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

JODY CRUZ, MICHELLE ROBICHAUX, and BRETT PLOWFIELD, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

PROGENESIS, INC.,

Defendant.

Case No. '24CV1789 JES AHG

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiffs Jody Cruz, Michelle Robichaux, and Brett Plowfield ("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 Progenesis, Inc. ("Progenesis" 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 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 a test 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 these statements. Defendant's misleading statements and omissions as described in detail below are false and misleading to any reasonable consumer because PGT-A testing is unproven, inaccurate, and unreliable.

INTRODUCTION

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

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

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

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

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

8. The IVF process begins with medication taken by women to stimulate the follicles to create several mature eggs for collection. Once the eggs are retrieved from the ovaries, they are then fertilized by the fertility clinic with sperm to create embryos. If the embryos reach the blastocyst stage, they are then ready for implantation to see if they will result in a pregnancy.

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

10. PGT-A testing is marketed by Defendants to people pursuing IVF as increasing the chance of implantation, increasing the likelihood of a successful pregnancy, decreasing the risk of miscarriage, reducing the time and costs of having a healthy baby, and benefiting couples of all ages undergoing IVF, especially those of advanced maternal age which Defendant identifies as above 35. Defendant also markets their PGT-A tests as being 97-98% 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 Defendant.

11. The above representations by Defendant are false and misleading. 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 97 to 98% accurate.

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

13. Insurance companies have independently determined that there is insufficient basis to support the use of PGT-A. Thus, PGT-A testing is rarely covered by insurance and is primarily sold to consumers as an additional out-of-pocket expense in addition to the expensive cost of IVF.

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

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

16. 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.

17. Despite scientific research and studies showing insufficient evidence of efficacy, the use of PGT-A testing 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.

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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.

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

19. Defendant has known for years that there is insufficient evidence of efficacy of PGT-A testing, and that PGT-A testing 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 continued to aggressively promote PGT-A testing to vulnerable and unsuspecting consumers.

20. Defendant has known for years that its PGT-A testing is not 97-98% accurate.

21. Defendant has affirmatively misled patients with false and deceptive marketing and advertising in exchange for the opportunity to reap millions of dollars in profit each year from selling PGT-A testing.

22. 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.

23. 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 Defendants as alleged herein.

PARTIES

24. Plaintiff Jody Cruz is a resident of Ventura, California and received fertility treatment in Santa Monica, California.

25. Plaintiff Michelle Robichaux is a resident of Rhome, Texas and received fertility treatment in Frisco and Southlake, Texas.

26. Plaintiff Brett Plowfield is a resident of Winter Springs, Florida and received fertility treatment in Winter Park, Florida.

27. Defendant is headquartered at 4150 Regents Park Row, Suite 245, La Jolla, California 92037.

28. Defendant lists its principal place of business as 4150 Regents Park Row, Suite 245, La Jolla, California 92037.

29. Defendant indicates that it is a "pioneer in genetic services" that specializes in preimplantation genetic testing and is at the "forefront of advancing reproductive and personalized healthcare."[3]

30. Defendant markets, advertises, and sells PGT-A testing throughout the United States from California where its headquarters and laboratory are located.

JURISDICTION AND VENUE

31. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2)(A), 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 Defendant are citizens of different states.

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

33. The injuries and damages upon which this action is based occurred or arose out of activities engaged in by Defendant within, affecting, and emanating from 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 that are performed in California. Defendant has engaged, and continues to engage, in substantial and continuous business practices California, emanating across the country.

34. 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 in this District.

[3] https://progenesis.com/ (last visited September 19, 2024).

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

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

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

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

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

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

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

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

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

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

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

45. Embryos are fragile and vulnerable to damage from biopsy and the freezing and thawing process necessary for PGT-A testing to be performed.[4]

46. For this reason, experts caution that performing additional biopsies for PGT-A testing, which requires thawing and refreezing the embryo, can cause additional damage to the embryo and negatively affect IVF outcomes.[5] It can also result in a reduced chance of pregnancy.[6]

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

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

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

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

[5] *Id.*

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

the chance of embryo attachment ("implantation"); and (c) cryopreservation (freezing) of eggs or embryos.

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

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

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

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

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

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

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

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

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

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

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

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

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

63. In selling PGT-A to consumers, Defendant represents that PGT-A testing is (a) 97-98% accurate; (b) increases the chance of implantation, (c) increases the likelihood of a successful pregnancy, (d) decreases the risk of miscarriage, (e) reduces the time and costs of having a healthy baby, and (f) benefits couples of all ages undergoing IVF, especially those of advanced maternal age which Defendant identifies as above 35.

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

B. History of PGT-A Testing

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

66. In 1996, the hypothesis was first proposed that preimplantation genetic screening ("PGS") that eliminated aneuploid embryos prior to transfer would improve implantation rates of remaining embryos in IVF, increase pregnancy and live birth rates, and reduce miscarriages.[7]

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

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

69. Defendant claims that its Scientific Director, Santiago Munne, has been involved in this field for "over 30 years of experience," which is misleading as it suggests that the technology is a mature, established diagnostic technique. Indeed, as shown below,

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

PGT-A is unproven, lacking in validation, and unable to provide reliably accurate results, but Defendant fails to disclose this to consumers.

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

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

72. This method, described as PGS 1.0, became increasingly popular despite that researchers in 2005 were still unable to demonstrate outcome benefits.[8]

73. 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 obtained after IVF without PGS.[9]

74. 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.[10]

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

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[8] 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.

[9] 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).

[10] *Id*.

