UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

NOELIA DONAMARIA, individually and on behalf of all others similarly situated, Plaintiff, v. REPRODUCTIVE GENETIC INNOVATIONS, INC., Defendant.	Case No. **CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

Plaintiff Noelia Donamaria ("Plaintiff"), individually and on behalf of all others similarly situated, through her undersigned attorneys, alleges as follows based upon personal knowledge as to her individual allegations, and the investigation of her counsel, against Defendant Reproductive Genetic Innovations, Inc. ("RGI" or "Defendant").

NATURE OF THE ACTION

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

2. Plaintiff files this lawsuit to remedy the unfair and deceptive business practices arising from Defendant's 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 has proven otherwise. Defendant's misleading statements and omissions as described in detail below are false and misleading to any reasonable consumer because science has shown that 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. As a result, 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 every 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, increasing from 368,502 in 2021 to 389,993 in 2022.

6. 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.

7. PGT-A testing is marketed by Defendant to people undergoing IVF as improving pregnancy rates, reducing the chance of miscarriage, increasing the success of IVF, and increasing the chances of a healthy baby. Defendant also markets its PGT-A tests as being 98% accurate. Based on these material representations – and the material omissions that underlay them as detailed below – people undergoing IVF choose to purchase PGT-A testing from Defendant and are charged a biopsy and testing fee.

8. The representations made 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 what is represented by Defendant.

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

10. Insurance companies have independently determined that there is insufficient basis to support the use of PGT-A testing. 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.

11. 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."[1] 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] *See* United Healthcare Commercial and Individual Exchange Medical Policy, Preimplantation Genetic Testing and Related Services, effective date June 1, 2024. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/index/commercial/preimplantation-genetic-testing-06012024.pdf (last visited October 4, 2024).

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

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

14. 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.

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

16. Defendant has known for years that PGT-A testing does not improve pregnancy rates, reduce the chance of miscarriage, increase the success of in vitro fertilization, or increase the chances of a healthy baby. Despite that, Defendant has continued to aggressively promote PGT-A testing to vulnerable and unsuspecting consumers.

17. Defendant has known for years that PGT-A testing is not 98% accurate.[3]

18. Despite this, Defendant has affirmatively misled patients with their 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.

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[2] *See* https://www.aetna.com/cpb/medical/data/300_399/0358.html.

[3] https://rgiscience.com and https://rgiscience.com/pgt-a/ (last visited October 2, 2024). Also Aneuploidy Testing by NGS Analysis Results Report dated October 24, 2022.

19. Plaintiff and Class members have relied upon 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.

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

PARTIES

21. Plaintiff Noelia Donamaria is a resident of Schaumburg, Illinois and received fertility treatment in Oak Brook, Illinois.

22. Defendant is headquartered at 2910 MacArthur Boulevard, Northbrook, Illinois, 60062.

23. Defendant asserts that it is "a pioneer in the field of preimplantation genetic testing" and continues its "tradition of innovation everyday by ensuring the latest technology, customized testing setup, and remaining dedicated to helping patients achieve healthy pregnancy and peace of mind."[4]

24. Defendant advertises, markets, and sells PGT-A testing throughout the United States from Illinois where its headquarters is located.

JURISDICTION AND VENUE

25. 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;

[4] https://rgiscience.com/about-pgt-at-rgi (last visited September 18, 2024).

and (ii) there is an aggregate amount in controversy exceeding $5,000,000, exclusive of interest and costs.

26. This Court has supplemental jurisdiction over any state law claims pursuant to 28 U.S.C. § 1367.

27. 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 Illinois. Defendant regularly conducts and/or solicits business in, engages in other persistent courses of conduct in, and/or derives substantial revenue from services provided to persons in Illinois. Defendant has engaged, and continues to engage, in substantial and continuous business practices in the State of Illinois and across the country.

28. 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 Illinois, including in this District.

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

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

30. 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.

31. 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.

32. 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.

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

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

35. 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.

36. 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.

37. For those who purchase PGT-A testing from Defendant, the removed cells are then sent to Defendant's laboratory for PGT-A testing.

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

39. Embryos are fragile and vulnerable to damage from biopsy and the freezing and thawing process necessary for PGT-A testing to be performed.[5]

40. 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.[6] It can also result in a reduced chance of pregnancy.[7]

41. As a result, if Plaintiff and other Class Members were aware that PGT-A is unproven, and of the true efficacy and accuracy rates of PGT-A, they would forego such testing.

42. 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.

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

44. 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.

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

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

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

47. Defendant's PGT-A testing sold to Plaintiff and Class members has substantial ramifications including the costs that are paid for such testing and related procedures.

48. 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.

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

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

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

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

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

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

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

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

57. In selling PGT-A to consumers, Defendant represents that PGT-A testing is (a) 98% accurate, (b) improves pregnancy rates, (c) reduces the chance of miscarriage, (d) increases the success of IVF, and (e) increases the chances of a healthy baby.

58. These representations are false and misleading, and Plaintiff 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

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

60. In 1989, Yuri Verlinsky established RGI, the first U.S. lab to perform preimplantation genetic testing.[8]

61. 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.[9]

62. In reaching this hypothesis, the authors, including Mr. Verlinsky, made at least five assumptions: (a) most IVF cycles fail because of aneuploid embryos; (b) their elimination prior to

[8] https://www.youtube.com/watch?v=mqdW-I1U19s&t=31s (last visited September 18, 2024).
[9] Verlinsky, Y. and Kuliev, A., *Preimplantation diagnosis of common aneuploidies in infertile couples of advanced maternal age*. Hum. Reprod. 1996, 11:2076-7.

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.

63. 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.

64. Defendant claims that it has "over 30 years of experience" and helped "facilitate the birth of more than 10,000 healthy babies" but this statement is misleading because it suggests that the technology is a mature and established diagnostic technique. In fact, PGT-A is unproven, lacking in validation, and unable to provide reliably accurate results, but Defendant fails to disclose these important facts to consumers.

65. In fact, as of 2024, there have been no randomized, properly structured, non-commercial trials to support Defendant's marketing that PGT-A is accurate and reliable.

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

67. This method, described as PGS 1.0, became increasingly popular despite that researchers in 2005 were still unable to demonstrate outcome benefits.[10]

[10] 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.

