IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ERIN WEINBERG, E.V., JAIME MAGNETICO-WALSH, ERIN VEDRODE, SARAH URBANSKI, ALLISON URBANSKI, RYAN McELROY, and CHARITY BILLINGS, individually and on behalf of all others similarly situated, Plaintiffs, v. COOPERGENOMICS, INC., COOPERSURGICAL, INC., and THE COOPER COMPANIES, INC., Defendants.	Case No. **CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

Plaintiffs Erin Weinberg, E.V., Jaime Magnetico-Walsh, Erin Vedrode, Sarah Urbanski, Allison Urbanski, Ryan McElroy, and Charity Billings, individually and on behalf of all others similarly situated, through their undersigned attorneys, allege as follows based upon personal knowledge as to the individual allegations pertaining to each of them, and the investigation of their counsel, against Defendants CooperGenomics, Inc., CooperSurgical, Inc., and The Cooper Companies, Inc. (collectively, "Defendants").

NATURE OF THE ACTION

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

2. Plaintiffs file this lawsuit to remedy Defendants' unfair and deceptive business practices arising from Defendants' 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. Defendants' misleading statements and omissions as described in detail below are false and misleading to any reasonable consumer because PGT-A testing is unproven, inaccurate, and unreliable.

INTRODUCTION

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

4. According to the United States Centers for Disease Control ("CDC"), as of 2021, approximately 2.3% of all infants born in the United States 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, going from 368,502 in 2021 to 389,993 in 2022.

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

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

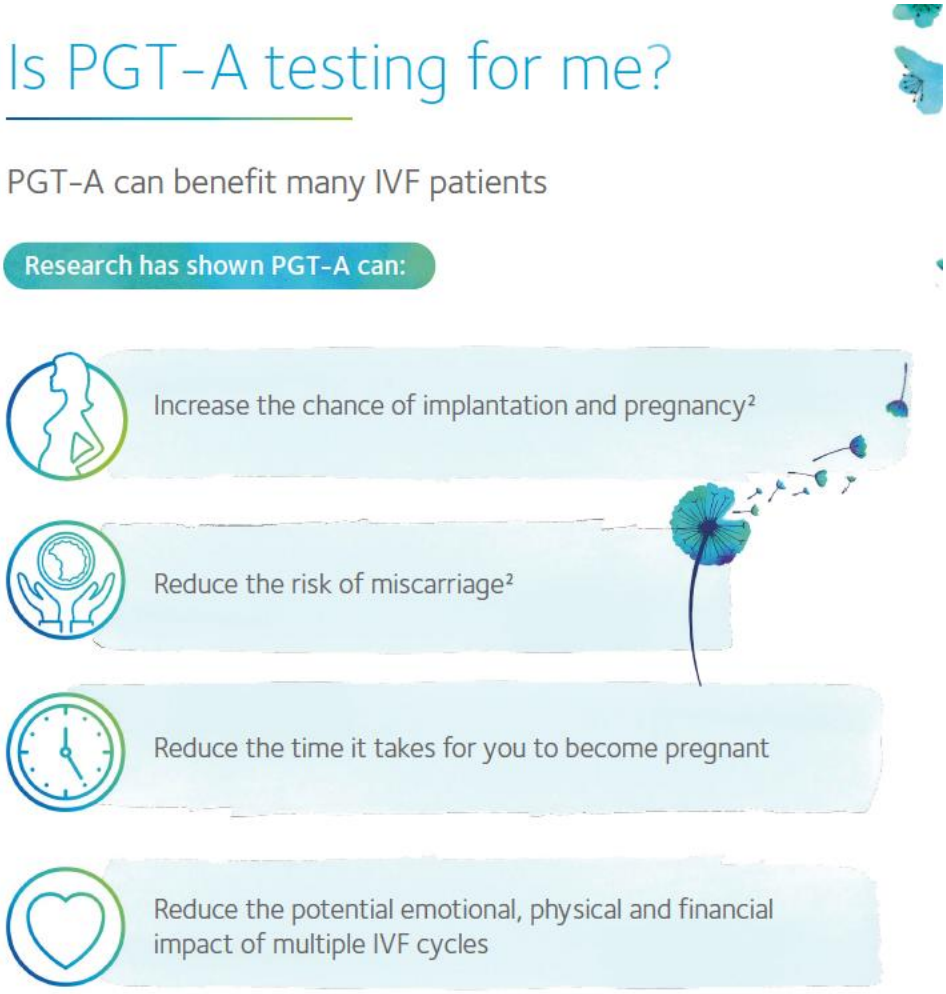
8. The IVF process begins with medication taken by women to stimulate the follicles to create several mature eggs for collection. Once the eggs are retrieved from the ovaries, they are then fertilized by the fertility clinic with sperm to create embryos. If the embryos reach the blastocyst stage, they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

9. PGT-A testing is marketed and sold by Defendants 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 Defendants who perform the PGT-A testing and provide results to the customer and their clinic. The results purport to determine which embryos are "euploid" or best suited for implantation and which embryos are "aneuploid" or abnormal and not suited for implantation.

10. PGT-A testing is marketed by Defendants to people undergoing IVF as increasing the success of IVF, decreasing the chance of miscarriage, leading to a higher chance of pregnancy, reducing the time to pregnancy, increasing live birth rates, increasing the chance of implantation and pregnancy, and reducing the emotional, physical, and financial impact of IVF. Defendants also market their PGT-A tests as being 97% 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 Defendants.

11. For example, Defendants' marketing includes the following affirmative statements:[1]

[1] PGT-A with Cooper Surgical Patient Guide, https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/0cc65fc8-b1b2-4552-98e7-f282e8706d0c (last visited September 9, 2024).



12. The above representations by Defendants are false and misleading. Studies show that when looking at clinic pregnancy, miscarriage, or live-birth rates, there is no difference between cycles utilizing PGT-A and cycles not utilizing PGT-A. Studies also show the accuracy rating for PGT-A is significantly lower than 97%.

13. Defendants' false and misleading statements have severe consequences including ascertainable economic losses in the thousands of dollars suffered by Plaintiffs and Class members.

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

15. 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."[2] 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."

16. Likewise, another large health insurance company, Aetna, states that PGT-A testing is "experimental, investigational, or unproven."[3]

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

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

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

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

20. Defendants have known for years that there is insufficient evidence of efficacy of PGT-A testing, and that it does not increase the success of IVF, decrease the chance of miscarriage, lead to a higher chance of pregnancy, reduce the time to pregnancy, increase live-birth rates across all age groups, increase the chance of implantation and pregnancy, or reduce the emotional, physical, and financial impact of IVF. Despite that, they have continued to aggressively promote PGT-A testing to vulnerable and unsuspecting consumers.

21. Defendants have known for years that PGT-A testing is significantly less than 97% accurate.

22. Despite this, Defendants have 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.

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

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

PARTIES

25. Plaintiff Erin Weinberg is a resident of Branford, Connecticut and received fertility treatment in Trumbull, Connecticut.

26. Plaintiff E.V. is a resident of Colorado and received fertility treatment in Colorado Springs, Colorado. Given the sensitive nature of her claim, Plaintiff Doe is using a pseudonym to protect her privacy. Plaintiff E.V. will seek appropriate permission to proceed under this pseudonym if required by Defendant.

27. Plaintiff Jaime Magnetico-Walsh is a resident of Sarasota, Florida and received fertility treatment in Sarasota, Florida.

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

29. Plaintiff Sarah Urbanski is a resident of Buffalo, New York and received fertility treatment in Syracuse, New York.

30. Plaintiff Allison Urbanski is a resident of Buffalo, New York and received fertility treatment in Syracuse, New York.

31. Ryan McElroy is a resident of Austin, Texas and received fertility treatment in San Francisco, California.

32. Plaintiff Charity Billings is a resident of Winston-Salem, North Carolina and received fertility treatment in Winston-Salem, North Carolina.

33. Defendant The Cooper Companies, Inc. ("TCC") is headquartered at 6101 Bollinger Canyon Road, Suite 500, San Roman, California 94583, and is incorporated in Delaware. TCC promotes itself as a global medical device company that operates through two business segments, CooperVision and CooperSurgical.

34. Defendant CooperSurgical, Inc. ("CooperSurgical") is a wholly owned subsidiary of TCC and is headquartered at 75 Corporate Drive, Trumbull, Connecticut 06611. CooperSurgical is incorporated in Delaware. It manufactures, sells, and promotes products and services focused on fertility and women's health, including genetic testing.

35. TCC is closely involved in the operations of CooperSurgical. TCC employs directly and controls CooperSurgical's top executive, President Holly Sheffield.[4]

36. Defendant CooperGenomics, Inc. ("CooperGenomics") is a CooperSurgical company, which, in turn, is a subsidiary of TCC. CooperGenomics is headquartered at 3 Regents Street, Suite 301, Livingston, New Jersey 07039 and is described by CooperSurgical as the premier provider of genetic testing for every step of the family planning journey. CooperGenomics is located in New Jersey and sells PGT-A testing both to consumers in and outside of New Jersey.

37. Together, Defendants advertise, market, and sell PGT-A testing throughout the United States from New Jersey where CooperGenomics has its office and laboratory.

JURISDICTION AND VENUE

38. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2)(A), because: (i) there are 100 or more Class members; (ii) there is an aggregate amount in controversy exceeding

[4] TCC FY23 Form 10-K (December 8, 2023); Employment Agreement between The Cooper Companies and Holly Sheffield (incorporated and attached to TCC 2023 10-K). Under her employment agreement with TCC, Ms. Sheffield "shall render exclusive, full-time services to [TCC] and its subsidiaries, and exercise such authority and perform such duties as assigned to [Ms. Sheffield] by [TCC's] Chief Executive Officer (the 'CEO')." *Id*. Duties may be modified "at the sole discretion of the CEO" or TCC's Board of Directors. *Id*.

$5,000,000, exclusive of interest and costs; and (iii) Plaintiffs and Defendant are citizens of different states.

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

40. The damages upon which this action is based occurred or arose out of activities engaged in by Defendants within, affecting, and emanating from New Jersey. Defendants regularly conduct and/or solicit business in, engage in other persistent courses of conduct in, and/or derive substantial revenue from services provided to persons that are performed in New Jersey. Defendants have engaged, and continue to engage, in substantial and continuous business practices in New Jersey, emanating across the country.

41. 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 New Jersey, including in this District.

SUBSTANTIVE ALLEGATIONS

A. Relevant Background Concerning IVF and PGT-A Testing

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

43. 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.

44. 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.

45. 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.

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

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

48. 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.

49. 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.

50. For those who purchase PGT-A testing from Defendants, the removed cells are then sent to the CooperGenomics laboratory in Livingston, New Jersey for PGT-A testing.