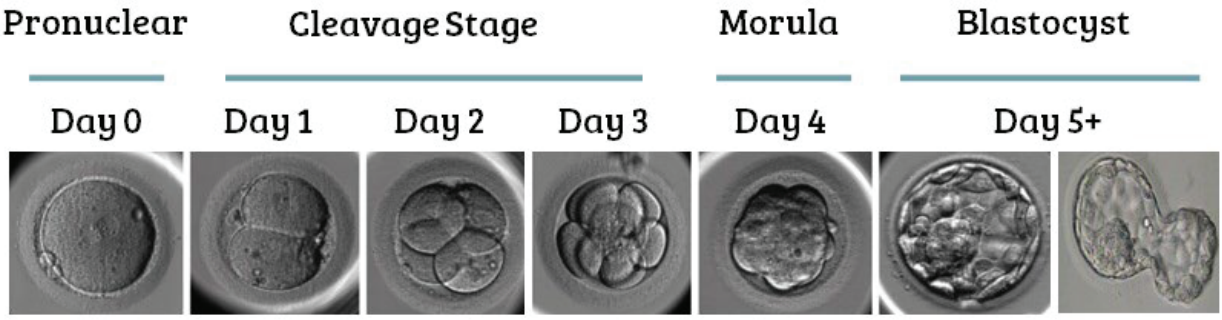
[11] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).

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

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

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

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



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

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

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[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.
[16] Scott, R., et al., *Cleavage-stage biopsy significantly impairs human embryonic implantation potential while blastocyst biopsy does not: a randomized and paired clinical trial*, Fertility and Sterility Vol. 100, No. 3, September 2013 0015-0282.
[17] *Id.*

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

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

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

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

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

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

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

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

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

[18] *Id.*

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

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

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

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

95. In 2015, as laboratories began to question the effectiveness of PGS, Defendant was established as a "pioneer in genetic services" and specializing the preimplantation genetic testing.[19]

96. Soon after Defendant was established, in a study in 2016, researchers tested embryos that had previously been tested and deemed aneuploid.[20] 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.[21]

97. 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%.[22]

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[19] https://progenesis.com/ (last visited September 19, 2024).

[20] 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.

[21] *Id*.

[22] *Id.*

98. 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.[23]

99. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[24]

100. 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.[25]

101. 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.[26] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

102. 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.[27]

103. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[28]

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[23] *Id*.

[24] *Id*.

[25] 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.

[26] 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).

[27] 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.

[28] *Id.*

104. 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.

105. 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.

106. 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.

107. 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."

108. 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.

109. It was founded by Yuri Verlinsky, who created Reproductive Genetic Innovations, Inc. ("RGI"), and Santiago Munne, who is the Scientific Director of Defendant.[29]

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

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

112. Research conducted the following year in 2017, shed even more light on the issues with PGS testing, now known as PGT-A. Specifically, the authors conducted a review of 455 publications related to testing, and concluded that all five assumptions made in 1996 are scientifically unsupportable and the hypotheses of PGS were discredited.[30]

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[29] https://progenesis.com/our-team/ (last visited September 19, 2024).

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

113. 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.[31]

114. 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.

115. 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.

116. 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.[32] 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.[33]

117. 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.[34]

118. 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

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[31] *Id.*

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

[33] *Id.*

[34] 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.

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."[35] 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.

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

120. In 2018, the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART") issued a committee opinion on PGS/PGT-A, concluding that "the value of PGS/PGT-A as a screening test for IVF patients has yet to be determined."[36]

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

122. In 2019, Santiago Munne, Defendant's Scientific Director, conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[37]

123. 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.[38]

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[35] *Id.*

[36] 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.

[37] 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.

[38] *Id.*

124. 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."[39]

125. Defendant, however, continued to promote PGT-A to customers and potential customers, including by making the specific affirmative misrepresentations that PGT-A testing increases the chance of implantation, increases the likelihood of a successful pregnancy, decreases the risk of miscarriage, reduces the time and costs of having a healthy baby, and benefits couples of all ages undergoing IVF, especially those of advanced maternal age which Defendant identifies as above 35.

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

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

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

129. 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,

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

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

[41] *Id*.

but researchers found that among the educational materials examined, none met the CDC standard.[42]

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

131. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[44] The authors of the 2020 study found that PGT-A resulted in a lower chance of live birth in all age groups compared to transfer of embryos without PGT-A.[45]

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

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

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

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

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

[45] *Id*.

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

[47] *Id.*

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

135. The authors of the study concluded:

a. Trophectoderm biopsy may be harmful;[49]

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

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

136. 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.[52]

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[48] *Id*. at 2054.
[49] *Id*. at 2056.
[50] *Id.*
[51] *Id*.
[52] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.

137. Despite all these findings, Defendant continued to advertise, market, and affirmatively 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.