68. 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.[11]

69. 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.[12]

70. In 2011, researchers conducted a meta-analysis of randomized control trials on the effect of PGS on the probability of live birth after IVF.[13]

71. 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.[14]

72. 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.[15]

73. The authors cautioned that new approaches in the application of PGS should be carefully evaluated before introduction into clinical practice.[16]

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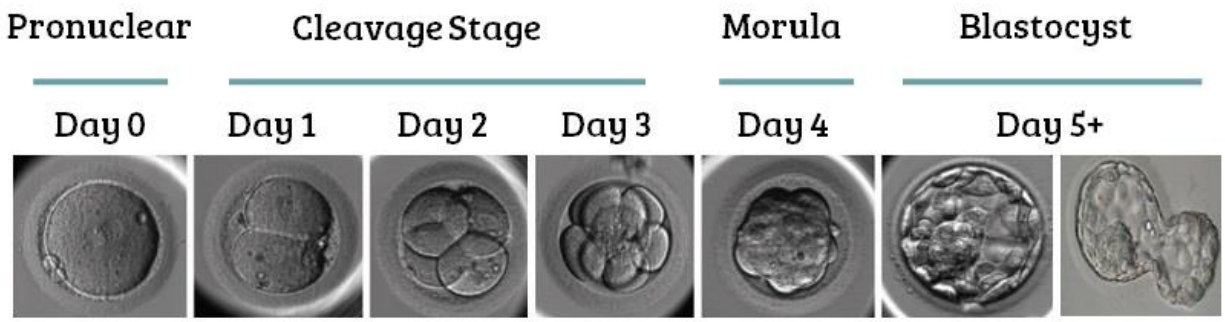
[11] Twisk, M., Mastenbroek, S., et al., *No beneficial effect of preimplantation genetic screening in women of advanced maternal age with a high risk for embryonic aneuploidy*. Human Reproduction, Vol. 23, No. 12 pp. 2813-2817 (2008).
[12] *Id*.
[13] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).
[14] *Id.*
[15] *Id*.
[16] *Id.*

74. In a 2013 paired randomized clinical trial on 116 patients, scientists sought to evaluate if cleavage[17] stage or blastocyst stage embryo biopsy affects reproductive competence.[18]



75. 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.

76. The authors concluded that cleavage-stage biopsy markedly reduced embryonic reproductive potential.[19]

77. The authors 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.[20]

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

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

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[17] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.
[18] 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.
[19] *Id*.
[20] *Id*.

80. 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.

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

82. 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.

83. 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.

84. 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.

85. 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.

86. 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.

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

88. 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.

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

90. In a study in 2016, researchers tested embryos that had previously been tested and deemed aneuploid.[21] 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.[22]

91. 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%.[23]

92. 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.[24]

93. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[25]

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[21] 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.
[22] *Id*.
[23] *Id.*
[24] *Id*.
[25] *Id*.

94. In another 2016 study, researchers analyzed ART 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.[26]

95. 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.[27] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

96. 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.[28]

97. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[29]

98. The proponents of PGS, including Defendant, were aware of the above scientific literature, and 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.

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[26] 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.
[27] 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).
[28] 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.
[29] *Id.*

99. Defendant, however, did not incorporate this knowledge into its marketing and advertising, or inform its customers regarding the state of scientific knowledge and the issues inherent in PGS testing.

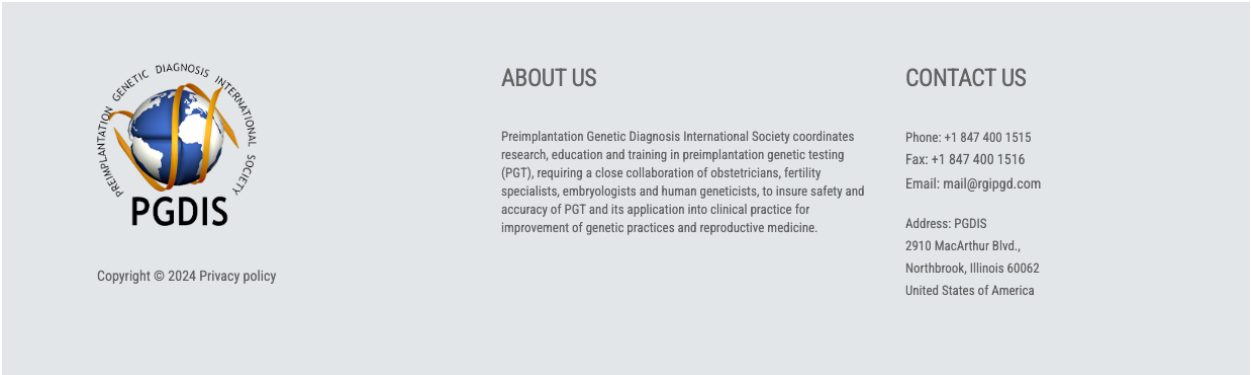
100. Despite the mounting research, the Preimplantation Genetic Diagnosis International Society ("PGDIS") published practice guidance for PGS on its website for the first time in July 2016.

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

102. PGDIS is heavily influenced by and comprised of influential members of the genetic testing industry.

103. PGDIS was founded by Yuri Verlinsky, who created Defendant RGI, and Santiago Munne, who was the Chief Scientific Officer of another genetic testing laboratory, CooperGenomics, at that time.

104. In fact, PGDIS has its headquarters at the same location as the headquarters of Defendant.[30]



[30] https://pgdis.org/ (last visited September 18, 2024).

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

106. 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 of a 2017 study 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.[31]

107. 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.[32]

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

109. 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.

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

110. 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.[33] 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.[34]

111. 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.[35]

112. The author commented, "I have been appalled at the implementation into clinical practice of novel technology without the appropriate underpinning science. Saddest of all is the peddling, not infrequently for substantial pecuniary gain, of these unproven techniques to vulnerable people – older age women, or those with repeated IVF failure or recurrent miscarriage – as miracle treatments that will change their blighted lives."[36] 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.

113. Subsequently, no such study was conducted, or sponsored by Defendant notwithstanding its affiliation with PGDIS.

114. In 2018, the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART") issued a committee opinion on

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[33] Paulson, R., *Preimplantation genetic screening: what is the clinical efficiency?* Fert. Ster. Vo. 108 No. 2, August 2017.
[34] *Id.*
[35] 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.
[36] *Id.*

PGS/PGT-A, concluding that "the value of PGS/PGT-A as a screening test for IVF patients has yet to be determined."[37]

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

116. In 2019, Santiago Munne conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[38]

117. The researchers found that PGT-A did not improve overall pregnancy outcomes, did not improve live birth rates, and did not reduce miscarriage rates.[39]

118. 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."[40]

119. Defendant, however, continued to promote PGT-A to customers and potential customers, including by making the specific affirmative misrepresentations that PGT-A is for "every couple" and that it improves pregnancy rates, reduces the chance of miscarriage, increases the success of IVF, and increases the chances of a healthy baby all while omitting to inform customers concerning the truth about PGT-A.

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

120. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[41]

121. 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.[42]

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

123. The United States Centers for Disease Control and Prevention ("CDC") requires that patient education materials be written at or below a fifth-grade reading level, but researchers found that among the educational materials examined, none met the CDC standard.[43]

124. 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.[44]

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[41] 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).

[42] *Id*.

[43] 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).

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

125. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[45] 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.[46]

126. In November 2021, the preeminent New England Journal of Medicine published the results of a randomized controlled trial to assess whether PGT-A improves the cumulative live-birth rate as compared with conventional IVF.[47]

127. 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."[48]

128. 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."[49]

129. The authors of the study concluded:

a. Trophectoderm biopsy may be harmful;[50]

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

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

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

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

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

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

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

d. Whether PGT-A improves live birth outcomes has yet to be proven.[53]

131. Despite all these findings, Defendant continued to advertise, market, and affirmatively misrepresent the purported benefits of PGT-A in ways that were not supported by science to vulnerable consumers, while at the same time, omitting material information concerning the efficacy of PGT-A.