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

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

[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.

53. 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]

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

55. Defendants are 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.

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

57. 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

[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.

this supply diminishes at a rate of about 1,000 eggs per month as part of the natural aging process.

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

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

60. Defendants' PGT-A testing sold to Plaintiffs and Class members by Defendants has substantial ramifications including the costs that are paid for such testing.

61. Defendants promote PGT-A testing as an add-on to the IVF process, and strongly encourage individuals to purchase PGT-A testing to determine which embryos are suitable to transfer.

62. In selling PGT-A testing to consumers, Defendants represent that their testing is (a) greater than 97% accurate, (b) increases the success rate of IVF, (c) decreases the chance of miscarriage, (d) leads to a higher chance of pregnancy, (e) reduces the time to pregnancy, (f) increases live birth rate across all age groups, (g)

increases the chance of implantation and pregnancy, and (h) reduces the emotional, physical, and financial impact of IVF.

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

B. History of PGT-A Testing and Relevant Scientific Literature

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

65. In 1996, the hypothesis was 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.[8]

66. In reaching this hypothesis, the authors made at least five assumptions: (a) most IVF cycles fail because of aneuploid embryos; (b) their elimination prior to embryo transfer will improve IVF outcomes; (c) a single trophectoderm biopsy at blastocyst stage is representative of the whole trophectoderm ("TE"); (d) TE ploidy

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

reliably represents the inner cell mass ("ICM"); and (e) ploidy does not self-correct downstream from blastocyst stage.

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

68. Defendants claim that "PGT-A has been available since the early 1990's" but this statement is misleading because it suggests that the technology is a mature, established diagnostic technique. In fact, PGT-A is unproven, lacking in validation, and unable to provide reliably accurate results,[9] but Defendants fail to disclose this to consumers.

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

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

[9] https://www.coopergenomics.com/during-ivf/recent-nyu-fertility-center-study-shows-coopergenomics-innovative-pgt-a-leads-to-increased-pregnancy-and-live-birth-rates/ (last visited September 4, 2024).

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

72. In 2008, a randomized clinical trial sought to study one of the above-stated hypotheses: whether the effect of PGS on live births rates differs in women of advanced maternal age with variable risks for embryonic aneuploidy, and weighed these effects against the results obtained after IVF without PGS.[11]

73. The authors of this study concluded that PGS had no clinical benefit over standard IVF in women of advanced maternal age regardless of their risk for embryonic aneuploidy.[12]

74. 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]

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[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.

[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*.

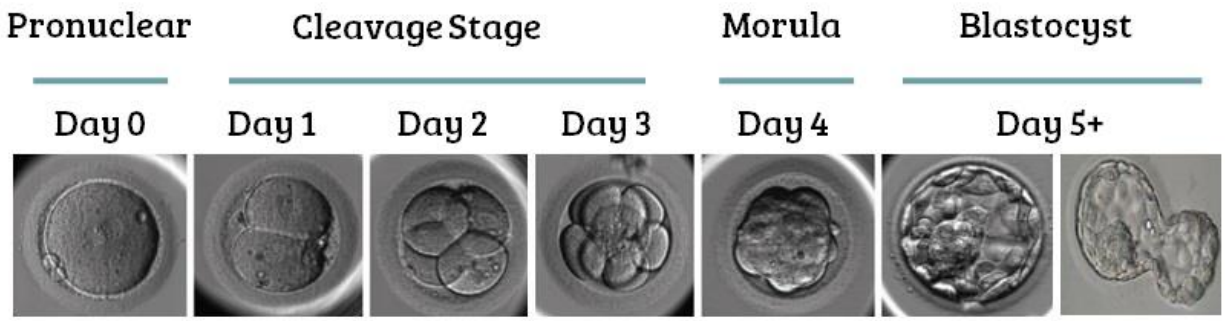
[13] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).

75. 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]

76. 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 underlaid the inefficiency of PGS.[15]

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

78. 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]



[14] Id.
[15] *Id.*
[16] *Id.*
[17] Cleavage stage refers to embryos at day 2-3 while blastocyst stage 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.

79. 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.

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

81. 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]

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

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

84. The approach most widely adopted in practice today to obtain DNA is by performing a biopsy at the blastocyst stage 5 to 6 days after conception.

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

[19] *Id.*
[20] *Id.*

86. 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.

87. 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.

88. 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.

89. 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.

90. 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.

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

92. 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.

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

94. Despite the lack of research and sound scientific basis for the effectiveness of PGS, on August 10, 2015, TCC announced that CooperSurgical had acquired Reprogenetics UK. The press release[21] issued at that time provided, in pertinent part:

> CooperSurgical a leading provider of women's health care and Assisted Reproductive Technology (ART) solutions has acquired Reprogenetics UK of Oxford, United Kingdom. Reprogenetics UK is one of the preeminent genetics laboratories specializing in preimplantation screening (PGS) and preimplantation diagnosis (PGD) in Europe. Reprogenetics UK will maintain its close association with Reprogenetics, its US counterpart, while being folded into CooperSurgical's formidable lineup of ART genetic testing companies which

[21] https://www.coopersurgical.com/wp-content/uploads/ReprogeneticsUKReleaseFinalRev2.pdf (last visited September 4, 2024).

> include Reprogenetics, Genesis Genetics (including its UK division) and newly acquired Recombine.

The press release noted that CooperSurgical since its founding in 1990 had "researched, developed and manufactured a wide range of trusted brands that have advanced the standard of care for families" and that its portfolio of products and services "focuses on women's health, fertility and diagnostics."

95. Robert S. Weiss, the president and chief executive officer of TCC, stated that the acquisition strengthened their industry-leading IVF business by positioning them at the "forefront of the emerging field of genetic testing targeted to improve IVF pregnancy rates while helping to eliminate severe genetic disorders."[22]

96. Approximately eight months later, on April 4, 2016, TCC announced another significant acquisition, in that CooperSurgical had acquired Genesis Genetics, a genetics laboratory specializing in preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD) used during the IVF process.[23]

97. Mr. Weiss again stated that the acquisition strengthened Defendants' IVF business and extended their reach in "the emerging field of genetic testing

[22] *Id.*

[23] https://investor.coopercos.com/static-files/e0d06a89-6137-4af4-8f85-25e0742ad5c5 (last visited September 9, 2024)

targeted to improving IVF pregnancy rates while helping to eliminate severe genetic disorders."[24]

98. About a month and a half later, on May 25, 2016, TCC announced yet another acquisition, namely, that CooperSurgical had acquired Recombine, Inc., another clinical genetic testing company.[25]

99. Mr. Weiss stated that this latest acquisition was "an exceptional fit for CooperSurgical as it adds the premier carrier screening test sold within the IVF marketplace to our existing IVF genetic testing platform."[26]

100. Under the CooperSurgical family, Reprogenetics, Recombine, and Genesis Genetics were united as Defendant CooperGenomics.

101. While Defendants extended their reach in the field of genetic testing, the research community continued to question the underlying assumption that a single trophectoderm biopsy can reliably determine embryo ploidy.

102. In a 2016 study, researchers retested embryos that had previously been tested via PGS testing and deemed aneuploid.[27] Six out of eleven embryos upon

[24] *Id.*
[25] https://investor.coopercos.com/news-releases/news-release-details/cooper-companies-acquires-assets-recombine (last visited September 9, 2024).
[26] *Id.*
[27] 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.

retesting were determined to be either definitively normal or mosaic with the potential to be normal, thus offering a chance for pregnancy if transferred.[28]

103. 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 rate of almost 50%.[29]

104. 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.[30]

105. Based upon their findings, the authors urged careful reassessment of PGS, especially in light of its increasing use.[31]

106. In another 2016 study, researchers analyzed ART used 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.[32]

107. In yet another 2016 study, researchers re-biopsied 37 embryos determined to be "abnormal" and found that 33% of embryos originally reported to

[28] *Id*.
[29] *Id.*
[30] *Id*.
[31] *Id*.
[32] 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.

be "aneuploid" were found to be "euploid" upon repeat assessment.[33] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

108. 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.[34]

109. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[35]

110. By this time, proponents of PGS were aware as a result of the above scientific literature that a problem existed with 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.

111. Defendants, have not, however, incorporated this knowledge into their marketing and advertising, to inform their customers about the issues inherent in PGS testing.

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[33] 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).
[34] 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.
[35] *Id.*

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

113. At the same time, the PGDIS announced a name change from PGS to PGT-A. This change included replacing the term "screening" with the term "testing."

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

115. PGDIS was cofounded by Santiago Munne, who co-founded Reprogenetics and Recombine, and was the Chief Scientific Officer ("CSO") of CooperGenomics in 2016 and 2017.

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

117. Research conducted the following year, in 2017, shed more light on the issues with PGS testing, now known as PGT-A. Specifically, the authors conducted a review of 455 publications related to testing, and concluded that all five

assumptions made in 1996 are scientifically unsupportable and the hypotheses of PGS were discredited.[36]

118. 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.[37]

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

120. 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.

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

121. 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.[38] 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.[39]

122. 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.[40]

123. 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."[41] (Emphasis added.) The author called for registered, randomized, properly structured, non-commercial trials before clinical application

[38] Paulson, R., *Preimplantation genetic screening: what is the clinical efficiency?* Fert. Ster. Vo. 108 No. 2, August 2017.
[39] *Id.*
[40] 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.
[41] *Id.*

of a technology that can lead to such devastating consequences as viable embryo destruction.

124. Subsequently, no such study was conducted, and no such study was sponsored or proposed by Defendants.

125. Instead, Defendants ramped up their marketing efforts to obtain greater market share in the PGT-A industry and continued not to disclose the truth about PGT-A to their vulnerable customers.

126. In 2018, the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART") issued a committee opinion on PGS/PGT-A, concluding that "the value of PGS/PGT-A as a screening test for IVF patients has yet to be determined."[42]

127. Defendants, however, materially omitted to inform their customers and potential customers of this important pronouncement by the leading organization for reproductive medicine.

128. In 2019, Santiago Munne, who previously served as the Chief Scientific Officer for CooperGenomics and is still listed as an expert for Defendants,[43]

[42] 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.
[43] https://fertility.coopersurgical.com/our_experts/santiago-munne-phd/ (last visited September 9, 2024).

conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[44]

129. The researchers found that PGT-A did not improve overall pregnancy outcomes, did not improve live birth rates, and did not reduce miscarriage rates.[45]

130. 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."[46]

131. Defendants, however, continued to promote PGT-A including by making the specific affirmative misrepresentation that PGT-A is for "all IVF patients" and that it may increase the likelihood of achieving a successful pregnancy, increase implantation rates, reduce miscarriage rates, and increase live birth rates, all while omitting to inform customers concerning the truth about PGT-A.