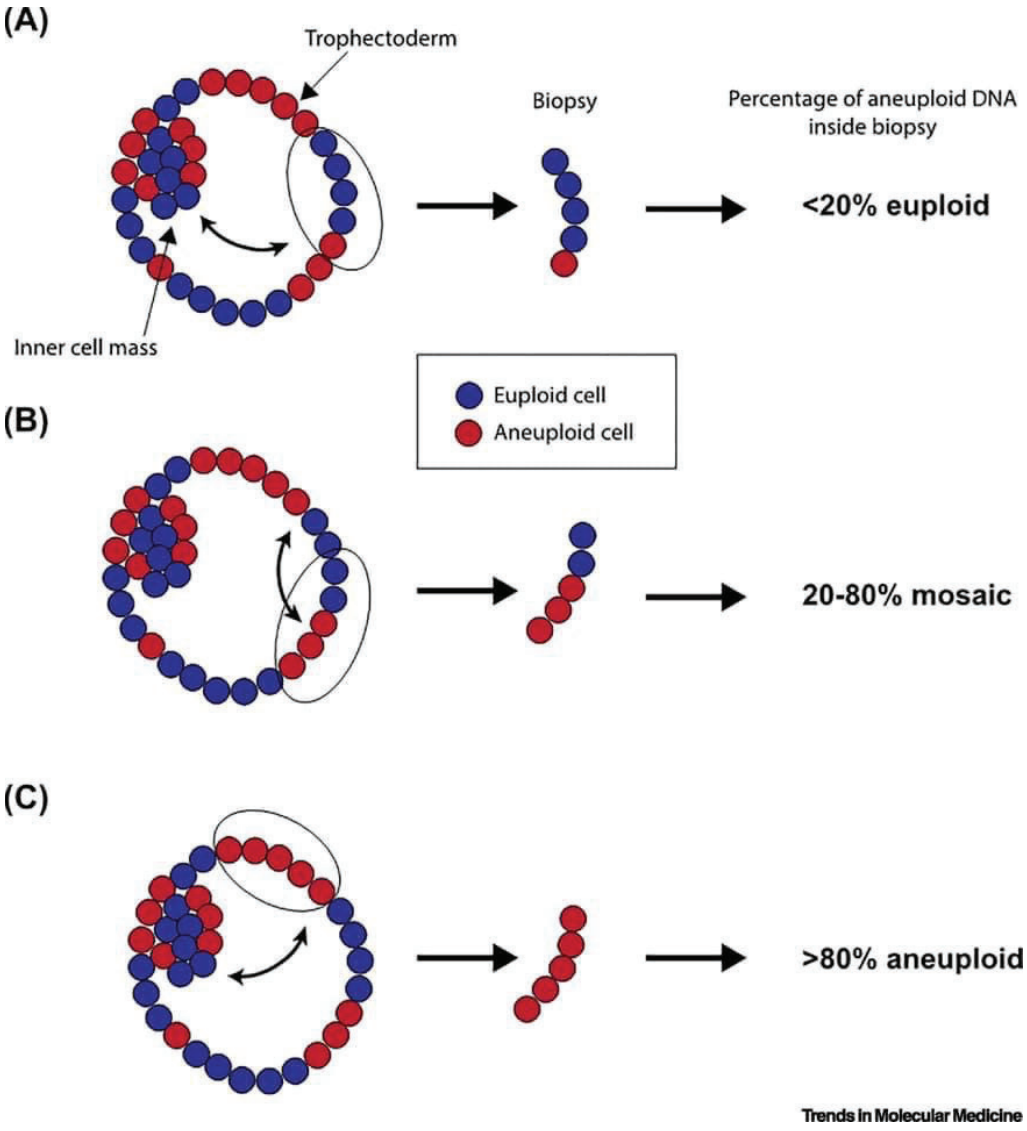
138. Another study in 2021 also reconfirmed a known observation that term placentas, which are what the trophectoderm becomes, are inherently mosaic, characterized by a substantial number of chromosomal abnormalities, even if the fetus is completely euploid.[53]

139. 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.

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

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

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



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

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

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

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

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.[57]

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

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

145. Defendant, however, has 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, Defendant artificially and materially inflates and misrepresents the utility of PGT-A on increasing the chance of implantation, increasing the likelihood of a successful pregnancy, and reducing the time and costs of having a healthy baby.

146. 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;

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

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.[60]

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

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

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

150. 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

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

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

[62] *Id.*

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

that did not have PGT-A testing performed, and a reduction in live birth rates for the group where PGT-A was utilized.[64]

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

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

153. 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.

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

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

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

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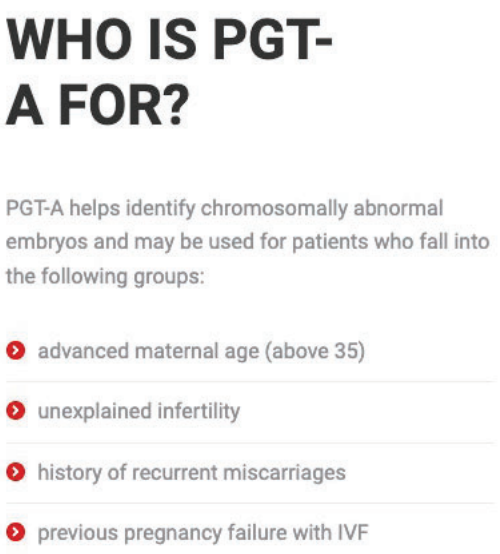
[64] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).

[65] *Id*.

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

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

[68] https://progenesis.com/previda/(last visited September 19, 2024).



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

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

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

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

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

159. Defendant has not conducted such studies and 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.

160. In November 2023, ASRM again stated emphatically and clearly that the "value of preimplantation genetic testing for aneuploidy (PGT-A) as a universal screening

[69] *Id.*

test for all patients undergoing in vitro fertilization (IVF) has not been established." (emphasis added).[70]

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

162. 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.[71]

163. An article published in March of 2024 noted that it was imperative to acknowledge the inherent risks associated with PGT-A, including the potential for misdiagnosis and the risk of embryo damage during biopsy.[72]

164. 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.[73]

165. 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.[74]

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[70] 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.

[71] *Id.*

[72] 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.

[73] *Id.*

[74] 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).

166. For this reason, the HFEA cautions that "Until larger trials have been run and we have more evidence, there's no guarantee that PGT-A can improve your chances of a successful pregnancy."[75]

167. 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.[76]

168. 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.[77]

169. 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".[78]

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[75] *Id.*

[76] *Id.*

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

[78] 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.

170. In addition, a review of 552 pregnancies of mosaic embryo transfers found that only 7 of the 552 pregnancies revealed the mosaicism that had been detected in the PGT-A testing.[79]

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

172. 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.[80]

173. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[81]

174. In May 2024, ASRM and SART issued another committee opinion to replace their prior committee opinion of the same name published in 2018 and discussed above. ASRM and SART reiterated that the value of PGT-A as a universal screening test for all patients undergoing IVF had not been demonstrated.[82]

175. ASRM further noted that two recent, multicenter, randomized control trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[83]

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[79] 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

[80] 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.

[81] 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.

[82] 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.

[83] *Id.*

176. Defendant omitted to include these material facts in their advertising and marketing materials.

177. 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.[84]

178. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[85]

179. Following the May 2024 committee opinion by ASRM and SART, researchers re-examined the PGT-A results of embryos that were determined to be abnormal by PGT-A testing and again found a low rate of concordance between the initial PGT-A testing result and PGT-A testing result of the re-biopsy.[86]

180. 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.[87]

181. 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.

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

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[84] *Id.*

[85] *Id.*

[86] 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.

[87] *Id.*

C. Defendant Has Utilized False and Misleading Statements to Increase Sales of PGT-A

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

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

185. Defendant's false and misleading statements include, without limitation, the following:

a. PGT-A testing is 97 to 98% accurate;

b. PGT-A testing improves pregnancy rates;

c. PGT-A testing improves pregnancy rates by 20%;

d. PGT-A testing benefits every couple, especially individuals of advanced maternal age;

e. PGT-A testing increases the success of IVF;

f. PGT-A testing reduces the number of cycles needed to get pregnant;

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

h. PGT-A testing reduces the chance of miscarriage by three times; and

i. PGT-A increases the chance of a healthy baby.