132. Another study in 2021 also reconfirmed a known observation that term placentas, which are what the trophectoderm becomes, are inherently mosaic, characterized by a substantial number of chromosomal abnormalities, even if the fetus is completely euploid.[54]

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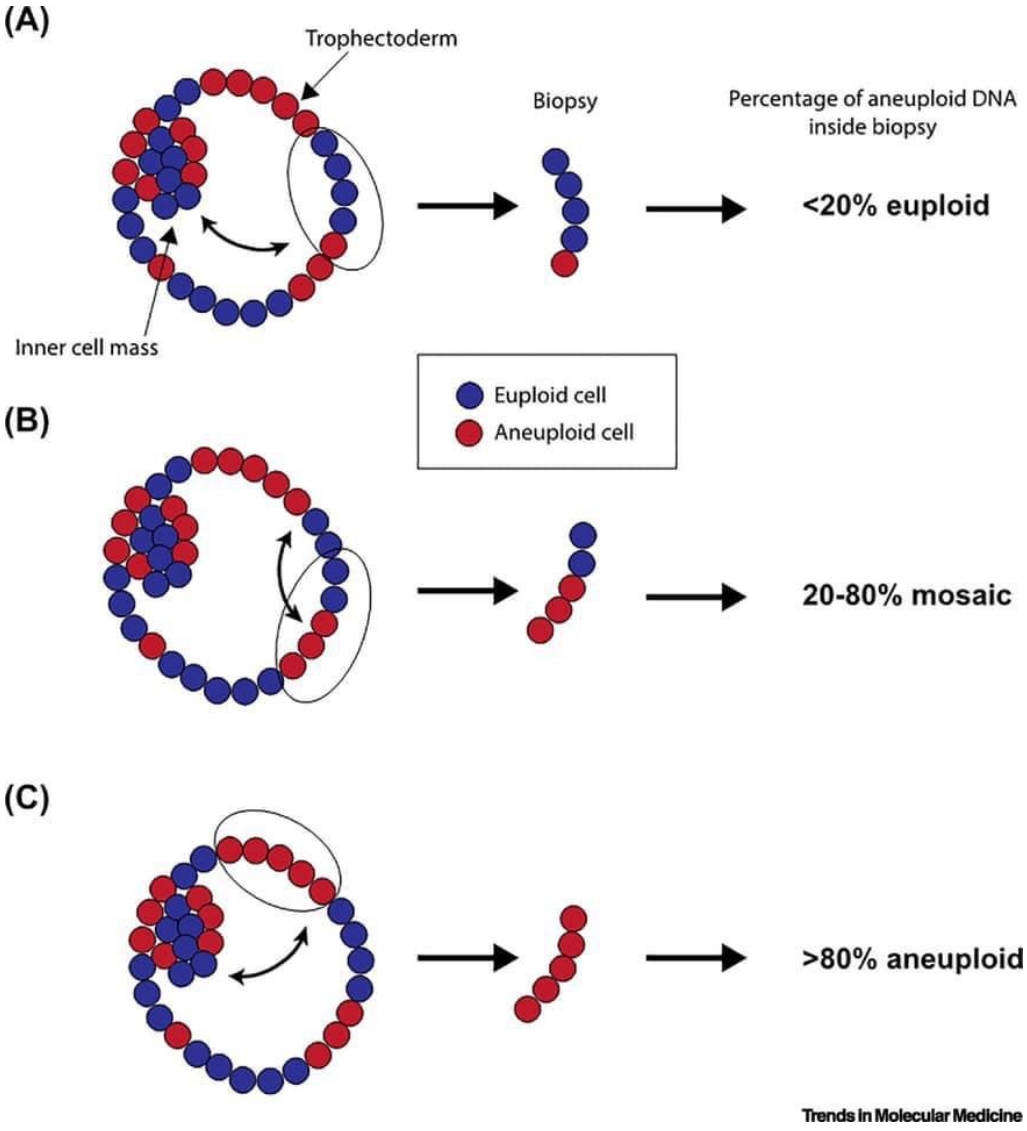
[52] *Id*.
[53] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.
[54] Coorens, et al., *Inherent mosaicism and extensive mutation of human placentas*. Nature 592, 80-85 (2021).

133. 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.

134. For this reason, where the trophectoderm biopsy is taken from may alter the results of PGT-A such that the test does not accurately predict the entire trophectoderm or the inner cell mass, as shown in the following illustration:[55]

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



135. In March 2022, an opinion based upon a review of the recent scientific literature was published in Human Reproduction, urging that PGT-A be restricted to only research protocols.[56]

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

136. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[57] The authors noted that an improvement in cumulative live birth rates with PGT-A utilization, calculated per cycle start, cannot be assumed because simply testing embryos for aneuploidy does not increase the number of euploid embryos, nor does it decrease the number of aneuploid embryos.[58]

137. 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."[59]

138. 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."[60]

139. Defendant, however, continues to advertise and market PGT-A based upon live birth rates per embryo transfer thereby excluding from analysis any IVF cycles without transferrable embryos.[61] As a result, Defendant artificially and materially inflates and misrepresents the utility of PGT-A on improving pregnancy rates, increasing the success of IVF, and increasing the chances of a healthy baby.

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[57] 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.
[58] *Id*.
[59] *Id*.
[60] *Id*.
[61] https://rgiscience.com/patients/ (last visited October 2, 2024).

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

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

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

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

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

e. PGT-A has not been validated;

f. High false positive rates are extremely concerning;

g. Use in particular age groups is uncertain;

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

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

j. Industry self-regulation has shown to be insufficient.[62]

141. As further proof of the concern raised by the authors in Human Genomics regarding the high false positive rates, a re-biopsy and repeat of PGT-A testing on fifty-eight embryos that were originally determined to be chaotically abnormal concluded that twenty-two of the embryos had a euploid result.[63]

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

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

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

[64] *Id.*

143. These findings were further supported a year later when researchers re-biopsied sixty-four embryos reported as "chaotic", which they defined as an embryo with a PGT-A result of more than six chromosome aneuploidies and found concordance of only 67%.[65]

144. Then in April 2023, Dr. Robert Casper determined that when the research data utilized all IVF cycles, and not just the ones where there was a transferrable embryo following PGT-A, there was actually a threefold increase in live birth rates for the group that did not have PGT-A testing performed, and a reduction in live birth rates for the group where PGT-A was utilized.[66]

145. Based upon his findings, Dr. Casper raised concerns that PGT-A caused irreparable harm to patients with diminished ovary reserve who lost their only chance to have a baby from their cycle of IVF.[67]

146. 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 2023 in which it was determined that PGT-A was not currently recommended for routine clinical use.[68]

147. 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.

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[65] Lim, Joshua, et al., Corcordance of Repeat Biopsy Results Among Embryos with 6 or More Aneuploidies. Fertility and Sterility. Vol. 120, Issue 4. October 2023.
[66] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).
[67] *Id*.
[68] Lundin, K., et al., *Good Practice Recommendations on Add-Ons in Reproductive Medicine*. Human Reproduction. Vol, 38, Issue 11. November 2023.