[44] 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.
[45] *Id.*
[46] Orvieto, R., *Preimplantation genetic testing for aneuploidy (PGT-A- finally revealed)*. Journal of Assisted Reproduction and Genetics (2020) 37-669-672.

132. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[47]

133. 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.[48]

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

135. The 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.[49]

136. 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

[47] 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).
[48] *Id*.
[49] 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).

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.[50]

137. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[51] 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.[52]

138. In November 2021, the preeminent New England Journal of Medicine published the results of a randomized controlled trial to assess whether PGT-A improves the cumulative life-birth rate as compared with conventional IVF.[53]

139. 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."[54]

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[50] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: Challenges in clinical practice,* Human Genomics, article 69 (2022).
[51] 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).
[52] Id.
[53] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[54] *Id.*

140. 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."[55]

141. The authors of the study concluded:

a. Trophectoderm biopsy may be harmful;[56]

b. No benefit for PGT-A regardless of age on cumulative live-birth rate;[57] and

c. No benefit for PGT-A for ongoing pregnancy and live birth rates after first frozen embryo transfer.[58]

142. 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

[55] *Id*. at 2054.
[56] *Id*. at 2056.
[57] *Id.*
[58] *Id*.

d. Whether PGT-A improves live birth outcomes has yet to be proven.[59]

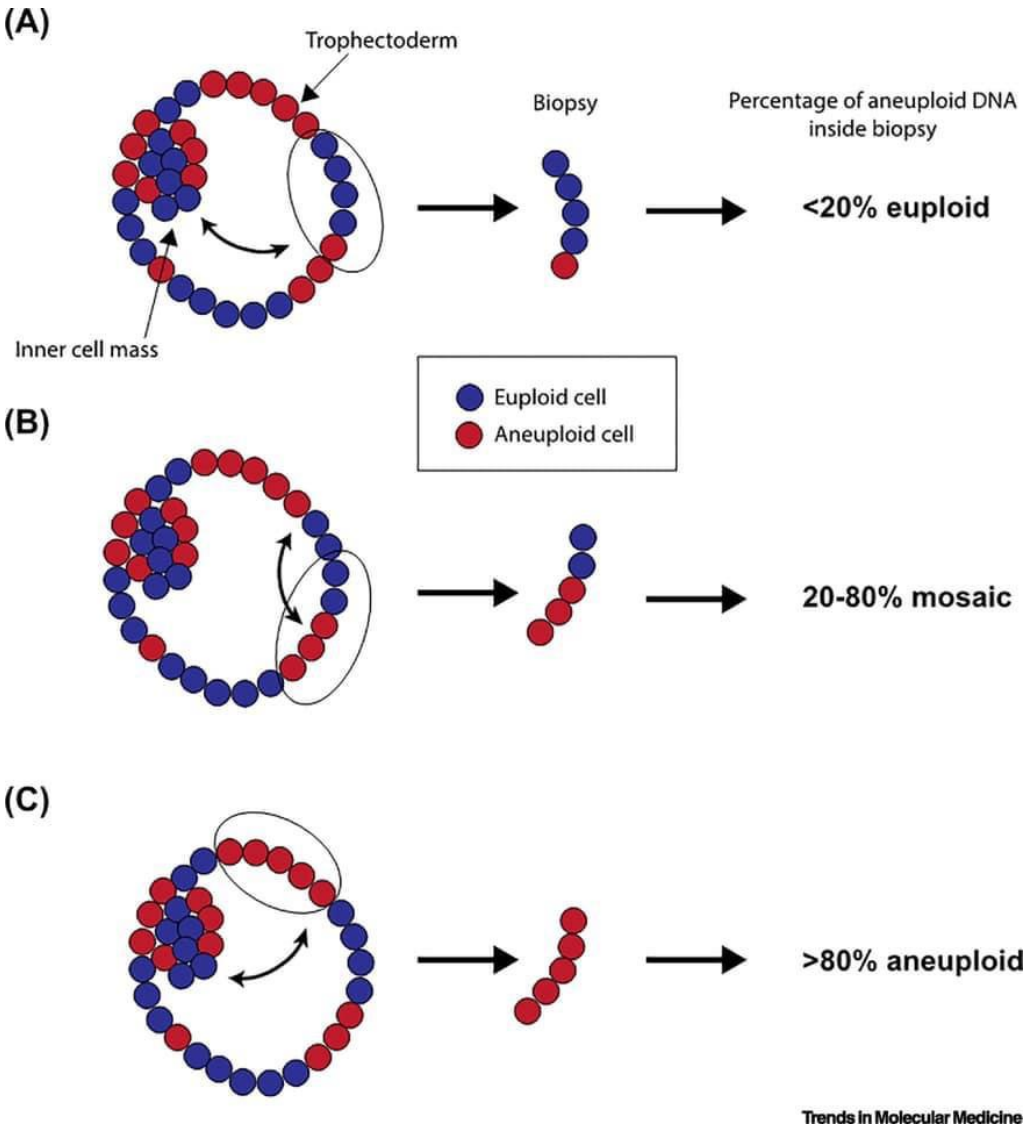
143. Despite all of these findings, Defendants continued to advertise, market, and affirmatively misrepresent non-existent benefits of PGT-A that are not supported by science to vulnerable consumers, while at the same time omitting material information concerning the efficacy of PGT-A.

144. 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.[60]

145. The results of the 2021 study conflict with and further undermine Defendants' 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.

[59] 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.
[60] Coorens, et al., *Inherent mosaicism and extensive mutation of human placentas*. Nature 592, 80-85 (2021).

146. 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:[61]



[61] 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).

147. 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.[62]

148. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[63] 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.[64]

149. 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."[65]

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[62] 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).
[63] 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.
[64] *Id*.
[65] *Id*.

150. 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."[66]

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

152. 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;

[66] *Id.*

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.[67]

153. 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.[68]

154. The researchers noted that the euploid rate suggested that chaotic abnormal results on PGT-A have "reduced predictive value."[69]

155. 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%.[70]

[67] Yang, H., et al. *Preimplantation genetic testing for aneuploidy: challenges in clinical practice*, Human Genomics (2022)16.69.
[68] 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.
[69] *Id.*
[70] 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.

156. 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.[71]

157. 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.[72]

158. The European Society of Human Reproduction and Embryology ("ESHRE") add-ons working group released its good practice recommendations on add-ons in reproductive medicine in September of 2023 in which it was determined that PGT-A was not currently recommended for routine clinical use.[73]

159. 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.

[71] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).
[72] *Id*.
[73] Lundin, K., et al, *Good Practice Recommendations on Add-Ons in Reproductive Medicine*. Human Reproduction. Vol, 38, Issue 11. November 2023.

160. Then in October 2023, it was recognized in the scientific literature that "there is currently insufficient evidence to prove the effectiveness of PGT-A in patients with unexplained recurrent implantation failure."[74]

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

162. 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.[75]

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

[74] 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.
[75] *Id.*

164. But Defendants have not conducted such studies and have continued to falsely and misleadingly market and advertise the purported benefits of PGT-A.

165. 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).[76]

166. Defendants have omitted to include this material fact in their advertising and marketing materials.

167. 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.[77]

168. An article published in March of 2024 noted that it was imperative to acknowledge the inherent risks associated with PGT-A, including the potential for misdiagnosis and the risk of embryo damage during biopsy.[78]

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[76] 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.

[77] *Id.*

[78] 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.

169. In support of the importance of acknowledging the risks associated with PGT-A, the authors cited to the Human Fertilisation & Embryology Authority ("HFEA"), which is the United Kingdom's government's independent regulator of fertility treatment and research involving human embryos.[79]

170. 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.[80]

171. For this reason, the HFEA cautions that "Until larger trials have been run and we have more evidence, there's no guarantee that PGT-A can improve your chances of a successful pregnancy."[81]

172. 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.[82]

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

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[79] Id.
[80] 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).
[81] *Id.*
[82] *Id.*

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

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

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

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

e. Embryos can continue to develop successfully after a few cells have been removed, however, removing cells from the embryo may damage it and prevent it from successfully developing.[83]

174. 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

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

chromosomes revealed that 24.6 percent of those embryos were in fact euploid or "normal".[84]

175. 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.[85]

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

177. 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.[86]

178. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[87]

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[84] 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.

[85] 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

[86] 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.

[87] 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.

179. 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.[88]

180. 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.[89]

181. Defendants have omitted to include this material fact in their advertising and marketing materials.

182. 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.[90]

183. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[91]

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[88] 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.
[89] *Id.*
[90] *Id.*
[91] *Id.*

184. 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 and again found a low rate of concordance between the initial PGT-A testing result and PGT-A testing result of the re-biopsy.[92]

185. 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.[93]

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

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

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

[92] 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.
[93] Id.

188. As a result of Defendants' 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.

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

190. Defendants' false and misleading statements include, without limitation, the following:

a. PGT-A testing is greater than 97% accurate;

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

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

d. PGT-A testing leads to a higher chance of pregnancy;

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

f. PGT-A testing increases live birth rates across all age groups;

g. PGT-A testing increases the chance of implantation; and

h. PGT-A testing reduces the emotional, physical, and financial impacts of IVF.

191. Furthermore, in making the above statements, Defendants have 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.

192. Defendants' 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. Defendants Falsely That State Their PGT-A Testing Is Greater Than 97% Accurate

193. Defendants' advertising statements on their joint website at CooperGenomics.com (a page which prominently displays the name of CooperSurgical at the top of the page), which potential customers read before determining whether to purchase PGT-A, include the following misrepresentations:[94]

> The results of many PGT-A tests ***are typically greater than 97% accurate, and, most importantly, they are***

[94] https://www.coopergenomics.com/during-ivf/how-pgt-a-can-help-reduce-the-chance-of-having-a-miscarriage/ (footnotes omitted) (emphasis added).

> ***actionable!*** After reviewing your PGT-A results with your doctor, the two of you may work together to prioritize embryos for transfer.
>
> Embryos identified as euploid have an increased chance of implantation when compared to mosaic and aneuploid embryos. In addition, pregnancies conceived after the transfer of a euploid embryo have a significantly lower risk of miscarriage when compared to mosaic and aneuploid embryos.

194. These are common misrepresentations made by Defendants. For example, David Chrimes, the Director of Global Genomics Business Development at CooperSurgical, also states that PGT-A has a "very high accuracy of 97 percent (or greater). If the trophectoderm biopsy says it's euploid, this means the inner cell mass is euploid in 97 or greater cases, and the same for aneuploidy. So, it's a very good screening test."

195. Likewise, the "informed consent" form provided by Defendants to their customers, *which every customer reads*, states that "[t]he NGS technology has an accuracy rate of >97% and all findings are reported within this accuracy."

