IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RACHEL KLOSOWSKI, ADAM KLOSOWSKI, MICHELLE SCHAFER, LAURA MENDOZA, DORI SHICK, SOUPHARACK VANNASING, LAUREN TEVERBAUGH, JANINE CARLIN, and JONATHAN CARLIN, individually and on behalf of all others similarly situated, Plaintiffs, v. FPG LABS, LLC d/b/a OVATION FERTILITY, US GENETIC LAB, LLC d/b/a OVATION GENETICS, and US FERTILITY LLC, Defendants.	Civil Action No. CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Rachel Klosowski, Adam Klosowski, Michelle Schafer, Laura Mendoza, Dori Shick, Soupharack Vannasing, Lauren Teverbaugh, Janine Carlin, and Jonathan Carlin, 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 FPG Labs, LLC d/b/a Ovation Fertility ("Ovation Fertility"), US Genetic Lab, LLC d/b/a Ovation Genetics ("Ovation Genetics") (collectively, Ovation Fertility and Ovation Genetics are referred to herein as "Ovation"), and US Fertility LLC ("US Fertility") (collectively with Ovation, "Defendants").

NATURE OF THE ACTION

1. Plaintiffs bring this class action lawsuit to recover economic losses suffered by Plaintiffs and Class members (defined below) arising from the false, deceptive, unfair, and

misleading advertising, marketing, and/or promotion of Ovation's preimplantation genetic testing for aneuploidy ("PGT-A" or "PGT-A testing"). Plaintiffs and Class members each spent thousands of dollars for PGT-A based on Defendants' material misrepresentations and omissions as detailed herein.

2. Plaintiffs file this lawsuit to remedy Defendants' unfair and deceptive business practices arising from the advertising, marketing, promotion, and/or sale of PGT-A as a proven, accurate, and reliable method to decrease the chance of miscarriage and increase the chance of giving birth to a healthy baby when science does not support this and does not validate the PGT-A test results. Defendants' misleading statements and omissions as described in detail below are false and misleading to any reasonable consumer because its PGT-A is unproven, unvalidated, 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 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 increasingly lucrative 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 is marketed and promoted by Defendants as an add-on to the IVF process and purports to screen embryos for chromosomal abnormalities. Before March 2023, Ovation operated under the ownership of its prior private equity owners, and since March 2023, when it was acquired by US Fertility, Ovation has been operated by US Fertility as an alter ego of US Fertility without regard for corporate façade with the same individuals running both companies simultaneously.

10. With respect to PGT-A conducted by Ovation, IVF clinics perform a biopsy and send a small number of cells from the embryo to Ovation or an affiliate laboratory who performs the PGT-A testing and provides results to the customer and their clinic. The results purport to determine which embryos are "euploid" or best suited for implantation and which embryos are "aneuploid" or abnormal and not suited for implantation.

11. Ovation Fertility's PGT-A is promoted and marketed to patients of IVF who are pursuing IVF as increasing the chance of pregnancy, leading to a higher chance of a healthy pregnancy, reducing the risk of miscarriage, and reducing the time to pregnancy. It is also marketed as being greater than 98% accurate. Based on these material representations and just as importantly, the material omissions that underlay them as detailed below, people pursuing IVF choose to purchase PGT-A testing from Ovation. While the corporate form of the entities involved as changed over time because of acquisitions, Defendants continue to market the services described herein in various ways, including via the website www.ovationfertility.com.

12. The above representations are false, misleading, and deceptive, as well as omit critical material information as detailed below. 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 that the accuracy rating for PGT-A is significantly lower than 98%.

13. Ovation's false and misleading statements and material omissions have severe consequences, including, without limitation, causing 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." United Healthcare further states with respect to PGT-A that "[t]here is insufficient evidence to support the use of PGT for aneuploidy screening at this time."[1]

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

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

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

19. Despite scientific research and studies showing insufficient evidence of efficacy, the use of PGT-A has spiked in recent years due to Defendants' promotion. 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.

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

21. Defendants have known for years that PGT-A testing suffers from serious issues and does not increase the chance of pregnancy, lead to a higher chance of a healthy pregnancy, reduce the risk of miscarriage, reduce the time to pregnancy, and lead to no more mosaic embryos.

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

22. Defendants have known for years that its PGT-A testing is not greater than 98% accurate, and in fact is significantly lower, and that its testing has not been properly validated or proven.

23. Defendants have known for years about the scientific studies and evidence described in this Complaint below concerning the efficacy and problems with PGT-A.

24. Despite knowing all this, Defendants continuously act to mislead patients with false and deceptive marketing, advertising, and promotion of Ovation Fertility's PGT-A in exchange for the opportunity to reap millions of dollars in profit each year from selling PGT-A.

25. Plaintiffs and Class members who have purchased PGT-A testing from Ovation Fertility have relied on the false and deceptive advertising statements and promotional materials described herein, and just as importantly, material omissions concerning PGT-A, to their detriment, and have suffered economic losses.

26. Plaintiffs and Class members have relied on the false and deceptive statements described further below that PGT-A testing benefits customers, is greater than 98% accurate, increases the chance of pregnancy, leads to a higher chance of a healthy pregnancy, reduces the risk of miscarriage, reduces the time to pregnancy, and leads to no more mosaic embryos.

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

PARTIES

28. Plaintiff Rachel Klosowski is a resident of Belmont, North Carolina and received fertility treatment in Charlotte, North Carolina.

29. Plaintiff Adam Klosowski is a resident of Belmont, North Carolina and received fertility treatment in Charlotte, North Carolina.

30. Plaintiff Michelle Schafer is a resident of San Diego, California and received fertility treatment in Irvine, California.

31. Plaintiff Laura Mendoza is a resident of San Diego, California and received fertility treatment in San Diego, California.

32. Plaintiff Lauren Teverbaugh is a resident of New Orleans, Louisiana and received fertility treatment in Baton Rouge, Louisiana.