148. In October 2023, it was recognized in the scientific literature that "there is currently insufficient evidence to prove the effectiveness of PGT-A in patients with unexplained recurrent implantation failure."[69]

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

150. For example, Defendant's marketing specifically includes the following:[70]

151. 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.[71]

[69] Lui, Y., et al., *Preimplantation Genetic Testing for Aneuploidy Could Not Improve Cumulative Live Birth Rate Among 705 Couples with Unexplained Recurrent Implantation Failure*, The Application of Clinical Genetics 2024:17 1-13.
[70] https://rgiscience.com/pgt-a/ (last visited September 18, 2024).
[71] *Id.*

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

153. Defendant, however, has not conducted such studies and has continued to falsely and misleadingly market and advertise the purported benefits of PGT-A.

154. In November 2023, ASRM again stated emphatically and clearly that the *"**value of preimplantation genetic testing for aneuploidy (PGT-A) as a universal screening test for all patients undergoing in vitro fertilization (IVF) has not been established***." (emphasis added).[72]

155. Defendant has omitted to include this material fact in their advertising and marketing materials.

156. 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.[73]

157. An article published in March 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.[74]

158. 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

[72] 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.
[73] *Id.*
[74] 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.

United Kingdom's government's independent regulator of fertility treatment and research involving human embryos.[75]

159. 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.[76]

160. For this reason, the HFEA cautions that "[u]ntil 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."[77]

161. 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.[78]

162. In reviewing 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 the 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.

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[75] *Id.*

[76] 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).

[77] *Id.*

[78] *Id.*

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.[79]

163. 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."[80]

164. 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.[81]

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

166. 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.[82]

167. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[83]

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

[80] 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.

[81] 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

[82] 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.

[83] 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.

168. 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.[84]

169. 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.[85]

170. Defendant omitted to include these material facts in their advertising and marketing materials and disclose them to customers and potential customers.

171. 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.[86]

172. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[87]

173. Following the May 2024 committee opinion by ASRM and SART in, researchers re-examined the PGT-A results of embryos that were determined to be abnormal by PGT-A testing

[84] 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.
[85] *Id.*
[86] *Id.*
[87] *Id.*

and again found a low rate of concordance between the initial PGT-A testing result and PGT-A testing result of the re-biopsy.[88]

174. Specifically, 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.[89]

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

176. 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.[90]

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

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

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

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

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[88] 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.

[89] *Id.*

[90] https://rgiscience.com/pgt-a/ (last visited September 18, 2024).

a. PGT-A testing is 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.

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

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

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

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

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

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

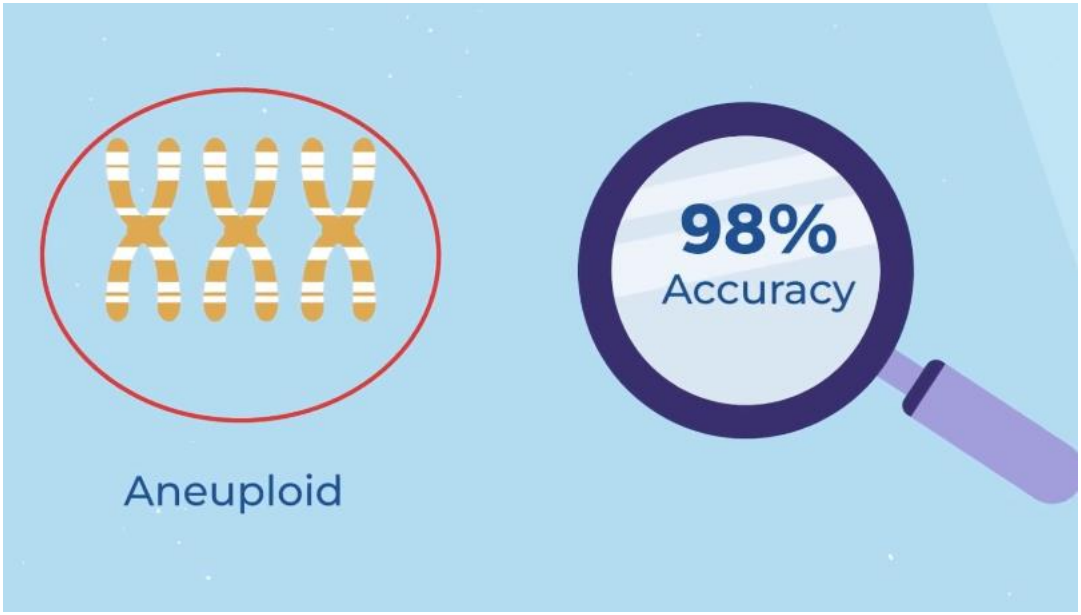
f. By failing to tell consumers that PGT-A results have a substantial degree of inaccuracy; and

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

181. 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 Their PGT-A Testing is 98% Accurate

182. Defendant's videos promoting the sale of PGT-A include the misrepresentation that their PGT-A testing is 98% accurate.



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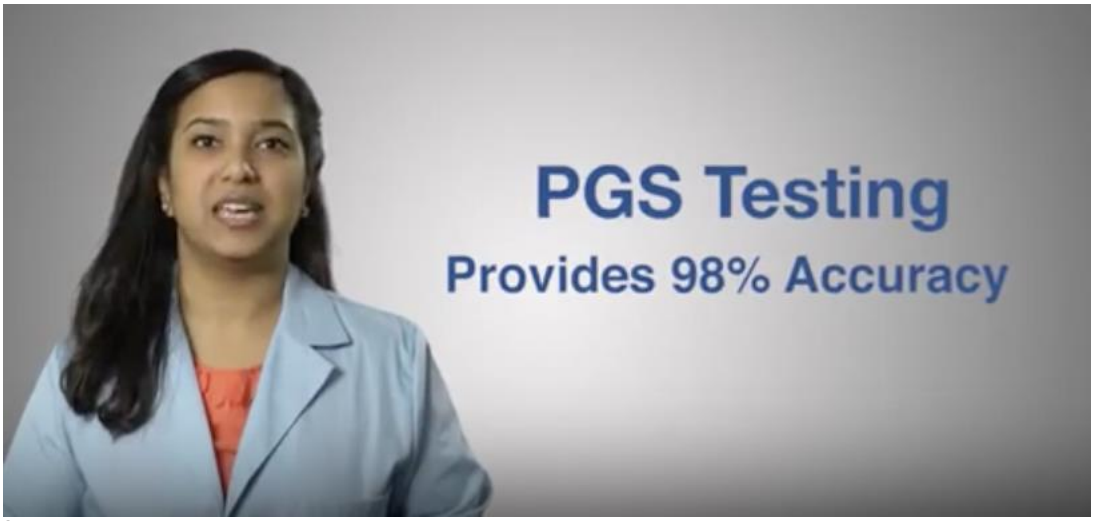
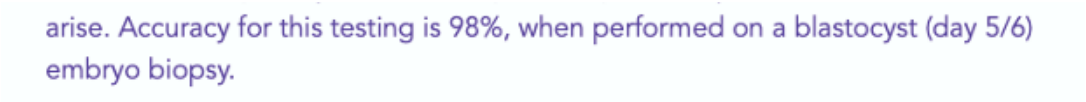


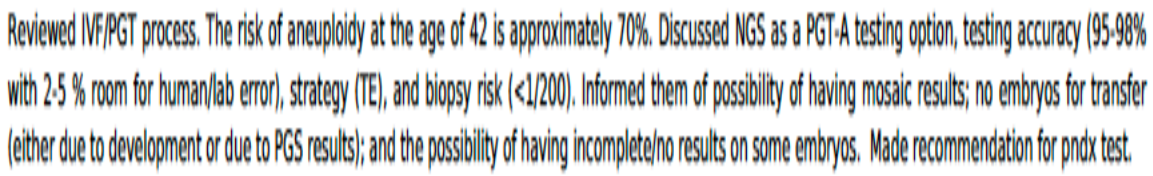
92

[91] https://rgiscience.com/pgt-a/ (last visited September 18, 2024).
[92] https://rgiscience.com/patients/ (last visited September 18, 2024).