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

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

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

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

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

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

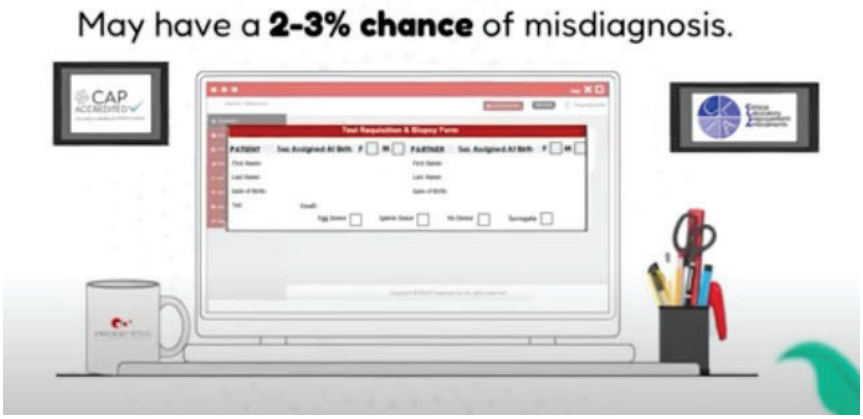
f. By failing to tell consumers that PGT-A results have a substantial degree of inaccuracy; and

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

187. 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 97 to 98% Accurate

188. Defendant repeatedly misrepresents that its PGT-A testing is 97-98% accurate. For example, in a video aimed at customer and potential customers on its website, Defendant states that the test is 97-98% accurate.[88]



189. In addition, Defendant's consent form states: "Although, this assay is highly sensitive and accurate, the known risk of misdiagnosis is reported at 2-3%."

190. Not only does Defendant fail to provide support for this assertion, but it is also belied by the scientific literature which has found concordance rates of reanalysis with

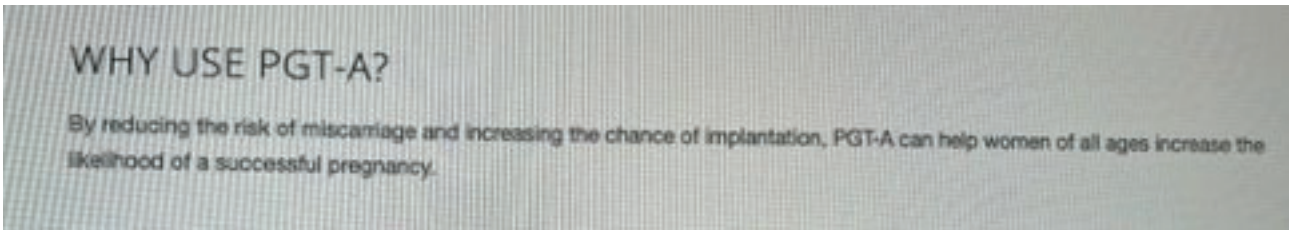
[88] https://progenesis.com/previda/ (last visited September 19, 2024).

original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results and 42.6% for mosaic aneuploid results.[89]

191. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[90]

2. Defendant Falsely States That Its PGT-A Increases The Likelihood Of Successful Pregnancy

192. On its website, Defendant markets and advertises to potential customers that PGT-A can help women of all ages increase the likelihood of a successful pregnancy.[91]



193. Defendant, however, knows this statement is false and misleading to consumers as no valid scientific research has concluded this to be accurate. In fact, research has shown that pregnancy outcomes were similar between conventional IVF and PGT-A.[92]

194. Researchers looking across age groups further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[93]

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[89] 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.

[90] 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.

[91] https://progenesis.com/previda/overview (last visited June 7, 2023).

[92] 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.

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

195. Published scientific results 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.[94]

196. In addition, ASRM has confirmed that PGT-A does not show an increase in successful pregnancy for all ages and has showed no improvement in live birth rates, particularly in women less than 38 years of age.[95]

197. 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."[96]

3. Defendant Falsely States That Its PGT-A Increases the Chance of Implantation

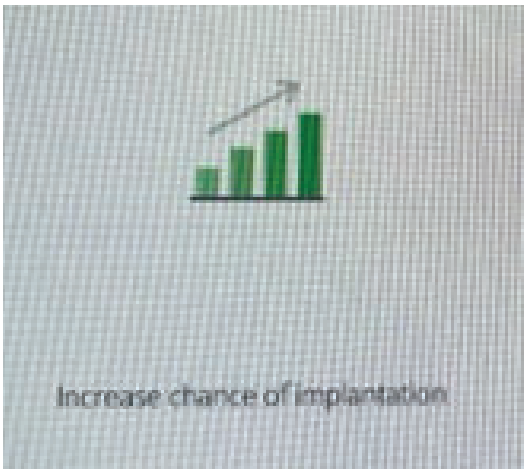
198. On its website, Defendant makes the false and misleading statement that PGT-A can increase the chance of implantation.[97]

[94] 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).

[95] 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.

[96] 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.

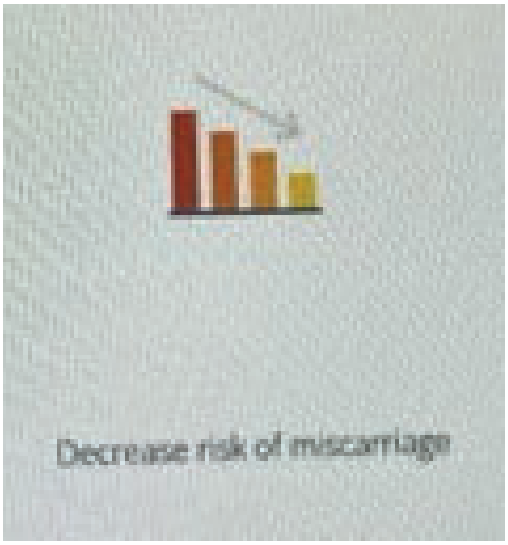
[97] https://progenesis.com/previda/overview (last visited June 7, 2023).