33. Plaintiff Dori Shick is a resident of Austin, Texas and received fertility treatment in Austin, Texas.

34. Plaintiff Soupharack Vannasing is a resident of Las Vegas, Nevada and received fertility treatment in Las Vegas, Nevada.

35. Plaintiff Janine Carlin is a resident of Gonzales, Louisiana and received fertility treatment in Baton Rouge, Louisiana.

36. Plaintiff Jonathan Carlin is a resident of Gonzales, Louisiana and received fertility treatment in Baton Rouge, Louisiana.

37. Defendant FPG Labs, LLC d/b/a Ovation Fertility ("Ovation Fertility") is a Delaware limited liability company headquartered at 105 West Park Drive, Suite 370, Brentwood, Tennessee 37027. Ovation Fertility promotes itself on its current website as a national leading network of fertility laboratories providing leading-edge treatment. During the relevant time period, Ovation Fertility has performed pre-implantation genetic testing through its network of laboratories called Ovation Genetics. Ovation Fertility maintains an active website at https://www.ovationfertility.com.

38. Defendant US Genetic Lab, LLC d/b/a Ovation Genetics ("Ovation Genetics") is a Delaware limited liability company headquartered at 125 Cool Springs Blvd., Suite 200, Franklin, Tennessee 37067, which at times during the period relevant to this Complaint conducted the PGT-A testing marketed and sold by Ovation. Upon information and belief, Ovation Fertility and US Fertility also outsource PGT-A testing to affiliate laboratories and curate the results.

39. Defendant US Fertility, LLC ("US Fertility") is a Delaware limited liability company headquartered at 9600 Blackwell Road, 5th Floor, Suite 500, Rockville, Maryland, 20850.

40. US Fertility was formed in May 2020 through a private equity investment by Amulet Capital Partners, LP, in partnership with Shady Grove Fertility.[3] A September 22, 2020 press release provided a description of US Fertility:

> US Fertility ("USF"), the largest physician-owned and physician-led management services organization supporting leading fertility programs across the United States and internationally, today announced it has created the largest physician partnership of reproductive endocrinologists in the U.S. Through this partnership, affiliated practices will gain access to best-in-class non-clinical, administrative, and technical platforms that streamline and simplify the delivery of fertility care.
>
> USF was formed earlier this year through a partnership between Amulet Capital Partners, LP ("Amulet"), a middle-market private equity investment firm based in Greenwich, CT, focused exclusively on the healthcare sector, and Shady Grove Fertility ("SGF"), the largest independent fertility practice in the U.S. The new entity offers a variety of technical platforms to effectively manage clinical and business information systems, facilities and operations, finance and accounting, physician recruitment and credentialing, legal, risk management, lab operations, business development, and fertility treatment financing programs, to name a few. …
>
> SGF is joined by Fertility Centers of Illinois ("FCI"), Reproductive Science Center of the San Francisco Bay Area ("RSC Bay"), and IVF Florida ("IVF FL") in becoming founding practices of US Fertility. Collectively, the USF network currently comprises 55 locations across 10 states and, through its

[3] https://www.shadygrovefertility.com/newsroom/us-fertility-announcement-2020/ (last visited October 29, 2024).

> clinics and over 80 physicians, completed nearly 25,000 IVF cycles in 2018.
> …
>
> About US Fertility
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> US Fertility is the largest, physician-owned and physician-led, integrated network of top-tier IVF/fertility practices in the United States, offering comprehensive fertility-market-focused non-clinical, administrative, and technical platforms that help domestic and international practices improve patient outcomes and increase profitability.

41. Thus, US Fertility markets itself as the "nation's leading fertility network."[4] US Fertility, according to its website, provides "administrative and operational support for more than 200 physicians in 100 locations and counting" to "extend market reach, increase profitability, and improve patient outcomes." US Fertility further bills itself as managing IVF laboratories for the practices it is affiliated with, stating, "Our laboratory management model allows fertility practices to shift their focus from managing IVF laboratories to delivering the highest standard of patient care."

42. On March 31, 2023, Ovation Fertility's private equity investor, Morgan Stanley Capital Partners, sold Ovation Fertility to US Fertility. According to the press release, US Fertility joined forces with Ovation Fertility when the two companies signed an agreement dated March 31, 2023.[5] The press release issued jointly by Ovation and US Fertility provided, in pertinent part:[6]

> US Fertility will continue to operate as a management service organization (MSO) and offer practice management solutions to fertility practices across the U.S. Ovation Fertility will continue to operate as a laboratory management service organization and offer laboratory management solutions to fertility practices across the U.S. Ovation will continue operating under its unique physician partnership model to offer its IVF

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[4] https://www.usfertility.com (last visited October 14, 2024).

[5] https://www.ovationfertility.com/pressreleases/us-fertility-and-ovation-combine-to-create-ivf-services-powerhouse-increasing-access-to-fertility-services/ (last visited October 29, 2024).

[6] https://www.prnewswire.com/news-releases/us-fertility-and-ovation-combine-to-create-ivf-services-powerhouse-increasing-access-to-fertility-services-301831541.html (last visited October 14, 2024).

> laboratory and ancillary services ***as a wholly owned subsidiary of US Fertility*** (emphasis added).

43. A press release further stated that US Fertility will "represent the world's premier reproductive medicine practices, embryology laboratories, and a suite of life science services ***that include diagnostic testing, genetic testing,*** … ***and data science*** that patients depend on along their journey to parenthood."[7]

44. Ovation Fertility, as a wholly owned subsidiary of US Fertility, markets, advertises, promotes, and sells PGT-A throughout the United States.

45. In actuality, however, since March 31, 2023, Ovation Fertility and US Fertility have operated and worked as alter egos of each other and, using their own words, as one "combined company."[8] Since being acquired by US Fertility, Ovation Fertility has served no separate existence or function outside of the corporate interests of US Fertility, as evidenced by the companies respective sharing of facilities, tools, employees, and offices. This sharing of services, assets, and personnel have resulted in an excessive comingling that far exceeds any norms that characterize an affiliated but separate company relationship. Since the 2023 acquisition, US Fertility has dominated and controlled Ovation Fertility in all respects.