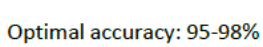
183. This is a common misrepresentation made by Defendant. On the PGT-A page of its website, Defendant also states that its testing is 98% accurate.[93]


arise. Accuracy for this testing is 98%, when performed on a blastocyst (day 5/6) embryo biopsy.

184. However, in their consent notes with Plaintiff, Defendant provides a conflicting accuracy rate of 95-98%.[94]


Reviewed IVF/PGT process. The risk of aneuploidy at the age of 42 is approximately 70%. Discussed NGS as a PGT-A testing option, testing accuracy (95-98% with 2-5 % room for human/lab error), strategy (TE), and biopsy risk (<1/200). Informed them of possibility of having mosaic results; no embryos for transfer (either due to development or due to PGS results); and the possibility of having incomplete/no results on some embryos. Made recommendation for pndx test.

185. Further in their results report, Defendant again provided an accuracy rate of only 95-98%.[95]


Optimal accuracy: 95-98%

186. Whether 98% accurate or 95 to 98% accurate, not only does Defendant fail to provide support for its assertions, but the assertions are belied by the scientific literature which has found concordance rates of reanalysis with original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results and 42.6% for mosaic aneuploid results, and also found that PGT-A is unproven, as described above.[96]

[93] https://rgiscience.com/pgt-a/ (last visited September 18, 2024).
[94] RGI Consult Notes for Plaintiff dated October 7, 2022.
[95] Aneuploidy testing by NGS Analysis results report dated October 24, 2022.
[96] 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.

187. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[97]

2. Defendant Falsely States That Its PGT-A Improves Pregnancy Rates

188. On its website, Defendant markets and advertises that a reason for purchasing PGT-A testing is that it improves pregnancy rates by 20%.[98]

189. Defendant knows this statement is false and misleading to consumers, as well as omits material relevant information, as no valid scientific research has concluded this to be accurate. In fact, ASRM has repeatedly noted that trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[99]

3. Defendant Falsely States That Its PGT-A Benefits Every Couple and Especially Individuals of Advanced Maternal Age

190. Defendant falsely and misleading states on its website that its tests are the only way to determine if an "embryo contains the normal number of chromosomes" and therefore every couple benefits from PGT-A.[100]

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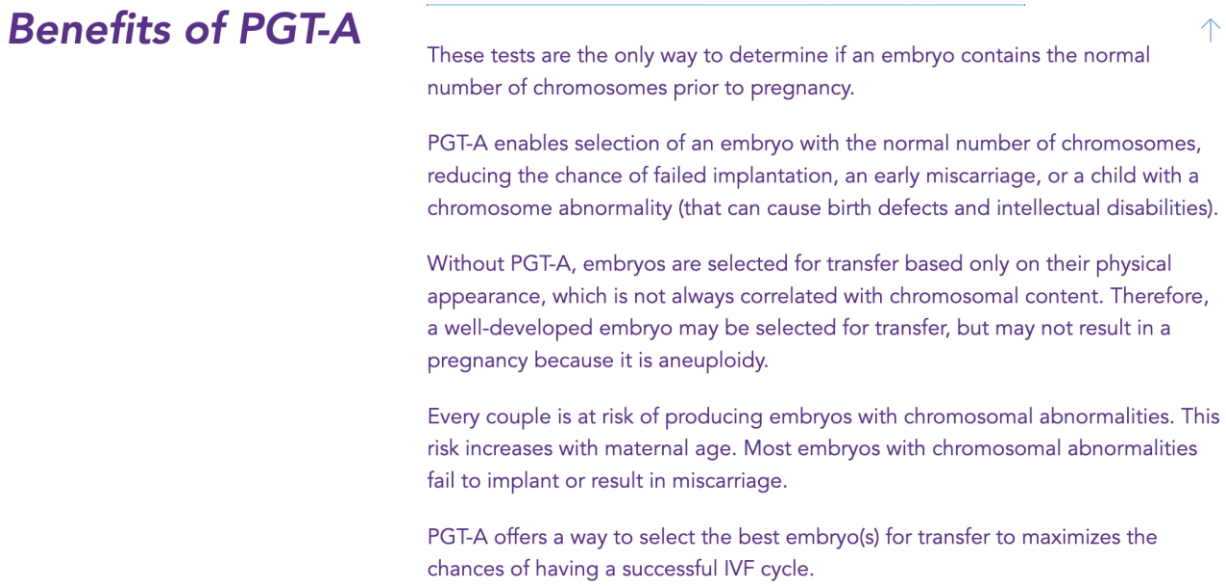
[97] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocriniology (2016) 14:54.
[98] https://rgiscience.com/patients/ (last visited September 18, 2024).
[99] Practice Committee of the American 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.
[100] https://rgiscience.com/pgt-a/ (last visited September 18, 2024).



191. 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.[101]

192. 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."[102]

193. In addition, Defendant also misleads consumers of advanced maternal age by indicating that they are further benefited by purchasing PGT-A.[103]

[101] 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).
[102] 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.
[103] https://rgiscience.com/pgt-a/ (last visited September 18, 2024).

194. Defendant's false and misleading claim is in direct conflict with evidence and scientific research that PGT-A use in older patients may reduce pregnancy and live birth chances.[104]