199. Defendant's false and misleading claim contradicts evidence and scientific research which does not show an increase in the chance of implantation with PGT-A. Rather, pregnancy outcomes were similar between conventional IVF and PGT-A.[98]

4. Defendant Falsely States That Its PGT-A Decreases the Risk of Miscarriage

200. Defendant further misleads consumers by stating that its PGT-A decreases the chance of miscarriage.[99]



[98]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.

[99] https://progenesis.com/previda/overview (last visited June 7, 2023).

201. Defendant also misleads consumers in its uniform consent form that PGT-A testing reduces the chance of implantation failure and miscarriage.

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

203. A randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer found that PGT-A did not reduce miscarriage rates.[100]

5. Defendant Falsely States That Its PGT-A Reduces the Time and Costs of Having a Healthy Baby

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

205. 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.

206. On its website, Defendant states that its PGT-A testing can reduce the time and costs of having a healthy baby.[101] [102]

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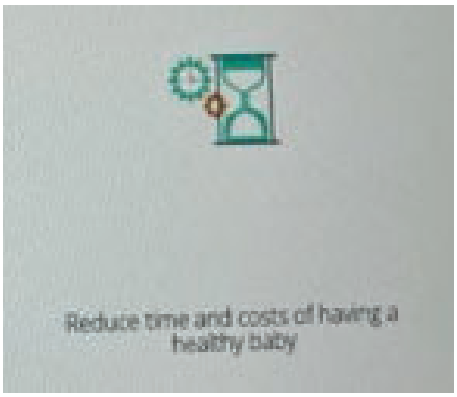
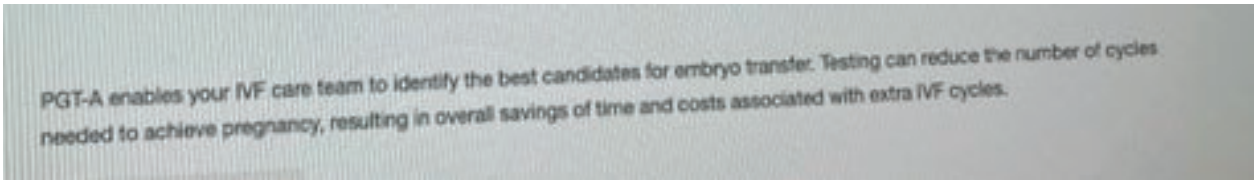
[100] Munne, S., et al., *Preimplantation genetic testing for aneuploidy versus morphology as selection criteria for single frozen-thawed embryo transfer in good-prognosis patients: a multicenter randomized clinical trial*. Fertility and Sterility, Vol. 112, No. 6, December 2019.

[101] https://progenesis.com/previda/overview (last visited June 7, 2023).

[102] *Id*.





207. 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.[103]

208. 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.[104]

209. PGT-A also does not reduce the financial impact of IVF. Therefore, Defendant's statement that PGT-A reduces the cost of having a healthy baby is false and misleading.

210. PGT-A, in fact, increases the financial impact of IVF because it is an add-on expense that is almost never covered by insurance coverage.[105]

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

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

[105] United Healthcare Commercial and Individual Exchange Medical Policy, Preimplantation Genetic Testing and Related Services, effective date June 1, 2024.

6. Defendant Falsely States That Its PGT-A Benefits Couples of All Ages Undergoing IVF, Especially Individuals of Advanced Maternal Age

211. Defendant states on its website that PGT-A is a test for all couples undergoing IVF, which is a false and misleading statement, and material omission of the known scientific knowledge detailed above.[106]

> Previda® is a preimplantation genetic test for aneuploidies (PGT-A) designed for couples undergoing in vitro fertilization (IVF). This test assesses the aneuploidy status of embryos by

212. Defendant's false and misleading claim contradicts evidence and scientific research. Researchers looking across age groups have found no benefit for PGT-A regardless of age on cumulative live-birth rate.[107]

213. In addition, research has concluded that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[108]

214. 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."[109]

215. 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.[110]

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[106] https://progenesis.com/previda/ (last visited September 19, 2024).

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

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

[109] 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.

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

7. Defendant's Misrepresentations In Their Uniform Patient Consent Form Reviewed By All Customers

216. Defendant also provides a uniform Consent Form ("Consent Form") that all customers are asked to sign prior to obtaining their PGT-A testing.

217. The Consent Form states that Previda[111] is a preimplantation genetic screening test used to evaluate the copy number of chromosomes in each embryo.

218. The Consent Form also states that:

> *Decreased Miscarriage Rate*
> *Research indicates that embryos with abnormal chromosome copy number (aneuploidy embryos), may lead to implantation failure, miscarriage, or newborns with syndromes. Transferring embryos that are judged to be normal by PGT-A is expected to reduce the chance of these obstetrical outcomes.*

219. With regard to accuracy, the Consent Form states "Although this assay is highly sensitive and accurate, the known risk of misdiagnosis is reported at 2-3%." In making this statement, Defendant is advertising an accuracy rate of 97-98% to its customers, which is false and misleading.

220. The Consent Form includes false statements and misrepresentations that are viewed by every Class member and on which all Plaintiffs and Class members are intended to rely concerning their decision to purchase PGT-A.

221. These statements in the Consent Form mirror those that are discussed above, and include, for example, that (a) PGT-A is 97-98% accurate, (b) PGT-A increases the chance of implantation, (c) PGT-A increases the likelihood of a successful pregnancy, and (d) PGT-A decreases the risk of miscarriage.

D. Defendant's Additional Material Omissions

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

[111] This is the copyrighted name of Defendant's PGT-A sold to consumers.

223. Further, Defendant omits to inform consumers of the fact that damage to embryos caused by biopsy may be the reason for unsuccessful IVF outcomes following PGT-A.[112] Defendant claims that embryo biopsy and PGT-A are nearly harmless.

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

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

226. A tiny number of trophectoderm cells taken from one location at blastocyst—the method used by PGT-A—cannot reliably reflect whether an entire embryo is aneuploid, or will remain so. Defendant omits this information from its marketing and documents intended to be reviewed by consumers in deciding to purchase PGT-A from Defendant.