46. This is best evidenced by the fact of US Fertility's and Ovation Fertility's combined platform that share personnel that work for and oversee both companies *simultaneously* and which are equally responsible for all of the decisions of both US Fertility and Ovation Fertility, such that US Fertility manages, dominates, and controls decision-making at Ovation Fertility.

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[7] https://www.ovationfertility.com/pressreleases/us-fertility-and-ovation-combine-to-create-ivf-services-powerhouse-increasing-access-to-fertility-services/ (last visited October 14, 2024) (emphasis added).

[8] https://amuletcapital.com/2023/04/03/usf-and-ovation-fertility-to-combine-to-form-leading-national-fertility-platform/ (last visited October 29, 2024).

47. US Fertility and Ovation Fertility do not maintain separateness when it comes to running their "combined platform." Restated, pursuant to US Fertility's own website (there is no management team listed on Ovation Fertility's website), the top management of US Fertility is also the top management for Ovation Fertility since March 31, 2023, and is responsible for Ovation Fertility's actions, decisions, advertising, operations, legal counsel, business development, and other corporate functions, thus making US Fertility responsible for Ovation Fertility's conduct as alleged herein.

48. In illustration, Richard Jennings's biography on US Fertility's website lists him as both US Fertility's and – at the same time, Ovation Fertility's – Chief Executive Officer.[9]

49. Judah Shechter similarly holds a position as General Counsel to both US Fertility and Ovation Fertility, and in that role, advises "providers and laboratory managers regarding corporate transactions, regulatory compliance, strategic initiatives, physician employment and independent contract agreements, and corporate governance matters. Prior to joining US Fertility in 2020 and taking on the General Counsel role within Ovation Fertility in May 2023, Mr. Shechter was General Counsel to IntegraMed America, before which he was a Managing Director at JPMorgan Chase & Co., serving as General Counsel to One Equity Partners, which until 2015 was a subsidiary of JPMC and managed investments and commitments for JPMC in direct private equity investments."[10]

50. Likewise, while she works out of US Fertility's office, "Jaime Shamonki, M.D. serves as the Chief Operating Officer of US Fertility and Ovation Fertility, providing

[9] https://www.usfertility.com/leadership-team/richard-jennings (last visited October 29, 2024).
[10] https://www.ovationfertility.com/team/judah-shechter/ (last visited October 29, 2024).

administrative and operational support across the organization's growing international footprint."[11]

51. Similarly, Joshua Saipe is both US Fertility and Ovation Fertility's Chief Financial Officer. "Josh leverages his financial, strategic, operational, and leadership experience to lead all financial aspects of the Company, and to guide US Fertility and Ovation's strategic and business activities. His areas of responsibility include reporting and analysis, accounting, corporate development and strategy, M&A, key growth and business initiatives, planning, capital allocation, capital structure and investments, treasury, revenue cycle, and tax. Josh joined US Fertility in November 2021, as Chief Strategy Officer and expanded his role in 2022 as CFO. Josh's role expanded further to include CFO responsibilities for Ovation in May 2023."[12]

52. Similarly, Ethan Harris works as both US Fertility's and Ovation Fertility's Chief Information Officer. In this position, according to US Fertility's website, "Ethan leverages his deep experience in building, transforming, and leading Information Technology organizations to provide a world-class technology experience for patients, physicians, and staff that is aligned with the strategic direction of the company."[13] "He has spent considerable time leading the technology scope of mergers, acquisitions, and divestitures at both private and publicly traded organizations." *Id*.

53. And once again, Danny Charles is the Chief Development Officer for both US Fertility and Ovation Fertility. Mr. Charles "oversees the mergers and acquisitions team as they identify and execute opportunities to expand the US Fertility network of fertility practices, IVF

[11] https://www.usfertility.com/leadership-team/jaime-shamonki last visited October 29, 2024).
[12] https://www.usfertility.com/leadership-team/joshua-saipe (last visited October 29, 2024).
[13] https://www.usfertility.com/leadership-team/ethan-harris (last visited October 29, 2024).

laboratories, and life science offerings."[14] According to his website, Mr. Charles oversees the team that "supports the mission of US Fertility and Ovation by positioning ***the combined platform*** for continued growth and expansion thereby improving patient access, experience, and outcomes." *Id*. (emphasis added). Mr. Charles also served as "Vice President of Corporate Development at US Fertility and Ovation Fertility." *Id*. "Before joining US Fertility, Danny worked in healthcare transaction consulting, working with private equity firms and investors to help assess the financial and risk profiles of potential opportunities." *Id*.

54. Thus, based on the above, it is beyond dispute that US Fertility runs all aspects of Ovation Fertility's business and is responsible for it, and that Ovation Fertility is nothing more than a brand-name for US Fertility.