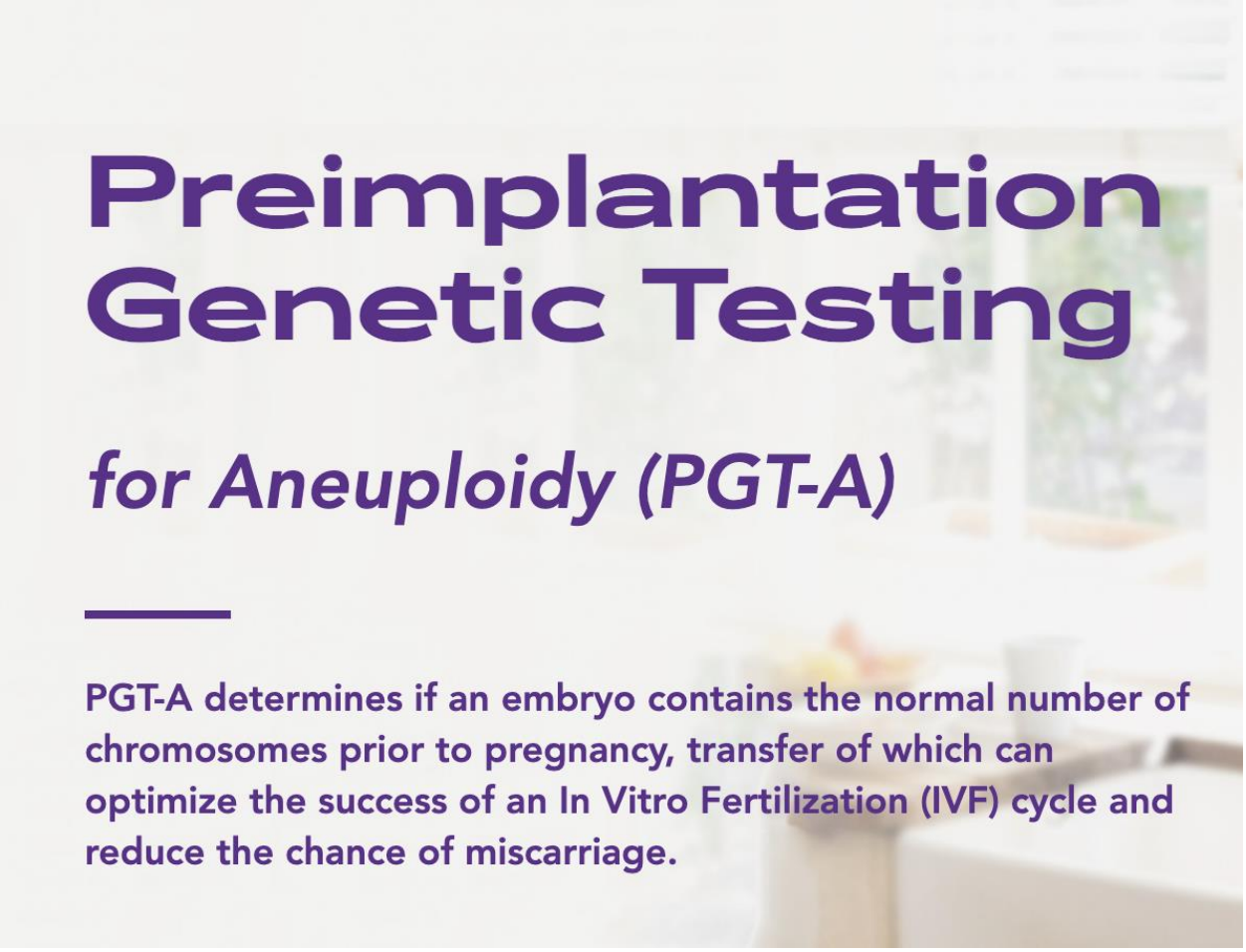
195. Researchers looking across age groups have further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[105]

196. Defendant's false and misleading statements promoting the use of PGT-A are also in direct contradiction to the ASRM which has concluded that PGT-A has showed no improvement in live birth rates, particularly in women less than 38 years of age.[106]

4. Defendant Falsely States That Its PGT-A Increases the Success of IVF

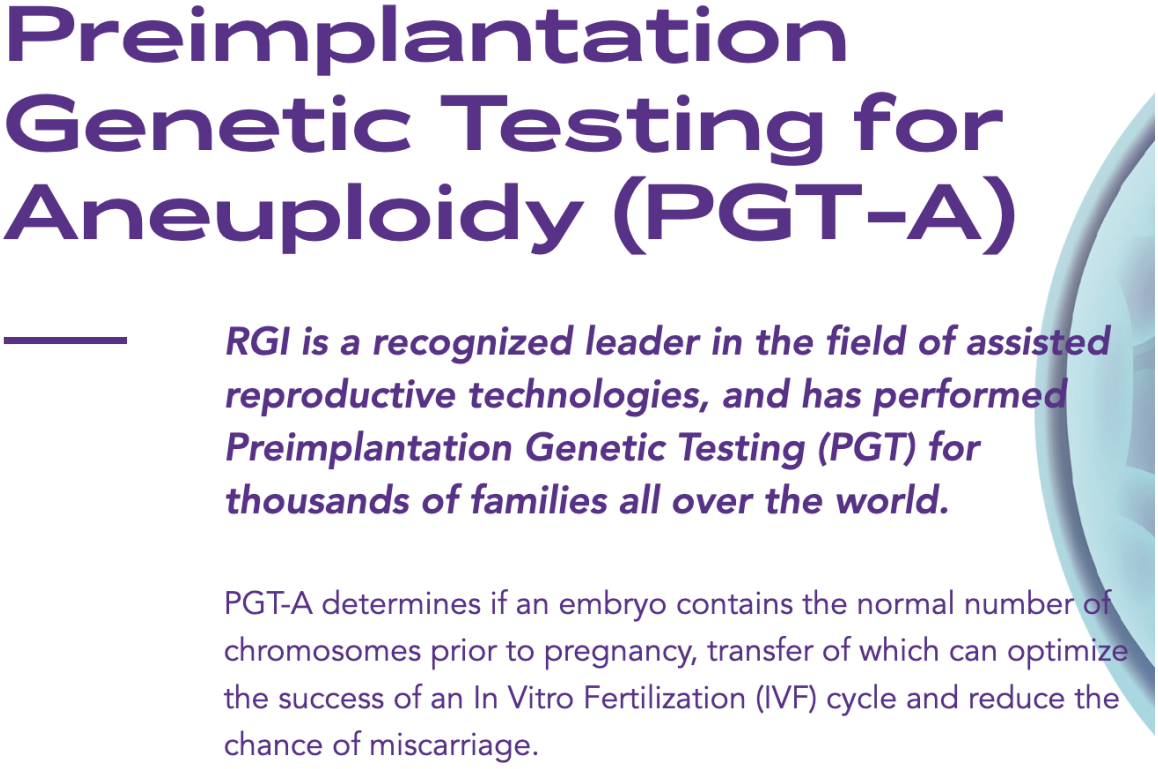
[104] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.
[105] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[106] [106] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

197. Throughout its website, Defendant makes the false and misleading statement that its PGT-A increases the success of IVF.[107]



198. This includes, on the patient page of Defendant's website, the following.[108]

[107] https://rgiscienceprod.wpengine.com/pgt-a/ (last visited September 18, 2024).
[108] https://rgiscience.com/patients/ (last visited September 18, 2024).



199. Defendant knows this statement is false and misleading to consumers as there is no valid and scientifically supportable evidence to show that PGT-A improves the success of IVF.

200. In fact, research as early as 2016 determined that PGT-A decreased live birth rates when compared to IVF without testing.[109]

201. To further support its false and misleading statement that PGT-A increases the success of IVF, Defendant also states that PGT-A reduces the number of cycles needed to get pregnant.[110]