227. However, Defendant admits on its website that a test limitation "intended for physicians only" is that PGT-A "is not necessarily a representation of the entire embryo."[113]

TEST LIMITATIONS (INTENDED FOR PHYSICIANS ONLY)

PGT-A tests assess a small number of cells present in the trophectoderm of an embryo. It is not necessarily a representation of the entire embryo.

228. Science shows that the inner cell mass is more effective in self-correcting than the trophectoderm. Chromosomal abnormal embryos may self-correct downstream, which renders earlier biopsy results irrelevant, but Defendant omits this from consumers.

229. The trophectoderm – from which the placenta develops – has been known to contain aneuploid cells even in chromosomally normal pregnancies, which means that the

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

[113] https://progenesis.com/previda/ (last visited September 19, 2024).

fetus, arising from the inner cell mass, remains chromosomally normal. Defendant omits this from consumers.

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

231. 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.

232. 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.

233. 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.[114]

234. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[115]

235. Instead of informing consumers how errors with PGT-A testing can severely impact consumers, Defendant advises consumers against the transfer of embryos determined to be "abnormal" or "mosaic."

236. On its website, Defendant advises that embryos found to be abnormal by its PGT-A testing are high risk.[116]

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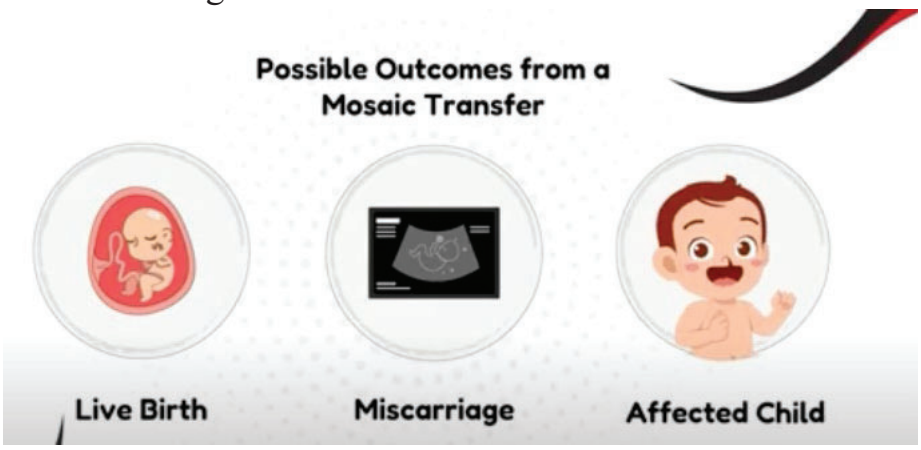
[114] Marin, D., et al., *Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance data.* Prenatal Diagnosis. Vol. 4, Issue 5. Pp. 545-553. April 2021.

[115] 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.

[116] https://progenesis.com/previda/ (last visited September 19, 2024).

237. Defendant also cautions in its video against the transfer of embryos deemed "mosaic" by PGT-A testing.[117]



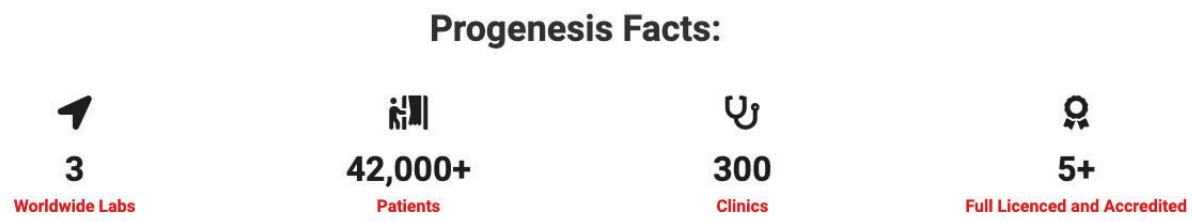
238. Further, Defendant includes the following statements in its Consent Form provided to all consumers: "All your embryos may be found to have a chromosomal or genetic abnormality and thus, may not be suitable for transfer" and "Progenesis does not recommend transfer of embryos diagnosed as mosaic".

[117] https://progenesis.com/previda/ (last visited September 19, 2024).

E. PGT-A Testing has Enriched Defendants

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

240. PGT-A is a lucrative business for Defendant, who states that it is a pioneer in genetic services and assisted more than 42,000 patients.[118]



241. Despite all the scientific literature concerning PGT-A set forth above, Defendant has continued to advertise and market PGT-A to consumers as 97-98% accurate, increasing the chance of implantation, increasing the likelihood of a successful pregnancy, decreasing the risk of miscarriage, reducing the time and costs of having a healthy baby, and benefiting couples of all ages undergoing IVF, especially those of advanced maternal age which Defendant identifies as above 35. Each of these claims are false and misleading, unsupported by scientific evidence, and made while Defendant omitted and withheld material information.

F. Plaintiffs' Experience with Defendant's PGT-A Testing

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

243. 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

[118] https://progenesis.com (last visited September 19, 2024).

and omissions detailed above. Each separate misstatement and omission by Defendant separately and independently gives rise to the causes of action alleged below.

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

1. Plaintiff Jody Cruz's Purchase of PGT-A Testing

245. Plaintiff Cruz purchased PGT-A testing from Defendant in July 2022 based upon Defendant's false and misleading statements, including that PGT-A testing increases the chance of implantation, increases the likelihood of a successful pregnancy, decreases the risk of miscarriage, and reduces the time and costs of having a healthy baby, as well as other misleading statements.

246. Plaintiff Cruz further purchased Defendant's PGT-A testing based upon Defendant's omissions of material information as detailed above.

247. Plaintiff Cruz relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $3,950 plus additional costs for PGT-A testing, which she would not have purchased absent the false and misleading misrepresentations and omissions.

2. Plaintiff Michelle Robichaux's Purchase of PGT-A Testing

248. Plaintiff Robichaux purchased PGT-A testing from Defendant in February 2022 based upon Defendant's false and misleading statements, including that PGT-A testing is 97-98% accurate, increases the chance of implantation, increases the likelihood of a successful pregnancy, decreases the risk of miscarriage, and reduces the time and costs of having a healthy baby, as well as other misleading statements.