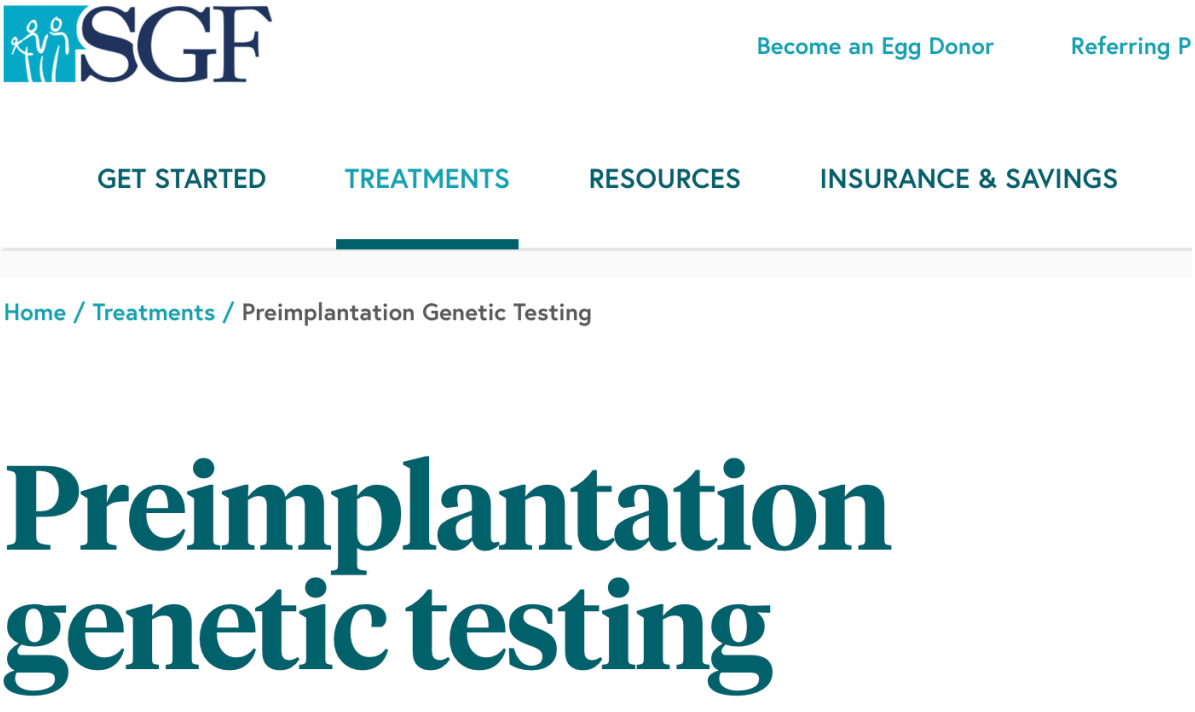
55. In slides prepared by Defendants, US Fertility and Ovation Fertility market their services as providing "two, best-in-class offerings" to IVF facilities across the United States including that "US Fertility offers practice management services as well as lab management services through Ovation Fertility. The combined US Fertility-Ovation platform is built for alignment and partnership."

56. Since its acquisition of Ovation Fertility, US Fertility is responsible for Ovation Fertility's website given the management structure detailed above. As such, US Fertility directly markets and promotes Ovation Fertility on US Fertility's website as well as marketing and promoting Fertility Centers of Illinois, PLLC, IVF Florida Holdings, LLC, Reproductive Medicine Associates of New York, LLP, Reproductive Science Center of SF Founder Holdings, Inc., and SGF Holdings, LLC, which are all members of US Fertility Holdings, LLC.[15]

[14] https://www.usfertility.com/leadership-team/danny-charles (last visited October 29, 2024).
[15] https://www.usfertility.com/ (last visited October 14, 2024).

57. As facilitated directly by US Fertility, which helps administer numerous large fertility practices, including by providing information and promotional materials to patients of the facilities, members of US Fertility Holdings market, advertise, and promote PGT-A sold by Ovation Fertility throughout the United States, and direct consumers and potential consumers to Ovation Fertility's website which contains many of the statements and omissions described herein.[16]

[16] https://www.shadygrovefertility.com/treatments/preimplantation-genetic-testing-embryos/ (last visited October 14, 2024).



58. Amulet Capital Partners, LP, which formed US Fertility, is an investor in Luminary Life Sciences, which added NextGen Genetics to its family of brands in October 2023 and renamed it Luminary Genetics.

59. Testing through Ovation is now performed by affiliate labs such as NextGen Genetics, which is invested in by Amulet Capital Partners, LP which formed US Fertility.

60. During discovery, Plaintiffs will obtain further information from Defendants and third parties concerning the roles of all the relevant entities mentioned above as well as third parties

whose names are not yet known and reserve their right to add additional Defendants at a later time based upon the discovery obtained.

JURISDICTION AND VENUE

61. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2)(A), because: (i) there are 100 or more Class members; (ii) there is an aggregate amount in controversy exceeding $5,000,000, exclusive of interest and costs; and (iii) Plaintiffs and Defendants are citizens of different states.

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

63. This Court has personal jurisdiction over Defendants because Defendants are Delaware limited liability companies and have consented to jurisdiction by registering to conduct business in the state; maintain sufficient minimum contacts in Delaware; and intentionally avails themselves of the markets within Delaware through their business activities which renders the exercise of jurisdiction by this Court proper and necessary as Defendants are "at home" in Delaware. Defendants have engaged and continue to engage in substantial and continuous business practices in the State of Delaware.

64. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) -(c). A substantial part of the events or omissions giving rise to the claims occurred in this District. Plaintiffs may properly sue Defendants in this District as Defendants are Delaware limited liability companies.

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

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

66. 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.

67. 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 they are 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.

68. 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.

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

70. 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.

71. 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.

72. 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.

73. For those who purchase PGT-A testing from Ovation Fertility, the removed cells are then sent to an affiliate laboratory utilized by Defendants for PGT-A testing.

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

75. Embryos are fragile and vulnerable to damage from biopsy and exertion of the freezing and thawing process necessary for PGT-A testing to be performed.[17]

76. 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.[18] It can also result in a reduced chance of pregnancy.[19]

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

78. 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.

79. 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.

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[17] 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.
[18] *Id.*
[19] Bradley, Cara. *Impact of multiple blastocyst biopsy and vitrification – warming procedures on pregnancy outcomes.* Fertility and Sterility. Vol. 108, Issue 6. December 2021.

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

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

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

83. PGT-A testing sold to Plaintiffs and Class members has substantial ramifications including, without limitation, the direct out-of-pocket costs that are paid for such testing.

84. US Fertility's clinic locations which are members of US Fertility Holdings and are affiliated with and managed by US Fertility, along with Ovation, promote PGT-A as an add-on to the IVF process, and encourage individuals to purchase PGT-A to determine which embryos are suitable to transfer.