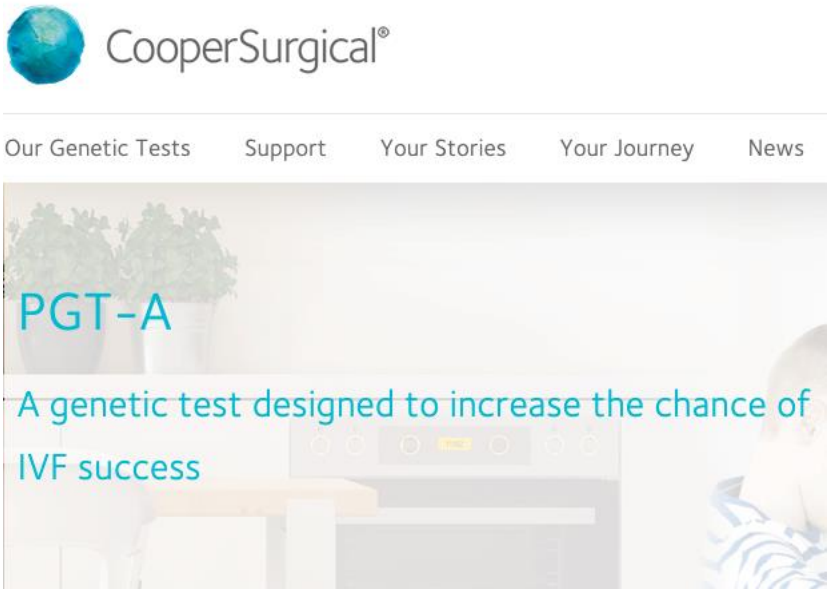
196. Not only do Defendants fail to provide support for this assertion but it is also belied by the scientific literature which has found concordance rates of

reanalysis with original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results and 42.6% for mosaic aneuploid results.[95]

197. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[96]

2. Defendants Falsely State That Their PGT-A Testing Increases The Success of IVF

198. The PGT-A page of Defendants CooperGenomics and CooperSurgical's website boldly proclaims that PGT-A is "designed to increase the chance of IVF success."[97]



[95] 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.
[96] 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.
[97] https://www.coopergenomics.com/pgta/ (last visited September 10, 2024).

199. In addition, promotional videos created by Defendants and contained on their website[98] for viewing by customers and potential customers also indicate that their PGT-A testing will increase IVF success.

200. Defendants know this statement is misleading to consumers as there is no valid and scientifically supportable evidence to show that PGT-A improves the success of IVF.

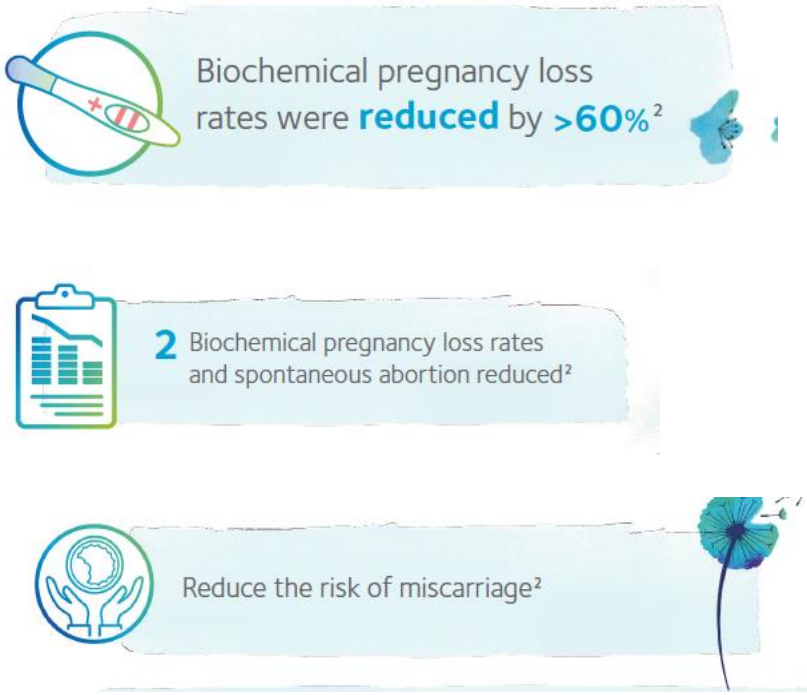
[98] CooperSurgical Fertility Solutions video titled Learn How the PGTai Platform Can Improve Your Chance of IVF Success. https://www.youtube.com/watch?v=IGV0GVHYhSg (last visited September 10, 2024).

201. In fact, research in 2016 had already shown that PGT-A *decreased* live birth rates when compared to IVF without testing.[99]

3. Defendants Falsely State That Their PGT-A Testing Decreases The Chance Of Miscarriage

202. Defendants also claim in their advertising materials that their PGT-A decreases the chance of miscarriage.

203. For example, in Defendants' Patient Guide on PGT-A, Defendants state that PGT-A will decrease the chance of miscarriage.[100]



[99] 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.

[100] PGT-A with Cooper Surgical Patient Guide, https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/0cc65fc8-b1b2-4552-98e7-f282e8706d0c (last visited September 9, 2024).

204. The brochure for clinicians includes the same statements regarding a decrease in the chance of miscarriage.[101]

205. Similar false statements are located on the CooperGenomics website.[102]

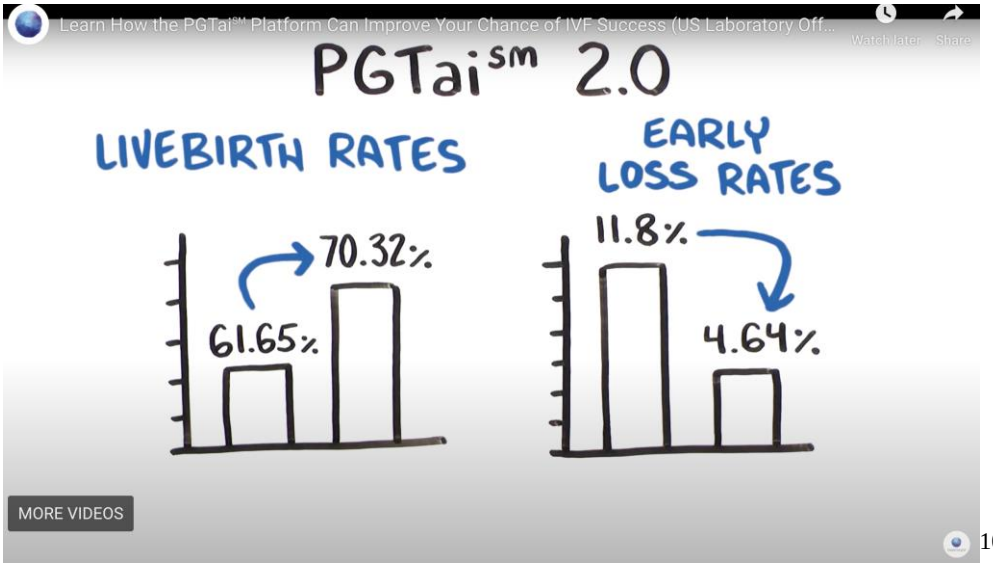
206. Defendants also provide additional patient marketing material and articles that further assert that PGT-A can reduce the chance of miscarriage.[103]

[101] CooperSurgical PGT-A Clinicians Brochure. https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/b6a266c3-4db1-43e5-94ac-295a67f95588 (last visited September 11, 2024).

[102] https://www.coopergenomics.com/preimplantation-genetic-testing-for-aneuploidies/ (last visited September 10, 2024).

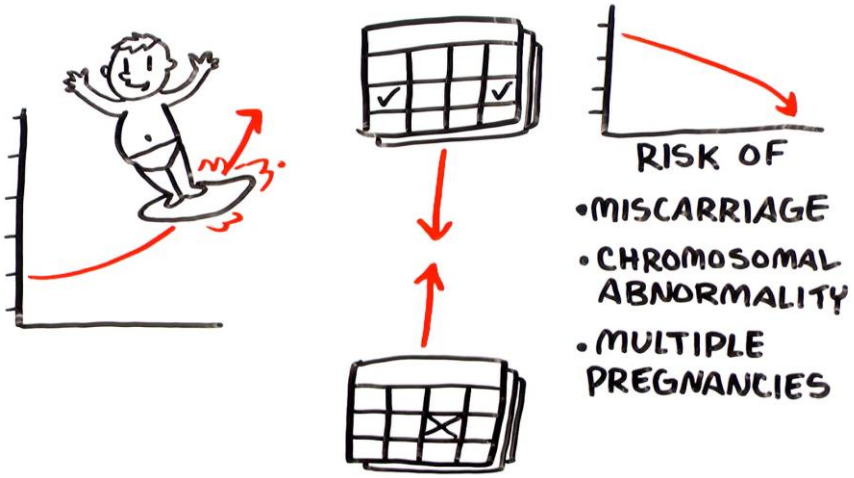
[103] https://www.coopersurgical.com/patient-article/how-pgt-a-can-help-reduce-the-chance-of-having-a-miscarriage/ (last visited September 10, 2024).

207. Defendants also make false statements regarding a reduction in miscarriage rates in their marketing videos.



[104]

[104] CooperSurgical Fertility Solutions video titled Learn How the PGTai Platform Can Improve Your Chance of IVF Success. https://www.youtube.com/watch?v=IGV0GVHYhSg (last visited September 10, 2024).



105

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

209. CooperGenomics own former Chief Scientific Officer, Santiago Munne, and current expert witness for Defendants,[106] conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer and found that PGT-A did not reduce miscarriage rates.[107]

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[105] CooperGenomics video titled How Preimplantation Genetic Screening Works. https://www.youtube.com/watch?v=5VQzPV3V9tE (last visited September 10, 2024).

[106] https://fertility.coopersurgical.com/our_experts/santiago-munne-phd/ (last visited September 9, 2024).

[107] 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.

210. Defendants omit this from their advertising and marketing materials, brochures, and website pages aimed at consumers for the purpose of increasing sales.

4. Defendants Falsely State That Their PGT-A Testing Leads To Higher Chances Of Pregnancy

211. On the CooperGenomics website, Defendants state directly to consumers that PGT-A leads to a higher chance of pregnancy.