249. Plaintiff Robichaux further purchased Defendant's PGT-A testing based upon Defendant's omissions of material information as detailed above.

250. Plaintiff Robichaux relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $5,271 plus additional costs for PGT-A testing, which she would not have purchased absent Defendant's false and misleading misrepresentations and omissions.

3. Plaintiff Brett Plowfield's Purchase of PGT-A Testing

251. Plaintiff Plowfield purchased PGT-A testing from Defendant in June 2024 based upon Defendant's false and misleading statements, including that PGT-A testing is 97-98% accurate, increases the likelihood of a successful pregnancy, and decreases the risk of miscarriage, as well as other misleading statements.

252. Plaintiff Plowfield further purchased Defendant's PGT-A testing based upon Defendant's omissions of material information as detailed above.

253. Plaintiff Plowfield relied upon Defendant's false and misleading misrepresentations and omissions and paid approximately $5,500 plus additional costs for PGT-A testing including the biopsy, which she would not have purchased absent Defendant's false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

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

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

256. In addition, Plaintiff Robichaux brings this lawsuit on behalf of a class of all persons in the State of Texas who purchased PGT-A testing from Defendant (the "Texas Class").

257. In addition, Plaintiff Plowfield brings this lawsuit on behalf of a class of all persons in the State of Florida who purchased PGT-A testing from Defendant (the "Florida Class").

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

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

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

261. Numerosity. Each defined Class defined is so numerous that the joinder of all Class member 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.

262. Defendant represents on their website that they are a pioneer in genetic services and assisted more than 42,000 patients throughout the country.[119]

263. Common Questions Exist and 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. Such questions in common include but are not limited to:

a. Whether Defendant made misstatements and omissions to Class members regarding PGT-A testing;

b. Whether a reasonable consumer would consider the misstatements and omissions to be material;

c. Whether a reasonable consumer would be misled by Defendant's advertising and marketing regarding PGT-A testing;

[119] https://progenesis.com/last visited September 19, 2024).

d. Whether a reasonable consumer would rely upon the misstatements and omissions regarding PGT-A testing;

e. Whether Defendant had knowledge of their misstatements and omissions;

f. The date of Defendant's knowledge;

g. Whether each of the alleged advertising misstatements described in detail above was false or misleading;

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

i. Whether Plaintiffs and the Class were harmed at the point of sale by Defendant's conduct;

j. Whether Defendant violated express and/or implied promises or warranties concerning the sale of PGT-A testing; and

k. Whether Defendant was unjustly enriched as a result of their conduct.

264. The 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.

265. Typicality. Plaintiffs' claims are typical of the claims of other members of the Class(es) they represent because, among other things, all such claims arise out of the same unlawful course of conduct by Defendant 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.

266. Adequacy of Representation. Plaintiffs will fairly and adequately protect the interests of all Class members. Plaintiffs have no interests that are in conflict with, or antagonistic to, the interests of Class members. Plaintiffs have retained highly competent and experienced class action attorneys to represent their interests and those of the Class members. 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 are determined to diligently discharge those duties.

267. 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.

268. 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.

269. Injunctive Relief. Class certification is also appropriate under Rule 23(b)(2) of the Federal Rules of Civil Procedure because Defendant 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

270. 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 does not apply to Class members residing outside of California for any reason, then Class members residing outside of California assert their claims under the laws of their respective states of residence.

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

271. Plaintiffs incorporate by reference all preceding allegations.

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

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

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

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

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

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

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

279. Because of their reliance on Defendant's misleading statements and omissions concerning Defendant's PGT-A testing, Plaintiff and Class members suffered an

ascertainable loss of money, property, and/or value, and were harmed and suffered actual damages.

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

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

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

283. The gravity of harm resulting from Defendant's unfair conduct outweighs any potential utility. The practice of falsely and deceptively marketing PGT-A as accurate and reliable to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

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

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

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

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

287. Plaintiff incorporates by reference all preceding allegations.

288. The UCL prohibits any "unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code

§ 17200 ("UCL"). By engaging in business practices which are also illegal, Defendant violated the UCL.

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

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

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

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

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

293. Plaintiffs incorporate by reference all preceding allegations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

300. Defendant had a duty to accurately disclose the validity of PGT-A, the unsupported claims that they were making to consumers, and to accurately disclose the

current state of science regarding PGT-A. Defendant had a duty not to mislead consumers through its advertising, marketing, and promotion of PGT-A.

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

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

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

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

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

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

COUNT IV
Violations of Texas Deceptive Trade Practices Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq.*
(On behalf of Michelle Robichaux and the Texas Class)

307. Plaintiffs incorporate by reference all preceding allegations.

308. Plaintiff Robichaux brings this count individually and on behalf of the Texas Class.

309. Plaintiff is a "consumer" within the meaning of Tex. Bus. & Com. Code Ann. § 17.45.

310. Defendant is engaged in "trade" and "commerce" within the meaning of Tex. Bus. & Com. Code Ann. § 17.45 as it markets, promotes, and sells PGT-A for sale to consumers within the State of Texas.

311. Defendant used and employed false, misleading, and deceptive acts and practices in the conduct of trade or commerce in violation of Tex. Bus. & Com. Code Ann. § 17.46.

312. Defendant's conduct is substantially injurious to consumers. Such conduct has, and continues to cause, substantial economic damages to consumers who would not have paid for Defendant's PGT-A but for its false, misleading, and deceptive acts and practices as set forth above.

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

314. 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.

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

316. Plaintiff and the Texas Class are entitled to recover damages and other appropriate relief pursuant to Tex. Bus. & Com. Code Ann. §17.50.

COUNT V
Violations of Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq.
(On behalf of Brett Plowfield and the Florida Class)

317. Plaintiffs incorporate by reference all preceding allegations.

318. Plaintiff Plowfield brings this count individually and on behalf of the Florida Class.

319. Plaintiff is a "consumer" within the meaning of Fla. Stat. § 501.203.

320. Defendant is engaged in "trade" and "commerce" within the meaning of Fla. Stat. § 501.203 as it markets, promotes, and sells PGT-A testing for sale to consumers within the State of Florida.