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

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

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

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

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

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

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

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

93. In selling PGT-A to consumers, Ovation Fertility represents that PGT-A (a) benefits everyone, (b) is greater than 98% accurate, (c) increases the chance of pregnancy, (d) leads to a higher chance of a healthy pregnancy, (e) reduces the risk of miscarriage, (f) reduces the time to pregnancy, and (g) leads to no more mosaic embryos.

94. These representations are false, deceptive, and misleading, especially when combined with the important and material omissions of critical information that accompanying them, and Plaintiffs and Class members would not have purchased PGT-A from Ovation Fertility had they known the truth about PGT-testing which was misrepresented and materially omitted from them.

B. History of PGT-A Testing

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

96. In 1996, the hypothesis was first proposed that preimplantation genetic screening ("PGS") that eliminated aneuploid embryos prior to transfer would improve implantation rates of remaining embryos in IVF, increase pregnancy and live birth rates, and reduce miscarriages.[20]

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

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

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

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

99. In fact, as of 2024, there have been no randomized, properly structured, non-commercial trials to support the basis of Ovation's marketing of its PGT-A.

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

101. This method, described as PGS 1.0, became increasingly popular despite researchers in 2005 still being unable to demonstrate outcome benefits.[21]

102. 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.[22]

103. 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.[23]

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[21] 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.

[22] 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).

[23] *Id*.

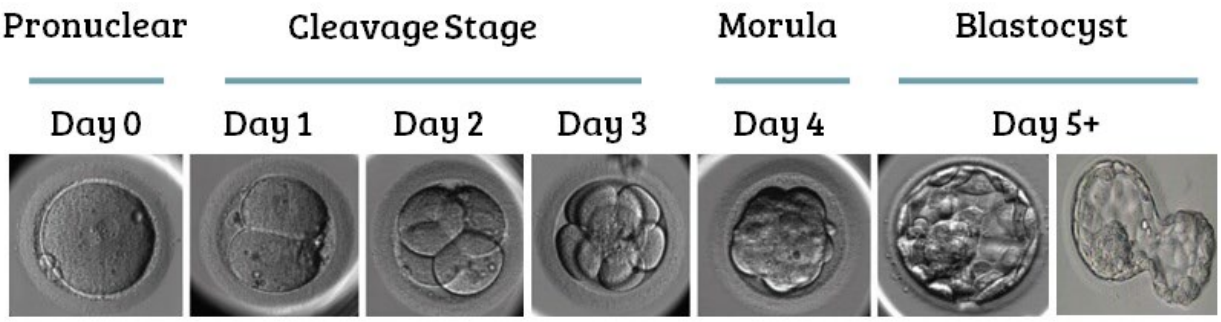
104. In 2011, researchers conducted a meta-analysis of randomized control trials on the effect of PGS on the probability of live birth after IVF.[24]

105. 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.[25]

106. In addition, the authors determined that PGS significantly *lowers* the live birth rate for women of advanced maternal age. The authors noted that technical drawbacks underlied the inefficiency of PGS.[26]

107. The authors cautioned that new approaches in the application of PGS should be carefully evaluated before introduction into clinical practice.[27]

108. In a 2013 paired randomized clinical trial on 116 patients, scientists sought to evaluate if cleavage[28] or blastocyst stage embryo biopsy affects reproductive competence.[29]



109. 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.

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[24] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).
[25] *Id.*
[26] *Id*.
[27] *Id.*
[28] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.
[29] 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.

110. The authors concluded that cleavage-stage biopsy markedly reduced embryonic reproductive potential.[30]

111. They further concluded that until laboratories demonstrated safety by applying a similar powerful study design, there remained insufficient evidence that biopsy at the blastocyst stage could be safely performed without impacting the reproductive potential of human embryos.[31]

112. Soon thereafter, the PGS testing labs began trophectoderm biopsy at the blastocyst stage without conducting any further study.

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

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

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

116. 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.

117. 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.

118. 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.

[30] *Id.*
[31] *Id.*

119. 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, 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.

120. 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.

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

122. 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 did not happen.

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

124. In 2015, as laboratories began to question the effectiveness of PGS, Ovation announced its new venture to combine some of the nation's IVF laboratories into one entity that "combines the strengths of each lab without requiring the physicians and scientist to sacrifice control or medical integrity to customary corporate oversight".[32]

[32] https://www.ovationfertility.com/ovagen-fertility-debuts-strategic-alliance-at-asrm2015/ (last visited October 14, 2024).

125. Following the announcement by Ovation, in 2016, researchers continued to question the biological basis of PGS based upon an assumption that a single trophectoderm biopsy can reliably determine embryo ploidy.

126. In a 2016 study, researchers tested embryos that had previously been tested and deemed aneuploid.[33] Six out of eleven embryos upon retesting were determined to be either definitively normal or mosaic with the potential to be normal, thus offering a chance for pregnancy if transferred.[34]

127. The authors of this 2016 study concluded that while the study was small, the numbers suggested a potential false positive rate of almost 55% and an intra-embryo discrepancy of almost 50%.[35]

128. 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.[36]

129. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[37]

130. In another 2016 study, researchers analyzed assisted reproductive technology in the United States from 2011 to 2012 and found that overall PGS was associated with a decreased live birth rate when compared to IVF without PGS.[38]

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[33] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocrinology (2016) 14:54.
[34] *Id*.
[35] *Id.*
[36] *Id*.
[37] *Id*.
[38] 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.

131. In yet another study in 2016, researchers re-biopsied 37 embryos determined to be "abnormal" and found that 33% of embryos originally reported to be "aneuploid" were found to be "euploid" upon repeat assessment.[39] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

132. 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.[40]

133. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[41]

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

135. Ovation, however, did not incorporate this knowledge into their marketing and advertising, to inform their customers about the issues inherent in PGS testing.