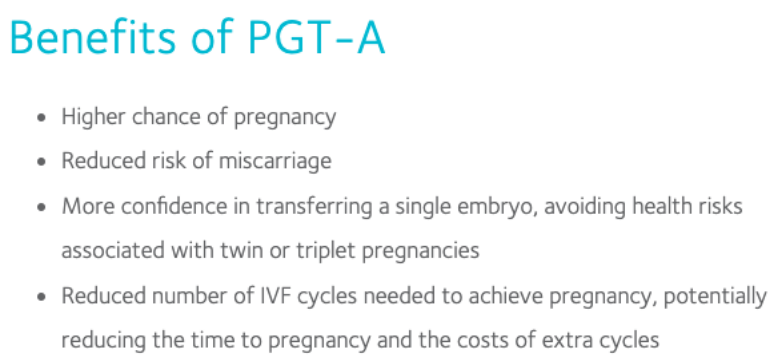
212. No valid scientific research, however, has concluded this to be accurate. In fact, ASRM has repeatedly noted that trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[108]

5. Defendants Falsely State That Their PGT-A Testing Reduces The Time To Pregnancy

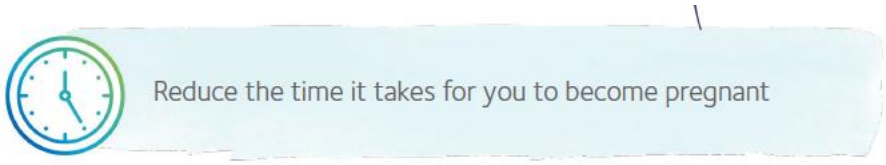
213. Defendants' website also states that PGT-A potentially reduces the time to pregnancy.[109]

[108]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.

[109] https://www.coopergenomics.com/pgta/ (last visited September 10, 2024).



214. Defendants' Patient Guide on PGT-A likewise states that research has shown PGT-A can reduce the time it takes for you to become pregnant.[110]



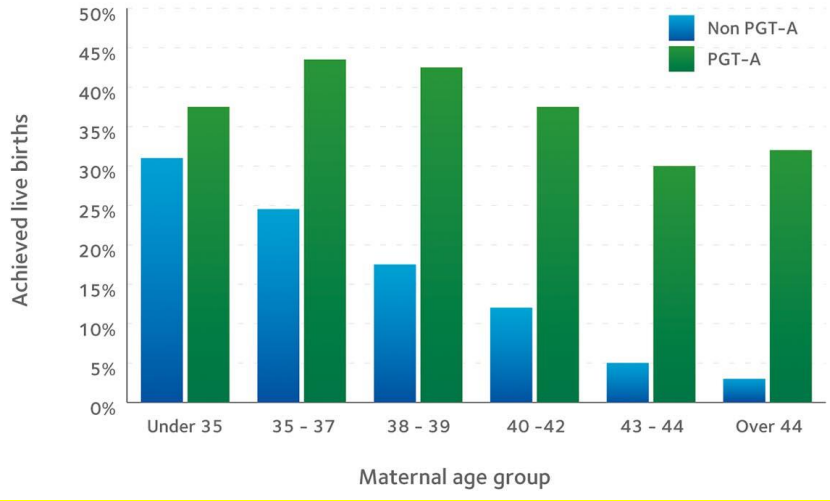
215. In fact, there is no valid scientific research to support this false and misleading statement, and in fact, research shows that utilizing PGT-A does not decrease time to pregnancy.[111]

6. Defendants Falsely State That Their PGT-A Testing Increases Live Birth Rates Across All Age Groups

[110] PGT-A with Cooper Surgical Patient Guide, https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/0cc65fc8-b1b2-4552-98e7-f282e8706d0c (last visited September 9, 2024).

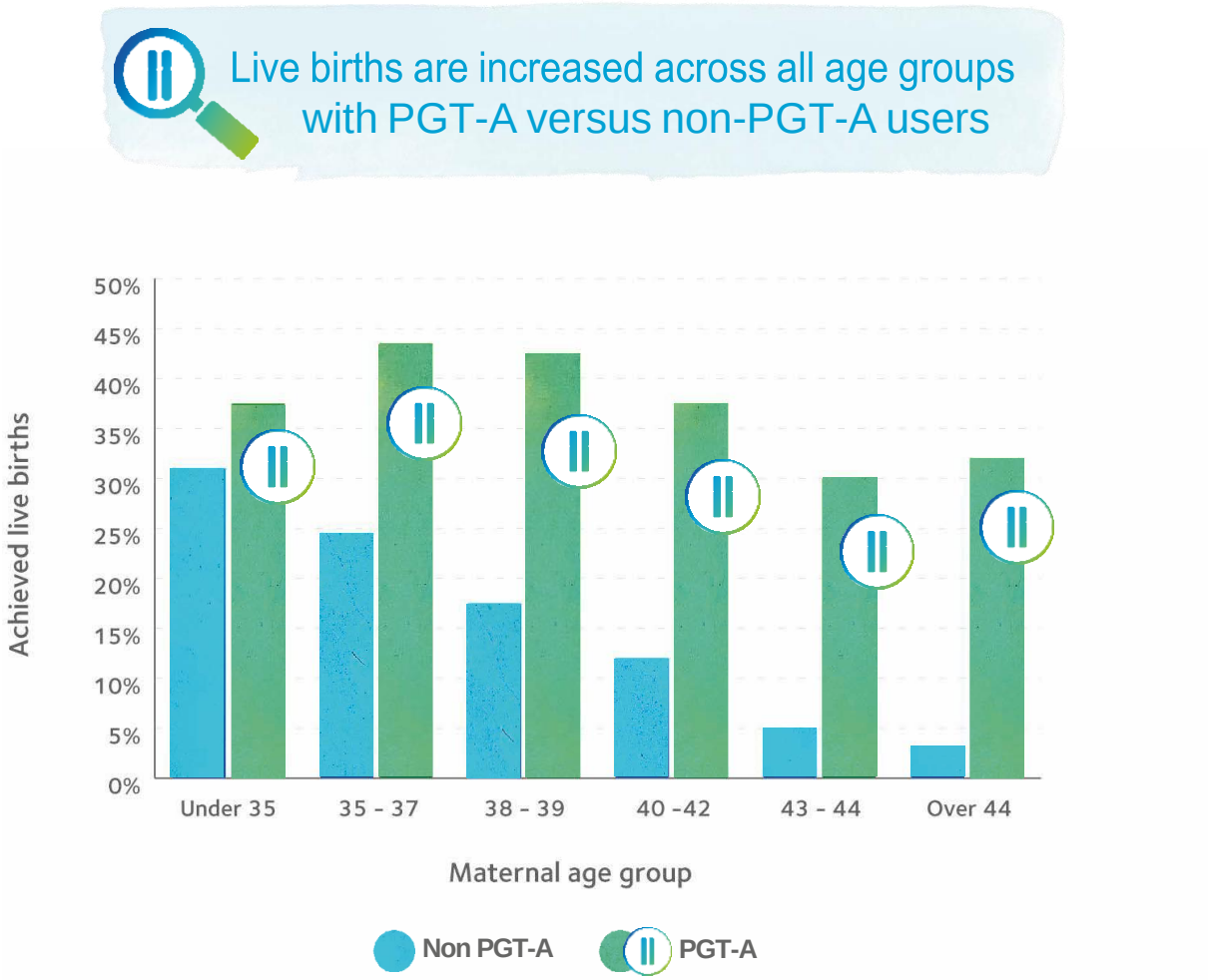
[111] Palmer, M., et al., Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy. Fertility and Sterility. Vol. 114, Issue 3. September 2020.

216. Despite the scientific research detailed above, Defendants' website aimed at consumers includes a graph indicating that PGT-A increases live birth rates among all age groups.[112]



217. The Patient Brochure for PGT-A issued by Defendants includes a similar graph.

[112] https://www.coopergenomics.com/preimplantation-genetic-testing-for-aneuploidies/ (last visited September 10, 2024).



Percentage of live births per embryo transferred with and without PGT-A. Data reached statistical significance.

218. As an example of a false and misleading statement, and material omission of the scientific knowledge detailed above of which Defendants are certainly aware, Defendants suggest with its graph that women under 35 years of age who used PGT-A were far more successful in achieving live birth than women who did not utilize PGT-A (~32% to 40%).

219. Published scientific results, however, have reported no benefit of PGT-A to live birth rates for women under 35 and unchanged ongoing embryo implantation rates of ~50% for PGT-A and non-PGT-A.[113]

220. Defendants' false and misleading claim also contradicts scientific research that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[114]

221. Further, scientists have found that "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative birth rate per cycle start."[115]

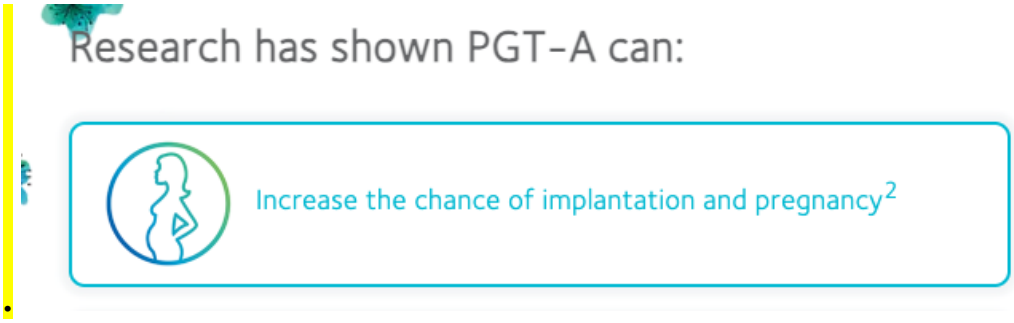
222. Researchers looking across age groups have further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[116]

[113] 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).
[114] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.
[115] 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.
[116] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.

223. Defendants' 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.[117]

7. Defendants Falsely State That Their PGT-A Testing Increases The Chance Of Implantation And Pregnancy

224. Defendants' Patient Guide on PGT-A falsely states that research has shown PGT-A can increase the chance of implantation and pregnancy.[118]

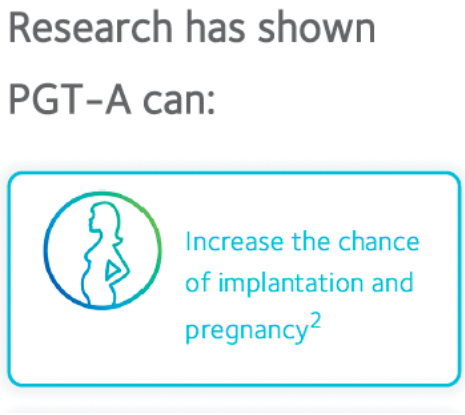


225. The same statement is on Defendants' website.[119]

[117] 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.

[118] https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/897bb073-5a5b-4b7d-93e7-33bc7119ae24 (last visited September 10, 2024).