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

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

323. Defendant's acts and practices offend public policy as established by statute. Defendant's acts and practices violate the Federal Trade Commission Act, which provides that "unfair or deceptive acts or practices in or affecting commerce . . . are . . . declared unlawful." 15 U.S.C. Sec. 45(a)(1). An act or practice is "unfair" if it "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

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

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

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

327. 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.

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

329. Plaintiff and the Florida Class are entitled to recover damages and other appropriate relief pursuant to Fla. Stat. § 501.211 and 501.2105.

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

330. Plaintiffs incorporate by reference all preceding allegations.

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

332. Such implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*;

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

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

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

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

336. Plaintiffs and the Class may also establish privity as the intended third-party beneficiaries of agreements between Defendant and the Plaintiffs' and Class Members' IVF clinics. The agreements between Defendant and Plaintiffs' and Class members' IVF clinics to use Defendant's PGT-A testing were designed and intended for the benefit of Plaintiffs and Class members to make decisions about their embryos and fertility treatment. Defendants understood that Plaintiffs and Class members would require that their PGT-A testing provide reliable and accurate information regarding their embryos and Defendant

delivered their PGT-A tests to Plaintiffs and Class members understanding the need to meet these requirements.

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

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

338. Plaintiffs incorporate by reference all preceding allegations.

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

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

341. Such implied warranty of usability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq*.; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq*.; Cal. Com. Code §§ 2314, *et seq*.; Colo. Rev. Stat. §§ 4-2-314, *et seq*.; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq*.; Del. Code Ann. tit. 6, §§ 2-314, *et seq*.; D.C. Code Ann. §§ 28:2-314, *et seq*.; Fla. Stat. Ann. §§ 672.314, *et seq*.; O.C.G.A. §§ 11-2-314, *et seq*.; Haw. Rev. Stat. §§ 490:2-314, *et seq*.; Idaho Code §§ 28-2-314, *et seq*.; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq*.; Ind. Code Ann. §§ 26-1-2-314, *et seq*.; Iowa Code Ann. §§ 554.2314, *et seq*.; Kan. Stat. Ann. §§ 84-2-314, *et seq*.; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq*.; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq*.; Md. Code Ann., Com. Law §§ 2-314, *et seq*.; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq*.; Mich. Comp. Laws Ann. §§ 440.2314, *et seq*.; Minn. Stat. Ann. §§ 336.2-314, *et seq*.; Miss. Code Ann. §§ 75-2-314, *et seq*.; Mo. Rev. Stat. §§ 400.2-314, *et seq*.; Mont. Code Ann. §§ 30-2-314, *et seq*.; Neb. Rev. Stat. §§ 2-314, *et seq*.; Nev. Rev. Stat. §§ 104.2314, *et seq*.; N.H.

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

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

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

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

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

346. Plaintiffs and the Class may also establish privity as the intended third-party beneficiaries of agreements between Defendant and the Plaintiffs' and Class Members' IVF clinics. The agreements between Defendant and Plaintiffs' and Class members' IVF clinics to use Defendant's PGT-A testing were designed and intended for the benefit of Plaintiffs and Class members to make decisions about their embryos and fertility treatment. Defendant understood that Plaintiffs and Class members would require that their PGT-A testing provide reliable and accurate information regarding their embryos and Defendant

delivered their PGT-A tests to Plaintiffs and Class members understanding the need to meet these requirements.

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

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

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

349. Plaintiffs incorporate by reference all preceding allegations.

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

a. PGT-A testing is 97-98% accurate;

b. PGT-A testing increase the chance of implantation;

c. PGT-A testing increases the likelihood of a successful pregnancy;

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

e. PGT-A testing reduces the time and costs of having a healthy baby;

f. PGT-A testing reduces the number of cycles needed to get pregnant; and

g. PGT-A testing benefits couples of all ages doing IVF, especially those of advanced maternal age.

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

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

353. Plaintiffs 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 Defendant.

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

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

356. 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.

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

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

358. Plaintiffs incorporate by reference all preceding allegations.

359. Defendant intentionally suppressed and concealed material facts about its PGT-A 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.

360. 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.

361. 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.

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

363. 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.

364. 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 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.

365. 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.

366. 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

their 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.

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

368. 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.

369. 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.

370. 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.

371. Defendant's fraudulent concealment was malicious, oppressive, deliberate, intended to defraud Plaintiffs and Class members, and intended to enrich Defendant, and has been in reckless disregard of Plaintiffs' and Class members' rights, interests, and well-being. Defendant's conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct, to be determined according to proof at trial.

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

372. Plaintiffs incorporate by reference all preceding allegations.

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

374. 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.

375. As a result, Defendant has been unjustly enriched.

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

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

378. These benefits were the result of Defendant acting in their pecuniary interest at the expense of their consumers.

379. 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 because of their wrongful conduct.

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

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

381. Plaintiffs incorporate by reference all preceding allegations.

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

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

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Class, respectfully requests that the Court:

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

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

c. Grant appropriate equitable relief, including, without limitation, an order requiring Defendant 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 Defendant is financially responsible for notifying the Class members of the pendency of this action;

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

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

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

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

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

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

DEMAND FOR JURY TRIAL

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

Dated: October 7, 2024

Respectfully submitted,

/s/ Sophia M. Rios

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*to be admitted *pro hac vice*

Attorneys for Plaintiffs

JS 44 (Rev. 03/24)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Jody Cruz, Michelle Robichaux, and Brett Plowfield

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

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

Sophia M. Rios, Berger Montague PC, 8241 La Mesa Blvd., Ste A, La Mesa, CA 91942 (619) 489-0300

DEFENDANTS

Progenesis, Inc.

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

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

Attorneys *(If Known)*

'24CV1789 JES AHG

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

TORTS

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

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

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

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

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

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

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

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

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

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

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

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

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Cal. Bus. & Prof. Code §§ 17200

Brief description of cause:
Action for false advertising

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
Oct 7, 2024

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

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____