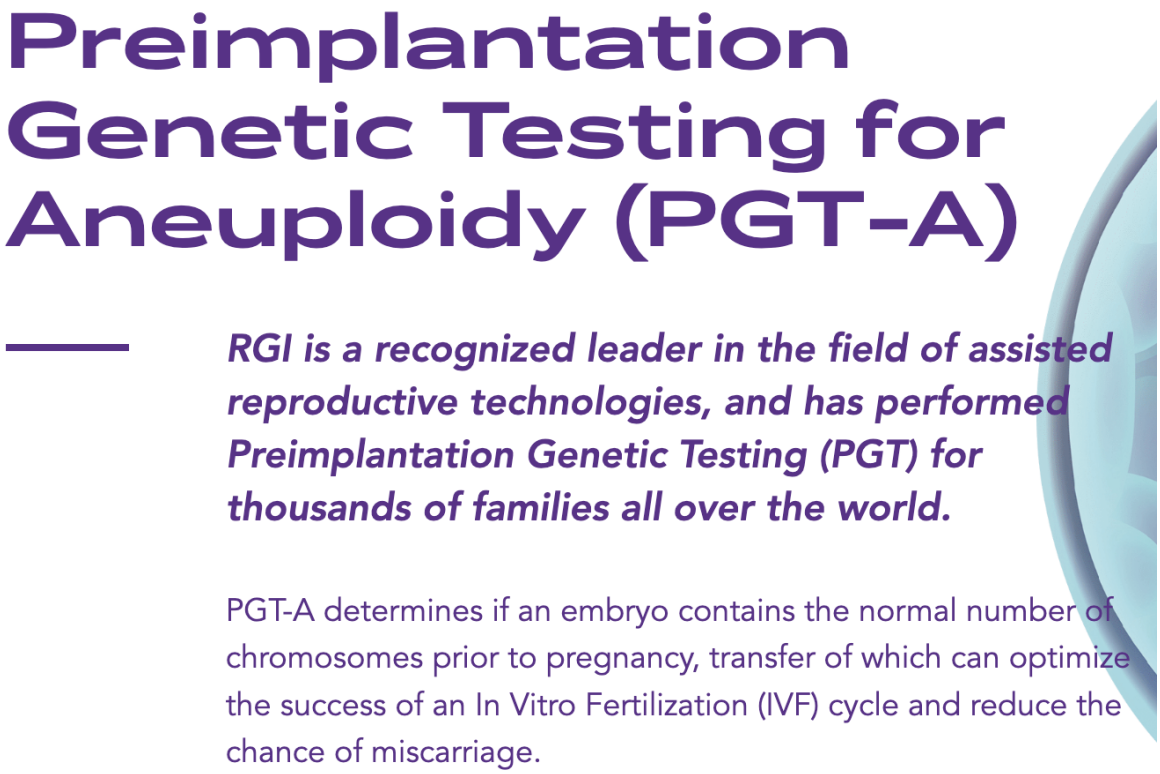
[109] Kushnir, VA, et al., *Effectiveness of in vitro fertilization with preimplantation genetic screening: a reanalysis of Unites States assisted reproductive technology data 2011-2012*. Fert Steril, 2016; 106(1): 75-9.

[110] https://www.youtube.com/watch?v=mqdW-I1U19s (last visited September 18, 2024).

202. 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.[111]

5. Defendant Falsely States That Its PGT-A Decreases the Chance of Miscarriage

203. On its website, Defendant misleads consumers by stating that its PGT-A will decrease the chance of miscarriage.[112]



204. Stunningly, Defendant goes even further by falsely stating that PGT-A will reduce the chance of miscarriage by three times.[113]

[111] Palmer, M., et al., *Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy*. Fertility and Sterility. Vol. 114, Issue 3. September 2020.
[112] https://rgiscience.com/patients/ (last visited September 18, 2024).
[113] https://rgiscience.com/patients/(last visited September 18, 2024)

205. Defendant knows 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, or does so by 3x.

206. 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.[114]

6. Defendant Falsely States That PGT-A Increases the Chance of a Healthy Baby

207. Defendant is aware that they are dealing with vulnerable and unsuspecting consumers who are relying on Defendant to provide accurate and truthful information.

208. Defendant falsely and misleadingly states that PGT-A testing increases the chance of a healthy baby.[115]

[114] 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.
[115] https://rgiscience.com/how-when-is-pgt-performed/(last visited September 18, 2024).

209. 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.[116]

210. In addition, Defendant knows that its statement is false and misleading because research has proven that trophectoderm biopsy cannot predict the inner cell mass[117] and PGT-A testing does not change the embryo.[118]

211. Defendant's statement that PGT-A increases the chance of a healthy baby is false and misleading and omits material information from customers and potential customers.

D. Defendant's Additional Material Omissions

212. 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.

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

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

[117] 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).

[118] Lamb, B., et al., *Pre-implantation genetic testing: decisional factors to accept or decline among in vitro fertilization patient.* Journal of Assisted Reproduction and Genetics, Vol. 35, pp. 1605-1612 (2018) 37-669-672.

214. Defendant omits to inform consumers that damage to embryos caused by biopsy may be the reason for unsuccessful IVF outcomes following PGT-A.[119] Defendant claim that embryo biopsy and PGT-A are nearly harmless.

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

216. 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, but Defendant omits this information from consumers, including in its marketing statements and documents intended to be reviewed by consumers in deciding whether to purchase PGT-A.

217. Science has shown 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.

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

219. 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.

[119] 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).

220. 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.

221. Defendant also omits to inform consumers concerning the false positives and false negatives that occur with PGT-A testing, and the actual rates of false positives and false negatives based on scientific research and study.

222. 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.[120]

223. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[121]

224. Instead of informing consumers of errors with PGT-A testing, Defendant advises customers against the transfer of embryos that Defendant's PGT-A testing determines to be "aneuploid" or "mosaic."[122]

Preimplantation Genetic Testing: Summary of Recommendations

Transfer Recommendations	NONE • None of the tested embryos are predicted to be euploid, therefore, **none** of the tested embryos are recommended for transfer.

[120] 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.
[121] 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.
[122] Aneuploidy testing by NGS Analysis results report dated July 26, 2023.

225. Further, Defendant includes a column on its testing result report provided to the consumer where Defendant clearly states whether an embryo should be transferred based upon the PGT-A testing result of its biopsy.[123]

Preimplantation Genetic Testing: Summary of Results

Embryo #	NGS Results (ngs)	Diagnosis	Embryo Transfer	Comments
3	47, XX, +15	ANEUPLOID	NO	
10	47, XY, +16, del(18)(p11.32; p11.1)	ANEUPLOID	NO	del(18) - 15.4Mb
11	45, XY, -20	ANEUPLOID	NO	
13	43, XX, -6, -16, -17	ANEUPLOID	NO	

E. PGT-A Has Enriched Defendant

226. 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.

227. PGT-A is a lucrative business for Defendant, who has stated that it is a pioneer in PGT-A testing and performed over 16,000 cycles.[124]

> RGI has performed PGT in over 25,000 cycles. This includes an estimated 7,500 cycles for over 646 different monogenic disorders, the largest testing catalog in the world. Our experience in PGT-A (chromosomal abnormalities) is even larger, approximating 16,000 cycles. The remaining cases are made up of PGT-SR and PGT-HLA. At present, RGI recommends PGT-M be accompanied by PGT-A.

228. Despite all of the scientific literature concerning PGT-A set forth above, Defendant has continued to advertise and market PGT-A to consumers as 98% accurate, improving pregnancy rates, reducing the chance of miscarriage, increasing the success of IVF, being a benefit for every couple, especially individuals of advanced maternal age, and increasing the chances of a healthy baby. Each of these claims are false and misleading as described with specificity above,

[123] Aneuploidy Testing by NGS Analysis Results Report dated July 26, 2023.
[124] https://rgiscience.com/published-works/ (last visited September 18, 2024).

unsupported by scientific evidence, and made while Defendant omitted and withheld material information, again, as described above in detail.