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

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[39] 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).
[40] 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.
[41] *Id.*

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

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

139. PGDIS was cofounded by Yuri Verlinsky, who created Reproductive Genetic Innovations, LLC ("RGI"), a large genetic testing laboratory that markets and sells PGT-A, and Santiago Munne, who co-founded Reprogenetics and Recombine and was the Chief Scientific Officer ("CSO") of CooperGenomics in 2016 and 2017, another large genetic testing laboratory that markets and sells PGT-A.

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

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

142. Research conducted the following year, 2017, shed even more light on the issues with PGS testing, now known as PGT-A. Specifically, the authors conducted a review of 455 publications related to testing, and concluded that all five assumptions made in 1996 are scientifically unsupportable and the hypotheses of PGS were discredited.[42]

143. 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

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

(*i.e.*, older patients) who were considered the best candidates for the test, testing may instead reduce pregnancy and live birth chances.[43]

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

145. Thereafter, PGT-A testing proponents pivoted again, and suggested that the threshold concept in which 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.

146. 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.[44] The author estimated that the proportion of normal embryos that are discarded based upon faulty results may be as high as 40%. He noted that this would lead to an overall decrease in the cumulative pregnancy rate achievable.[45]

147. 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.[46]

148. The author's commentary stated, "I have been appalled at the implementation into clinical practice of novel technology without the appropriate underpinning science. Saddest of all

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[43] *Id*.
[44] Paulson, R., *Preimplantation genetic screening: what is the clinical efficiency?* Fert. Ster. Vo. 108 No. 2, August 2017.
[45] *Id.*
[46] 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.

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."[47] The author called for registered, randomized, properly structured, non-commercial trials before clinical application of a technology that can lead to such devastating consequences like viable embryo destruction.

149. Subsequently, no such study was conducted, and no such study was sponsored or proposed by Ovation.

150. 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."[48]

151. Ovation, however, materially omitted to inform their customers and potential customers of this important pronouncement by the leading organization for reproductive medicine, that the value of PGS/PGT-A was yet to be determined.

152. In 2019, Santiago Munne conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[49]

153. The researchers found that PGT-A did not improve overall pregnancy outcomes, did not improve live birth rates, and did not reduce miscarriage rates.[50]

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

154. 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."[51]

155. Ovation, however, continued to promote PGT-A to IVF patients, including the specific affirmative misrepresentations detailed below that PGT-A benefits everyone, is greater than 98% accurate, increases the chance of pregnancy, leads to a higher chance of a healthy pregnancy, reduces the risk of miscarriage, reduces the time to pregnancy, and leads to no more mosaic embryos while omitting all the relevant and material scientific information about the issues with PGT-A as set forth herein.

156. At the same time, Morgan Stanley Capital Partners ("MSCP") had begun investing in Ovation in or around June 2019.[52] The June 2019 press release announcing the interest taken by MSCP provided:

> Ovation … is a leading provider of fertility laboratory services, including in-vitro fertilization laboratory services ("IVF"), genetic testing, egg & embryo storage and other services for the fertility industry. The Company provides services through eleven laboratories across the United States…
>
> "We are excited to work with premier fertility services provider, Ovation, and help the company execute its mission to serve individuals and couples across the United States and beyond," Steve Rodgers, Managing Director of MSCP. "We believe Ovation's talented management team has developed a best in class approach by acquiring highly attractive laboratories and partnering with industry leading physician groups. We look forward to supporting the company as it enters a new phase of growth."
>
> Nate Snyder, Chief Executive Officer of Ovation, said, "We believe our new partnership with Morgan Stanley Capital Partners will enable Ovation to extend our physician partnerships across the country and advance our

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

[52] *See* https://www.morganstanley.com/press-releases/morgan-stanley-capital-partners-completes-investment-in-ovation- (last visited October 28, 2024).

> collaborative medical model to drive down the average cost of a healthy baby through more efficient and effective infertility care."

157. Thus, there is no question that the involvement by private equity in the healthcare industry fueled the growth of Ovation and the dissemination of one of its primary tests – PGT-A, as a way to increase revenue for the company.

158. While the amount paid for the investment in Ovation by MSCP was undisclosed, it was reported in the media as being the result of an "auction" resulting in a large payment by MSCP speculated to be in the nine figures. One article at the time reported on the transaction as follows:[53]

> Morgan Stanley Wins Auction WindRose's Ovation Fertility
>
> -Deal said to command 12x Ebitda multiple
> -Los Angeles company encompasses 11 labs focused on reproductive health
> …
>
> The investment concludes what sources characterized as a robuse sponsor-focused auction for the Los Angeles network of in vitro fertility and genetic testing labs. …
>
> Ovation's Ebitda lies at approximately $12 million to $13 million, two sources said. One of the sources said the deal commanded an approximately 12x multiple of Ebitda, suggesting a valuation around the ballpark of $150 million. …
>
> MSCP, taking a majority stake, backed Ovation alongside existing management and physician shareholders. CEO Nate Snyder will continue to lead the company.
>
> New York's WindRose, then called MTS Health Investors, formed Ovation Fertility in 2015 through the marriage of four IVF labs across Tennessee, Texas, Nevada, and California.
>
> WindRose partner Alex Buzik declined to comment on deal metrics, but noted that "much of the success was due to Ovation's differentiated strategy of focusing on the IVF laboratories and related ancillary services in close partnership with its affiliated physician practices."

[53] *See* https://www.pehub.com/morgan-stanley-wins-auction-for-windroses-ovation-fertility/.

> While most existing investors in reproductive medicine are focused on infertility clinics or egg freezing, Ovation is unique in that it operates 11 labs across the U.S. that provide various tests and related services for infertility patients.

159. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[54]

160. 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.[55]

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

162. The United States Centers for Disease Control and Prevention ("CDC") requires that patient education materials be written at or below a fifth-grade reading level, but researchers found that among the educational materials examined, none met the CDC standard.[56]

163. These findings suggested that patient educational materials concerning PGT-A may not always be comprehensible or clear to all patients. Lack of appropriate educational materials that present information about PGT-A in an accessible, unbiased, and comprehensible manner

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[54] 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).
[55] *Id*.
[56] 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).

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.[57]

164. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[58] 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.[59]

165. In November 2021, the preeminent New England Journal of Medicine published the results of a randomized controlled trial to assess whether PGT-A improves the cumulative live-birth rate as compared with conventional IVF. [60]

166. 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."[61]

167. 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."[62]

168. The authors of the study concluded:

a. Trophectoderm biopsy may be harmful;[63]

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[57] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: Challenges in clinical practice*, Human Genomics, article 69 (2022).
[58] 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).
[59] Id.
[60] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[61] *Id.*
[62] *Id*. at 2054.
[63] *Id*. at 2056.

b. No benefit for PGT-A regardless of age on cumulative live-birth rate;[64] and

c. No benefit for PGT-A for ongoing pregnancy and live birth rates after first frozen embryo transfer.[65]

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

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

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

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

d. Whether PGT-A improves live birth outcomes has yet to be proven.[66]

170. Despite these findings Ovation Fertility 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 as described herein that was well-known to Ovation but not to consumers at the time.

171. 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.[67]

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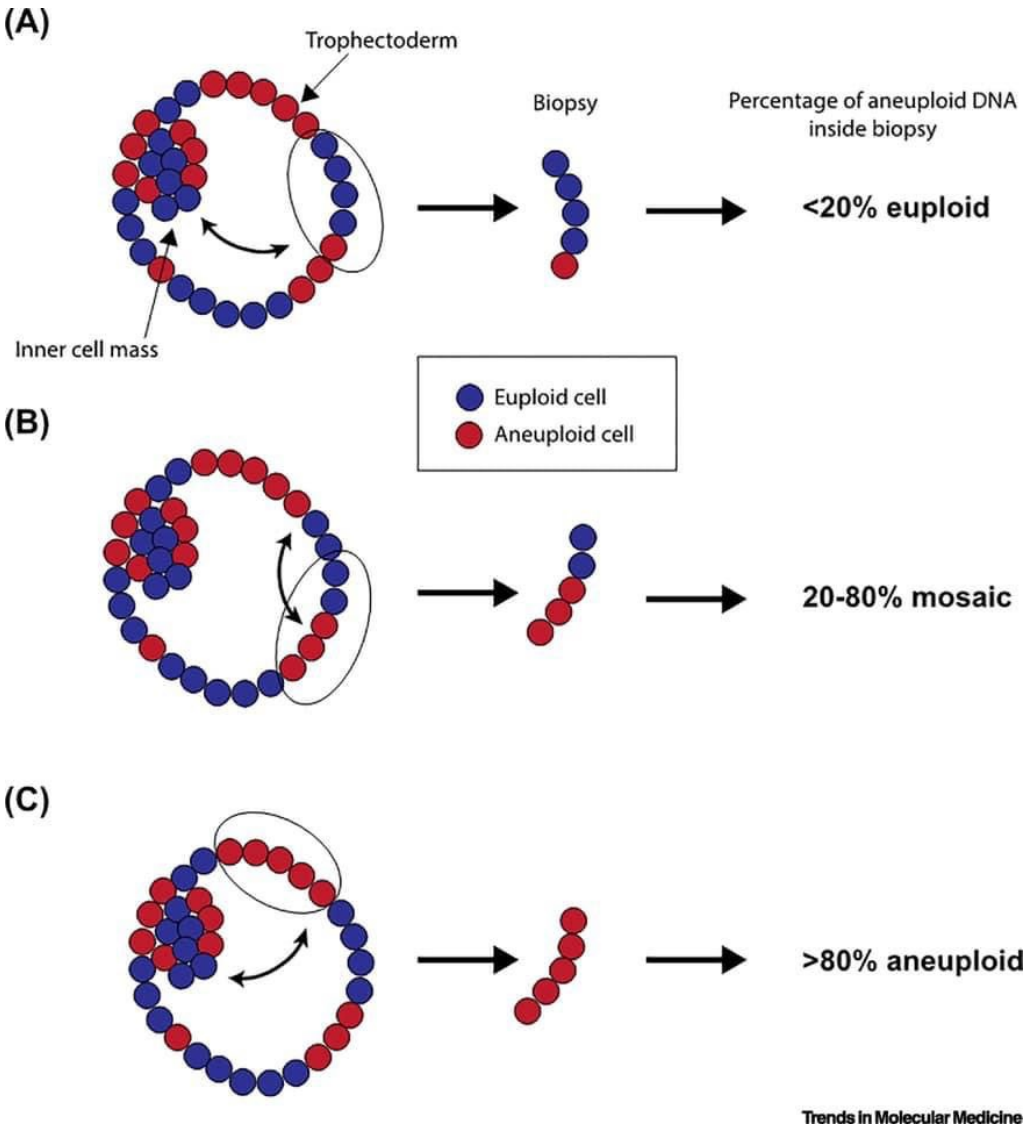
[64] *Id.*
[65] *Id*.
[66] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.
[67] Coorens, et al., *Inherent mosaicism and extensive mutation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

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

173. 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:[68]



[68] 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).

174. 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.[69]

175. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[70] 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.[71]

176. 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."[72]

177. 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."[73]

178. Ovation Fertility, however, continued to advertise and market PGT-A based upon live birth rates per embryo transfer thereby excluding from analysis any IVF cycles without

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[69] 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).
[70] 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.
[71] *Id*.
[72] *Id*.
[73] *Id*.

transferrable embryos. As a result, it artificially and materially inflated and misrepresented the utility of PGT-A on increasing the chance of pregnancy, leading to a higher chance of a healthy pregnancy, and reducing the time to pregnancy.