[119] https://www.coopergenomics.com/preimplantation-genetic-testing-for-aneuploidies/



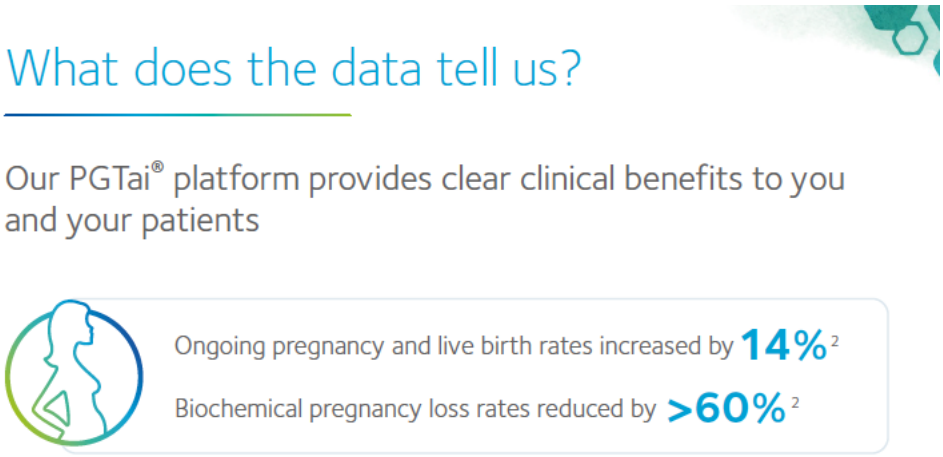
226. In addition, Defendants claim in their Patient Guide that their PGTai platform increased ongoing pregnancy and live birth rates by more than 13% and reduced biochemical pregnancy loss rates by more than 60% when compared to standard technology.

120

227. CooperSurgical's PGT-A brochure for clinics states that their PGTai platform increased ongoing pregnancy and live birth rates by more than 14% and reduced biochemical pregnancy loss rates by more than 60% when compared to standard technology.[121]

[120] PGT-A with Cooper Surgical Patient Guide, https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/0cc65fc8-b1b2-4552-98e7-f282e8706d0c (last visited September 9, 2024).

[121] CooperSurgical PGT-A Clinicians Brochure. https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/b6a266c3-4db1-43e5-94ac-295a67f95588 (last visited September 11, 2024).



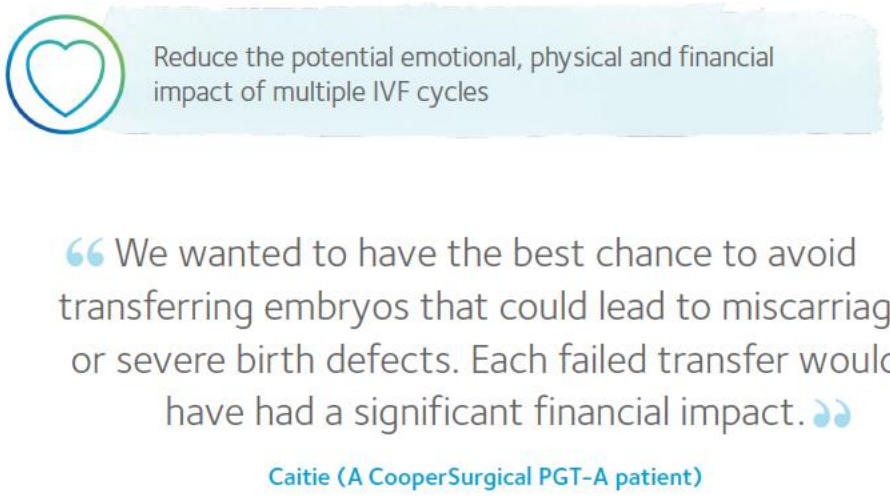
228. As previously discussed, the available science does not show an increase in the chance of implantation and pregnancy with PGT-A. To the contrary, pregnancy outcomes were similar between conventional IVF and PGT-A, but this fact is omitted to consumers by Defendants.[122]

8. Defendants Falsely State That Their PGT-A Testing Reduces The Emotional, Physical, and Financial Impact Of IVF

229. Defendants are well-aware that they are advertising, marketing, and selling their product to vulnerable consumers undergoing IVF, however, Defendants have utilized the emotional, physical, and financial impact of IVF to sell PGT-A.

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

230. In Defendants' Patient Guide, they state that PGT-A can reduce the impacts of IVF on patients.[123]



231. In furtherance of their marketing that PGT-A will reduce the impacts of IVF, Defendants enticingly utilize the stories of other IVF patients to sell their PGT-A testing to vulnerable consumers.

232. For example, Defendants' website features the following statement by a consumer to market PGT-A as reducing the emotional, physical, and financial impact of IVF.[124]

[123] https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/897bb073-5a5b-4b7d-93e7-33bc7119ae24 (last visited September 10, 2024).
[124] https://www.coopersurgical.com/changing-fertility-care/caities-story-how-pgtaism-helped-us-in-our-fertility-journey/ (last visited September 10, 2024).

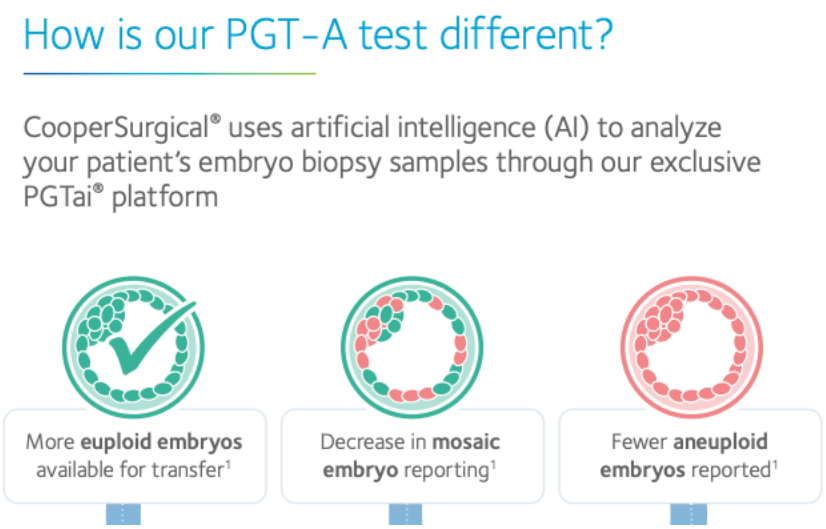
> We wanted to have the best chance possible and avoid transferring embryos that could potentially lead to miscarriage or severe birth defects. Each failed transfer would have cost us an additional $3,000 and we wanted to avoid that while also choosing a healthy embryo.

233. In addition, Defendants' website falsely states, based upon internal data, that their testing platform will provide more "euploid" (*i.e.*, "normal") embryos for transfer.[125]

234. This statement is false on its face.

235. The brochure for clinicians also indicates an increase in euploid embryos available for transfer, a decrease in mosaic embryo reporting, and fewer aneuploid embryos.

[125] PGT-A with Cooper Surgical Patient Guide, https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/0cc65fc8-b1b2-4552-98e7-f282e8706d0c (last visited September 9, 2024).



126

236. IVF *is* emotionally, physically, and financially difficult.

237. To reasonable consumers undergoing IVF, the promise that purchasing a test could reduce the emotional, physical, and financial impact is highly persuasive.

238. However, PGT-A testing does not reduce the emotional impact of IVF, and this statement is false and misleading, especially when considering all of the material information detailed herein that Defendants' omit concerning PGT-A.

239. Indeed, at least one study 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.[127]

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[126] CooperSurgical PGT-A Clinicians Brochure. https://coopersurgical.marketport.net/MarketingZone/MZDirect/Source/b6a266c3-4db1-43e5-94ac-295a67f95588 (last visited September 11, 2024).

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

240. For consumers who want to have a child, this demonstrates that PGT-A actually increases the emotional impact of IVF.

241. Further, scientific research has raised concerns about the irreparable harm to patients with diminished ovary reserve who lost their only chance to have a baby from their cycle of IVF due to PGT-A.[128]

242. PGT-A does not reduce the physical impact of IVF, and this is a false and misleading statement.

243. If PGT-A results determine that there are no embryos for transfer, then the individual must decide whether to do additional retrievals which results in further substantial physical impact.

244. PGT-A also causes physical impact to the embryo itself, so PGT-A does not reduce the physical impact of IVF.[129]

245. PGT-A does not reduce the financial impact of IVF, and this is a false and misleading statement.

246. PGT-A, in fact, increases the financial impact of IVF, by the cost of the PGT-A testing and additional related costs that consumers purchase based upon Defendants' false and misleading statements and material omissions.

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[128] *Id*.

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

247. In fact, scientific research has determined that PGT-A is not cost effective.[130]

9. Defendants' Misrepresentations In Their Uniform Patient Consent Form Reviewed By All Customers

248. Defendants provide a uniform Preimplantation Genetic Testing Patient Consent Form ("Consent Form") that all customers are asked to sign prior to obtaining their PGT-A testing.

249. The Consent Form states on the top of Page 1 that it is issued by Defendant CooperSurgical.

250. The Consent Form states in the footer that it is copyrighted by Defendant CooperSurgical, but also provides an email address of Defendant CooperGenomics.

251. The Consent Form states, with respect to payments, that:

> Fees for Tests are in addition to any other costs associated with your IVF cycle and fertility treatment. Unless your center has previously arranged to pay for your Testing ***all fees for Tests must be paid prior to reports being released***. [emphasis in original]
>
> In consideration of the services rendered, you agree to pay all charges not covered by your insurance company or any applicable health benefit including, but not limited to, deductibles co-payments, coinsurance, and non-covered

[130] Dunn, Ariel, et al., *Cost-effective analysis of PGT-A in Good Prognosis Patients.* Fertility and Sterility. Vol. 122, Issue 1. July 2024.

> services. You understand that it is your personal responsibility to pay for all charges for services rendered irrespective of any disputes or disagreements between you and your insurance company. We are entitled to full or partial payment in the event a Test is started but is cancelled or not performed.

252. The Consent Form states that "[t]he purpose of PGT-A is to evaluate whether embryos might have detectable chromosomal abnormalities or an abnormal number of chromosomes (aneuploidy)."

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

254. These statements in the Consent Form mirror those that are discussed above, and include, for example: (a) that PGT-A testing "prior to implantation may increase chances of a successful IVF outcome"; and (b) that PGT-A testing "may reduce the risk of implantation failure and miscarriage."

255. The Consent Form further states explicitly that "[t]he NGS technology [used to conduct PGT-A testing] has an accuracy rate of >97% and all findings are reported within this accuracy."

D. Defendants' Additional Material Omissions

256. 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 Defendants to consumers.

257. Defendants omit to inform consumers that damage to embryos caused by biopsy may be the reason for unsuccessful IVF outcomes following PGT-A.[131] Defendants claim that embryo biopsy and PGT-A are nearly harmless.