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

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

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

F. Plaintiff Noelia Donamaria's Purchase of PGT-A Testing

232. Plaintiff Donamaria purchased PGT-A testing from Defendant in October 2022 and July 2023 based upon Defendant's false and misleading statements, including that PGT-A testing is 98% accurate; improves pregnancy rates, reduces the chance of miscarriage, increases the success of IVF, and increases the chances of a healthy baby.

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

234. Plaintiff Donamaria relied upon Defendant's false and misleading misrepresentations and omissions to her detriment and paid approximately $6,000 plus additional

costs for PGT-A testing, which she would not have purchased absent Defendant's false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

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

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

237. The Nationwide Class and Illinois Class defined above are referred to collectively herein as the "Class."

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

239. Plaintiff reserves the right to modify, change, or amend the Class definitions set forth above based on discovery and further investigation.

240. **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. Plaintiff does not presently know the exact size of each Class but this information is in Defendant's possession and will be obtained in discovery.

241. **Common Questions Exist and Predominate**. This action involves common questions of law and fact to each Class member 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:

- Whether Defendant made misstatements and omissions to Class members regarding PGT-A testing;
- Whether a reasonable consumer would consider the misstatements and omissions to be material;
- Whether a reasonable consumer would be misled by Defendant's advertising and marketing regarding PGT-A testing;
- Whether a reasonable consumer would rely upon the misstatements and omissions regarding PGT-A testing;
- Whether Defendant had knowledge of their misstatements and omissions;
- The date of Defendant's knowledge;
- Whether each of the alleged advertising misstatements described in detail above was false or misleading;
- Whether Defendant's conduct violates each of the laws set forth in the causes of action below;
- Whether Plaintiff and the Class were harmed at the point of sale by Defendant's conduct;
- Whether Defendant violated express and/or implied promises or warranties concerning the sale of PGT-A testing; and
- Whether Defendant was unjustly enriched as a result of their conduct.

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.

242. **Typicality**. Plaintiff's 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. Plaintiff and Class members each

purchased PGT-A based on Defendant' misrepresentations and omissions and they all suffered economic damages as a result.

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

244. **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.

245. Plaintiff is 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.

246. **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

247. All Nationwide Class members have a nexus with Illinois such that Illinois law should apply to all of them. In the alternative, if the Court finds that Illinois law, including the Illinois Consumer Fraud and Deceptive Business Practices Act, does not apply to Class members residing outside of Illinois for any reason, then Class members residing outside of Illinois assert their claims under the laws of their respective states of residence.

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

248. Plaintiff incorporates by reference by reference all preceding allegations.

249. Plaintiff Donamaria brings this count individually and on behalf of the Illinois Class.

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

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

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

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

254. The Consumer Fraud Act prohibits any "unfair or deceptive [business] acts or practices," including the use of any "deception, fraud, false pretense, false promise,

misrepresentation, or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment . . . in the conduct of any trade or commerce." 815 ILCS 505/2.

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

a. PGT-A testing is 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.

256. Defendant's representations were, in fact, false and misleading. Defendant's PGT-A tests were neither reliable nor accurate. Defendant's PGT-A tests were not 98% accurate, did not improve pregnancy rates by 20%, did not benefit every couple, especially those individuals of advanced maternal age, did not increase the success of IVF, did not reduce the number of cycles needed to get pregnant, did not decrease the chance of miscarriage, did not reduce the chance of miscarriage by three times, and did not increase the chance of a healthy baby.

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

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

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

260. In the selling of PGT-A testing within the State, Defendant employs and uses fraud, misrepresentation, concealment, and omission of material facts within the State with the intention that consumers rely upon this fraud, misrepresentation, concealment and omission of fact. 815 Ill. Comp. Stat 505/2Defendant's unfair and deceptive acts and practices directly and proximately caused Plaintiff and the Class actual economic damages in the form of the amounts paid by Plaintiff and each Class member for PGT-A testing and other associated costs.

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

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

263. 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.

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

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

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

COUNT II
Breach of the Implied Warranty of Merchantability
(On behalf of Plaintiff and the Class)

267. Plaintiff incorporates by reference all preceding allegations.

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

269. 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.*

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

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

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

273. Plaintiff and the Class may also establish privity as the intended third-party beneficiaries of agreements between Defendant and the Plaintiff's and Class Members' IVF clinics. The agreements between Defendant and Plaintiff's and Class members' IVF clinics to use

Defendant's PGT-A testing were designed and intended for the benefit of Plaintiff and Class members to make decisions about their embryos and fertility treatment. Defendant understood that Plaintiff 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 Plaintiff and Class members understanding the need to meet these requirements.

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

COUNT III
Breach of the Implied Warranty of Usability
(On behalf of Plaintiff and the Class)

275. Plaintiff incorporates by reference all preceding allegations.

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

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

278. 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.*

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

280. 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.

281. 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.

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

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

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

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

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

286. Plaintiff incorporates by reference all preceding allegations.

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

a. PGT-A testing is 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.

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

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

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

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

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

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

294. As a result of Defendant's false and deceptive conduct, Plaintiff 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 V
Fraud by Concealment
(On behalf of Plaintiff and Class Members)

295. Plaintiff incorporates by reference all preceding allegations.

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

297. Plaintiff 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. Plaintiff and Class members did not and reasonably could not have discovered Defendant's deceit before they purchased PGT-A from Defendant.

298. Had Plaintiff 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.

299. 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.

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

301. Defendant had a duty to disclose the truth about PGT-A because, through Defendant's advertising, marketing, website statements, videos, testing reports, 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.

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

303. 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 Plaintiff and Class members were provided by Defendant, including advertisements, websites, brochures, or promotional materials, indicated the full truth about PGT-A testing as detailed herein.

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

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

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

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

308. Defendant's fraudulent concealment was malicious, oppressive, deliberate, intended to defraud Plaintiff and Class members, and intended to enrich Defendant, and has been in reckless disregard of Plaintiff's 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 VI
Unjust Enrichment
(On behalf of Plaintiff and Class Members)

309. Plaintiff incorporates by reference all preceding allegations.

310. Plaintiff pleads this claim in the alternative to their other claims to the extent there is no adequate remedy at law.

311. Defendant created and implemented a scheme to market for PGT-A testing to increase sales through numerous false and misleading statements and material omissions.

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

313. Defendant received a measurable benefit at the expense of Plaintiff and Class members in the form of payment for PGT-A testing.

314. Defendant accepted monetary benefits from Plaintiff and Class members at the detriment of Plaintiff and Class members.

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

316. 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.

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

Count VII
Breach of Express Warranty
(On behalf of Plaintiff and the Class)

318. Plaintiff incorporates by reference all preceding allegations.

319. By advertising and selling PGT-A testing, Defendant made promises and affirmations of fact about PGT-A testing through its marketing and advertising, consent form and test results.

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

321. Defendant purports, through its marketing and advertising, consent form and test results that its PGT-A testing is accurate and reliable, among other things as detailed here.

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

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

324. 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, 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 Plaintiff 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 Plaintiff 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 Defendant 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 Plaintiff's reasonable attorneys' fees, costs, and expenses, as provided by law;

i. Award Plaintiff 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), Plaintiff requests a trial by jury of all issues triable as of right.

Dated: October 4, 2024

Respectfully submitted,

/s/ Richard Schwartz

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