barth Menzies

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