258. If PGT-A were reliable, clinics treating similar patients would see similar rates of euploidy or aneuploidy, but this is not happening.

259. As detailed above, Defendants are aggressively marketing PGT-A via misleading and unsupported statements while omitting material information from consumers prior to their payment for PGT-A.

260. Defendants have failed to inform consumers concerning the numerous scientific studies and opinions of professional organizations detailed above.

261. 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 Defendants omit this information from any marketing or documents intended to be reviewed by consumers.

[131] 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).

262. Defendants' state that the chromosome results they see in the biopsy are the same as the inner cell mass.[132]

263. Defendants also and opposingly state that "no current technology can determine what is happening throughout the trophectoderm or the inner cell mass."[133]

264. 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 Defendants omit this from consumers.

265. 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. Defendants omit this from consumers.

266. 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 Defendants omit this from consumers.

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[132] https://www.coopergenomics.com/before-pregnancy/mosaic-pgt-a-results-an-update/ (last visited May 8, 2024).
[133] *Id.*

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

268. Defendants also omit 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.

269. 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.[134]

270. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[135]

271. Instead of informing consumers how errors with PGT-A testing can severely impact consumers, Defendants advise customers against the transfer of embryos that Defendants' PGT-A determine to be "aneuploid" or "mosaic."[136]

[134] 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.
[135] 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.
[136] https://www.coopergenomics.com/pgta/ (last visited September 10, 2024).

PGT-A Results

CooperGenomics uses the most advanced embryo screening technology available, providing the most complete picture of chromosomal health.

For each embryo tested, PGT-A results will fall into one of three categories: euploid, aneuploid, or mosaic. This information can help your care team select the best embryo for transfer.

	Euploid[1]	Aneuploid[1]	Mosaic[2,3]
			
Number of chromosomes per cell	Normal	Abnormal	Mixed (some normal & some abnormal)
Likelihood of producing a successful pregnancy	High	Very unlikely	Low, but possible
Recommended for transfer	Yes	No	No; provider may consider transfer if no euploid embryos available

E. PGT-A Has Enriched Defendants

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

273. PGT-A is a lucrative business for Defendants who conduct testing on approximately 500 biopsies per day.

274. CooperSurgical's CEO acknowledged that it experienced twelve consecutive quarters of "double-digit" growth in its fertility division, generating $1.2 billion in revenue last year.[137]

275. Despite all of the scientific literature concerning PGT-A set forth above, Defendants have continued to advertise and market PGT-A to consumers as 97% accurate, increasing the success of IVF, decreasing the chance of miscarriage,

[137] *See* https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/.

leading to a higher chance of pregnancy, reducing the time to pregnancy, increasing live birth rates across all age groups, increasing the chance of implantation and pregnancy, and reducing the emotional, physical, and financial impacts of IVF. Each of these claims are false and misleading, unsupported by scientific evidence, and made while Defendants omitted and withheld material information.

F. Plaintiffs' Experiences With Defendants' PGT-A

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

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

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

1. Erin Weinberg's Purchase of PGT-A Testing

279. Plaintiff Weinberg purchased PGT-A testing from Defendants in April 2021 based upon Defendants' false and misleading statements, including that PGT-A testing is greater than 97% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, reduces the time to pregnancy, increases live birth rate across all age groups, increases the chance of implantation and pregnancy, and reduces the emotional, physical, and financial impact of IVF.

280. Plaintiff Weinberg purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

281. Plaintiff Weinberg relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $8,880 plus additional costs for her PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

2. E.V.'s Purchase of PGT-A Testing

282. Plaintiff E.V. purchased PGT-A testing from Defendants in July 2022 based upon Defendants' false and misleading statements including that PGT-A testing leads to a higher chance of pregnancy, reduces the time to pregnancy, and increases the chance of implantation and pregnancy.

283. Plaintiff E.V. further purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

284. Plaintiff E.V. relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $3,000 plus additional costs for her PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

3. Jaime Magnetico-Walsh's Purchase of PGT-A Testing

285. Plaintiff Magnetico-Walsh purchased PGT-A testing from Defendants in ____ based upon Defendants' false and misleading statements, including that that PGT-A testing increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, increases live birth rate across all age groups, and increases the chance of implantation and pregnancy.

286. Plaintiff Magnetico-Walsh further purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

287. Plaintiff Magnetico-Walsh relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $2,350 plus additional costs for her PGT-A testing which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

4. Erin Vedrode's Purchase of PGT-A Testing

288. Plaintiff Vedrode purchased PGT-A testing from Defendants in March 2023 based upon Defendants' false and misleading statements, including that that PGT-A testing is greater than 97% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, reduces the time to pregnancy, increases live birth rate across all age groups, increases the chance of implantation and pregnancy, and reduces the emotional, physical, and financial impact of IVF.

289. Plaintiff Vedrode further purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

290. Plaintiff Vedrode relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $2,250 plus additional costs for her PGT-A testing which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

5. Sarah and Allison Urbanski's Purchase of PGT-A Testing

291. Sarah and Allison Urbanski purchased PGT-A testing from Defendants in July 2021 and October 2021 based upon Defendants' false and misleading statements, including that that PGT-A testing is greater than 97% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, reduces the time to pregnancy, increases live birth rate across all age

groups, increases the chance of implantation and pregnancy, and reduces the emotional, physical and financial impact of IVF.

292. Plaintiffs Sarah and Allison Urbanski further purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

293. Plaintiffs Sarah and Allison Urbanski relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $3,900 plus additional costs for the PGT-A testing which they would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

6. Charity Billings' Purchase of PGT-A Testing

294. Charity Billings purchased PGT-A testing from Defendants in ____ based upon Defendants' false and misleading statements, including that PGT-A testing is greater than 97% accurate and decreases the chance of miscarriage.

295. Plaintiff Billings further purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

296. Plaintiff Billings relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $4,000 plus additional costs for her PGT-A testing which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

7. Ryan McElroy's Purchase of PGT-A Testing

297. Ryan McElroy purchased PGT-A testing from Defendants in February 2024 based upon Defendants' false and misleading statements, including that PGT-A testing is greater than 97% accurate, increases the success of IVF, decreases the chance of miscarriage, leads to a higher chance of pregnancy, reduces the time to pregnancy, increases live birth rate across all age groups, increases the chance of implantation and pregnancy, and reduces the emotional, physical, and financial impact of IVF.

298. Plaintiff McElroy further purchased Defendants' PGT-A testing based upon Defendants' omissions of material information as detailed above.

299. Plaintiff McElroy relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $2,950 plus additional costs for PGT-A testing which would not have been purchased absent Defendants' false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

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

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

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

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

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

305. In addition, Plaintiffs Sarah and Allison Urbanski bring this lawsuit on behalf of a class of all residents of the State of New York who purchased PGT-A testing from Defendants (the "New York Class").

306. In addition, Plaintiff Billings bring this lawsuit on behalf of a class of all residents of the State of North Carolina who purchased PGT-A testing from Defendants (the "North Carolina Class").

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

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

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

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

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

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

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

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

313. **Typicality**. Plaintiffs' claims are typical of the claims of other Class members they seek to represent because, among other things, all such claims arise

out of the same unlawful course of conduct by Defendants as alleged herein. Plaintiffs and Class members each purchased PGT-A based on Defendants' misrepresentations and omissions and they all suffered economic damages as a result.

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

315. **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.

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

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

CAUSES OF ACTION

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

COUNT I
Violations of Connecticut Unfair Trade Practices Act,

Conn. Gen. Stat. Ann. § 42-110a, *et seq*. ("CUTPA")
(On behalf of Plaintiff Weinberg and the Connecticut Class)

319. Plaintiffs incorporate by reference all preceding allegations.

320. Plaintiff is a "person" within the meaning of Conn. Gen. Stat. Ann. § 42-110a.

321. Defendants are engaged in "trade" and "commerce" within the meaning of Conn. Gen. Stat. Ann. § 42-110a as they promote and sell PGT-A testing for sale to consumers within the State of Connecticut.

322. Defendants' representations were material to a reasonable consumer and likely to affect consumer decisions and conduct.

323. Defendants used and employed deceptive and unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce.

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

325. Defendants' acts and practices are immoral, unethical, oppressive, and unscrupulous.

326. Defendants' conduct is substantially injurious to consumers. Such conduct has, and continues to cause, substantial injury to consumers as they would not have paid for Defendants' PGT-A testing but for Defendants' false and misleading statements, omissions, and promotion as detailed throughout this Complaint. Plaintiffs and the Class are entitled to a full refund of all economic costs they incurred as a result of purchasing Defendants' PGT-A testing. In the alternative, Plaintiffs and Class members are entitled to the difference in value between the unreliable and unproven test Plaintiffs purchased and the reliable and proven test that Defendants advertised.

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

328. No benefit to consumers or competition results from Defendants' conduct. As consumers reasonably rely on Defendants' representations, they could not have reasonably avoided such injury.

329. The foregoing unfair and deceptive practices directly, foreseeably, and proximately caused Plaintiffs and the Connecticut Class to suffer an ascertainable

loss when they paid for PGT-A testing and incurred additional economic costs based on Defendants' false and misleading material statements and omissions.

330. Plaintiff and the Connecticut Class are entitled to recover damages and other appropriate relief.

COUNT II
Violations of the Colorado Consumer Protection Act,
C.R.S. 1963: §6-1-101, *et seq*.
(On behalf of E.V. and the Colorado Class)

331. Plaintiffs incorporate by reference all preceding allegations.

332. Plaintiff E.V. and Defendants are a "person" within the meaning of C.R.S. 1963: §6-1-102.

333. Defendants are engaged in "trade" and "commerce" within the meaning of C.R.S. 1963: §6-1-105 as they promote and sell PGT-A testing for sale to consumers within the State.

334. Defendants' representations and omissions were material to a reasonable consumer and likely to affect consumer decisions and conduct.

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

336. Defendants' acts and practices offend public policy as established by statute. Defendants' acts and practices violate the Federal Trade Commission Act,

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

337. Defendants' acts and practices as detailed herein violate C.R.S. 1963: §6-1-105 1(b), (c), (e), (g), (i), (u), (ee), and (rrr), among others.

338. Defendants' acts and practices are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

339. Defendants' conduct is substantially injurious to consumers. Such conduct has, and continues to cause, substantial economic injury to consumers because consumers would not have paid for Defendants' PGT-A testing and other related costs but for Defendants' false and misleading statements, omissions, and promotion.

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

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

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

343. Plaintiff and the Colorado Class are entitled to recover damages and other appropriate relief pursuant to C.R.S. 1963: §6-1-113.

COUNT III
Violations of Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq*.
(On behalf of Jaime Magnetico-Walsh and the Florida Class)

344. Plaintiffs incorporate by reference all preceding allegations.

345. Plaintiff Magnetico-Walsh is a "consumer" within the meaning of Fla. Stat. § 501.203.

346. Defendants are engaged in "trade" and "commerce" within the meaning of Fla. Stat. § 501.203 as they market, promote, and sell PGT-A testing for sale to consumers within the State of Florida.

347. Defendants' representations were material to a reasonable consumer and likely to affect consumer decisions and conduct.

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

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

350. Defendants' acts and practices are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

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

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

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

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

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

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

356. Plaintiffs incorporate by reference all preceding allegations.

357. Plaintiff Vedrode and Defendants are a "person" within the meaning of MCL § 445.902(d).

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

359. Defendants' representations were material to a reasonable consumer and likely to affect consumer decisions and conduct.

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

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

362. Defendants' acts and practices are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

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

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

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

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

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

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

COUNT V
Violations of New York Consumer Protection GBL § 349, *et seq*.
(On behalf of Allison and Sarah Urbanski and the New York Class)

369. Plaintiffs incorporate by reference all preceding allegations.

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

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

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

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

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

i. PGT-A testing is greater than 97% accurate;

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

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

l. Biochemical pregnancy loss rates were reduced by 60% when PGT-A with AI used versus standard PGT-A technology;

m. PGT-A testing leads to a higher chance of pregnancy;

n. Ongoing pregnancy and live birth rates increased by more than 13% when PGT-A with AI used versus standard PGT-A technology;

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

p. PGT-A testing increases live birth rates across all age groups;

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

r. PGT-A testing reduces the emotional, physical, and financial impacts of IVF;

s. A trophectoderm biopsy at blastocyst stage accurately reflects the entire embryo's ploidy status;

t. PGT-A allows for more euploid embryos available for transfer; and

u. The additional misstatements and omissions alleged herein.

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

375. Defendants further breached their duties to Plaintiffs as follows, without limitation:

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

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

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

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

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

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

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

376. Plaintiffs and the New York Class Members and all consumers nationwide have been injured because they paid for PGT-A sold by Defendants (and related costs) that they reasonably believed was accurate and reliable based on Defendants' misrepresentations and omissions as alleged herein. Accordingly,

Plaintiffs and the New York Class members incurred economic losses purchasing PGT-A that did not perform as advertised and did not have the qualities that were represented.

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

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

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

COUNT VI
Violations of New York Consumer Protection GBL § 350
(On behalf of Allison and Sarah Urbanski and the New York Class)

380. Plaintiffs incorporate by reference all preceding allegations.

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

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

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

Id. (emphasis added).

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

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

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

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

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

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

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

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

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

391. Plaintiffs incorporate by reference all preceding allegations.

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

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

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

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

396. Plaintiff and the California Class members have suffered injury in fact and have lost money as a result of Defendants' fraudulent business acts or practices.

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

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

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

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

401. Defendants' conduct in concealing and failing to disclose the inaccuracy and unreliability of PGT-A testing is unfair in violation of the UCL,

because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

402. Defendants acted in an immoral, unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner.

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

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

405. Through their unfair conduct, Defendants acquired money that Plaintiff and the California Class members once had ownership of.

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

COUNT XIII
Violations of California Unfair Competition Law,
Cal. Bus. & Prof. Code §§ 17200, *et seq*. (Unlawful Prong)

(On behalf of Ryan McElroy and the California Class)

407. Plaintiffs incorporate by reference all preceding allegations.

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

409. Defendants "unlawful" acts and practices include breach of the implied warranty of merchantability, breach of the implied warranty of usability, fraud-based omissions, and unjust enrichment.

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

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

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

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

413. Plaintiffs incorporate by reference all preceding allegations.

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

415. Defendants are "person[s]" as defined by Civil Code §§ 1761(c) and 1770 and has provided "services" as defined by Civil Code §§ 1761(b) and 1770.

416. Defendants' acts and practices as detailed herein, violated Civil Code § 1770 by the following:

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

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

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

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

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

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

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

c. By failing to have the above 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.

418. Defendants had ample means and opportunities to alert Plaintiffs and California Class members that PGT-A was not supported by science as claimed by Defendants' advertising, marketing, and promotional materials.

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

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

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

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

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

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

425. Plaintiffs accordingly are entitled to statutory relief, equitable relief, reasonable attorneys' fees and costs, declaratory relief, and a permanent injunction

enjoining Defendants from their continued unlawful, fraudulent, and deceitful activity.

426. Pursuant to Civil Code § 1782(a), on July 3, 2024, Plaintiffs, individually and on behalf of the Class, sent a letter to all three Defendants to notify them of their CLRA violations and afford them the opportunity to correct their business practices and rectify the harm they caused. The correspondence was mailed via first class certified mail with return receipt requested. Defendants failed to correct the acts and practices detailed herein within 30 days. Therefore, Plaintiff and the California Class Members seek money damages under CLRA.

COUNT X
Violation of North Carolina's Unfair Deceptive Trade Practices Act, N.C. Gen. Stat. Ann. § 75-1, *et seq.*
(On Behalf of Plaintiff Billings and North Carolina Class Members)

427. Plaintiffs incorporate by reference all preceding allegations.

428. Defendants are engaged in "trade" and "commerce" within the meaning of N.C. Gen. Stat. Ann. §75-1.1 as they market, promote, and sell PGT-A for sale to consumers within the State.

429. Defendants' representations and omissions were material to a reasonable consumer and likely to affect consumer decisions and conduct.

430. Defendants used and employed deceptive and unfair methods of competition and unfair or deceptive acts, practices, representations, and omissions, in the conduct of trade or commerce.

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

432. Defendants' acts and practices are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

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

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

435. No benefit to consumers or competition results from Defendants' conduct. Since consumers reasonably rely on Defendants' representations of their services, consumers could not have reasonably avoided such injury.

436. The foregoing unfair and deceptive practices directly, foreseeably, and proximately caused Plaintiff and the North Carolina Class to suffer an ascertainable loss in the form of economic losses when they paid for PGT-A testing based on Defendants' false and misleading material statements and omissions.

437. Plaintiff and the North Carolina Class are entitled to recover treble damages, statutory damages, and other appropriate relief pursuant to N.C. Gen. Stat. Ann. § 75-16.

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

438. Plaintiffs incorporate by reference all preceding allegations.

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

440. 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*.

441. Defendants breached the implied warranty of merchantability in connection with the sale of PGT-A. While Defendants advertise, market, and promote that their PGT-A testing is accurate and reliable, it is not, rendering it unsuitable for use.

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

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

444. Plaintiffs and the Class may also establish privity as the intended third-party beneficiaries of agreements between Defendants and the Plaintiffs' and Class Members' IVF clinics. The agreements between Defendants and Plaintiffs' and Class members' IVF clinics to use Defendants' PGT-A testing were designed and intended for the benefit of Plaintiffs and Class members to make decisions about their embryos and fertility treatment. Defendants understood that Plaintiffs and Class

members would require that their PGT-A testing provide reliable and accurate information regarding their embryos and Defendants delivered their PGT-A tests to Plaintiffs and Class members understanding the need to meet these requirements.

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

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

446. Plaintiffs incorporate by reference all preceding allegations.

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

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

449. 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*.

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

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

452. Defendants 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.

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

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

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

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

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

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

457. Plaintiffs incorporate by reference all preceding allegations.

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

a. PGT-A testing is greater than 97% accurate;

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

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

d. Biochemical pregnancy loss rates were reduced by 60% when PGT-A with AI used versus standard PGT-A technology;

e. PGT-A testing leads to a higher chance of pregnancy;

f. Ongoing pregnancy and live birth rates increased by more than 13% when PGT-A with AI used versus standard PGT-A technology;

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

h. PGT-A testing increases live birth rates across all age groups;

i. PGT-A testing increases the chance of implantation and pregnancy;

j. PGT-A testing reduces the emotional, physical, and financial impacts of IVF;

k. A trophectoderm biopsy at blastocyst stage accurately reflects the entire embryo's ploidy status; and

l. PGT-A allows for more euploid embryos available for transfer.

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

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

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

462. Defendants' false statements and omissions induced Plaintiffs and Class members to purchase Defendants' PGT-A.

463. Defendants' advertising, marketing, and promotion of PGT-A fraudulently concealed the truth about PGT-A as alleged herein. Accordingly,

Plaintiffs and the Class could not have known that they were subject to deceptive and misleading marketing and promotion.

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

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

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

466. Plaintiffs incorporate by reference all preceding allegations.

467. Defendants intentionally suppressed and concealed material facts about their PGT-A testing as alleged herein. Defendants 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 disclosed these material facts to Plaintiffs and Class members.

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

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

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

471. Defendants were aware of the scientific study and research concerning PGT-A as Defendants reviewed the research and publications concerning PGT-A, including from major medical associations such as ASRM.

472. Defendants had a duty to disclose the truth about PGT-A because, through Defendants' advertising, marketing, website statements, patient brochures, consent form, and other written statements made to consumers, Defendants 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.

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

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

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

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

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

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

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

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

480. Plaintiffs incorporate by reference paragraphs 1 through 318.

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

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

483. As a result, Defendants have been unjustly enriched.

484. Defendants received a measurable benefit at the expense of Plaintiffs and Class members in the form of payment for PGT-A testing.

485. Defendants accepted monetary benefits from Plaintiffs and Class members at the detriment of Plaintiffs and Class members.

486. These benefits were the result of Defendants acting in their pecuniary interest at the expense of their consumers.

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

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

PRAYER FOR RELIEF

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

a. Determine that Defendants are liable for the violations set forth above;

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

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

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

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

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

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

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

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

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

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

DEMAND FOR JURY TRIAL

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

Dated: September 27, 2024

Respectfully submitted,

/s/ Russell D. Paul
Russell D. Paul (NJ Bar. No. 037411989)
Shanon J. Carson (*pro hac vice forthcoming*)
Dena Young (NJ Bar No. 033022010)
Abigail J. Gertner (NJ Bar. No. 019632003)
Zoe Seaman-Grant (*pro hac vice forthcoming*)
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Tel.: (215) 875-3000
Email: rpaul@bm.net

scarson@bm.net
dyoung@bm.net
agertner@bm.net
zseamangrant@bm.net

Allison S. Freeman (*pro hac vice forthcoming*)
CONSTABLE LAW, P.A.
139 6th Avenue S
Safety Harbor, Florida 34695
Tel: (727) 797-0100
Email: allison@constable-law.com

Paula S. Bliss (*pro hac vice forthcoming*)
JUSTICE LAW COLLABORATIVE
210 Washington St.
No. Easton, MA 02356
Tel: (508) 230-2700
Email: paula@justicelc.com

Counsel for Plaintiffs