179. Then in October 2022, Ovation announced a new partnership that would "enhance and expand the genetic testing options available to hopeful parents" by licensing the LifeView platform for use in Ovation Genetics labs.[74]

180. PGT testing on the LifeView platform was sold by Ovation as "the most comprehensive preimplantation genetic testing available to aid in the selection of optimal-quality embryos to transfer as part of IVF".[75]

181. Following Ovation's announcement in October 2022, another article published in Human Genomics called for regulatory oversight, recognizing that PGT-A had regrettably become a routine add-on for IVF to improve clinical outcomes, and noted the following:

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

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

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

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

e. PGT-A has not been validated;

f. High false positive rates are extremely concerning;

g. Use in particular age groups is uncertain;

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

[74] https://www.ovationfertility.com/pressreleases/ovation-fertility-licenses-genomic-predictions-lifeview-pgt-platform/ (last visited October 14, 2024).
[75] *Id.*

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

j. Industry self-regulation has shown to be insufficient.[76]

182. 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.[77]

183. The researchers noted that the euploid rate suggested that chaotic abnormal results on PGT-A have "reduced predictive value."[78]

184. 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%.[79]

185. With the definitive agreement for MSCP to sell Ovation Fertility to US Fertility signed on March 31, 2023, US Fertility took over Ovation Fertility at that time, both becoming responsible and liable for all past and future actions of Ovation Fertility, including but not limited to because of the dominance and control that US Fertility exercises over Ovation Fertility as set forth in detail above, essentially running it as a brand of US Fertility.[80]

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

[77] 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.

[78] *Id.*

[79] 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.

[80] https://www.ovationfertility.com/pressreleases/us-fertility-and-ovation-combine-to-create-ivf-services-powerhouse-increasing-access-to-fertility-services/ (last visited October 14, 2024).

186. 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.[81]

187. 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.[82]

188. Within months thereafter, in September 2023, 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 which it was determined that PGT-A was not currently recommended for routine clinical use.[83]

189. 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.[84]

190. 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".[85]

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[81] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).
[82] *Id*.
[83] Lundin, K., et al., *Good Practice Recommendations on Add-Ons in Reproductive Medicine*. Human Reproduction. Vol, 38, Issue 11. November 2023.
[84] *Id.*
[85] 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.

191. Patients with unexplained recurrent implantation failure are precisely the vulnerable and unsuspecting consumers that Defendants target and market to with respect to PGT-A as set forth herein.

192. For example, Ovation Fertility's marketing included the following affirmative statements:[86]

Who benefits from PGT-A?

PGT-A is becoming a standard part of every IVF cycle at many leading fertility practices and across the world. It is also recommended in certain cases to increase the chance of IVF success, or to help diagnose and overcome hidden causes of infertility in:

- Women of advanced maternal age (typically 35 or older)
- Women or couples with unexplained infertility
- People who have experienced previous IVF failure
- Women who have had recurrent miscarriages
- Women who have had a previous abnormal pregnancy or a child with a genetic condition

193. 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;

[86] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited March 31, 2023).

c. Trials targeting older women found no improvement in the cumulative live birth rate after PGT-A.[87]

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

195. Defendants have not conducted such studies and continued to market and promote the benefits of PGT-A to consumers without having proof of same.

196. 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).[88]

197. 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.[89]

198. 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.[90]

199. 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

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[87] 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.

[88] 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.

[89] *Id.*

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

United Kingdom's government's independent regulator of fertility treatment and research involving human embryos.[91]

200. 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.[92]

201. 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."[93]

202. 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.[94]

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

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

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

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

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

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[91] *Id.*

[92] 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).

[93] *Id.*

[94] *Id.*

e. Embryos can continue to develop successfully after a few cells have been removed, however, removing cells from the embryo may damage it and prevent it from successfully developing.[95]

204. Further research conducted in 2024 supported HFEA's position that PGT-A testing may give the wrong result. A re-biopsy and PGT-A testing of 69 embryos previously determined as abnormal with a result of more than five abnormal chromosomes revealed that 24.6 percent of those embryos were in fact euploid or "normal".[96]

205. 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.[97]

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

207. 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.[98]

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

[96] 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.

[97] 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

[98] 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.

208. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[99]

209. 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.[100]

210. 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.[101]

211. Defendants omitted these material facts in their advertising, promotional, and marketing materials for PGT-A.

212. 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.[102]

213. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[103]

214. Still, Defendants have continued to promote the widespread use of PGT-A to patients of the IVF clinic facilities that US Fertility helps to manage.

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[99] 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.

[100] 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.

[101] *Id.*

[102] *Id.*

[103] *Id.*

215. 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.[104]

216. 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.[105]

217. Despite the lack of supporting research and scientific basis as well as the recommendations of ASRM and SART, Defendants have continued to promote and encourage customers undergoing IVF to use Ovation Fertility's PGT-A services which promote its PGT-A as having benefits and properties that it does not have and have omitted the disclosure of material and relevant information to consumers.

218. Plaintiff 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. False And Misleading Statements To Increase Sales Of PGT-A

219. As a result of 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.

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

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[104] 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.

[105] *Id.*

221. Defendants' false and misleading statements (US Fertility is equally responsible as since March 2023 they have controlled all actions of Ovation Fertility as detailed above) include, without limitation, the following:

a. PGT-A benefits everyone pursuing IVF;

b. PGT-A is greater than 98% accurate;

c. PGT-A increases the chance of pregnancy;

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

e. PGT-A reduces the risk of miscarriage;

f. PGT-A reduces the time to pregnancy;

g. PGT-A increases the chance of IVF success; and

h. PGT-A leads to no more mosaic embryos.

222. Further, in making the above affirmative statements, Defendants concealed and omitted material information from consumers that combines to render these statements deceptive and misleading, 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 state that the above statements are not 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.

223. Defendants' false and misleading promotional statements, which include the following, have played a key role in driving up the use of PGT-A in the United States.

1. Falsely Stating That Ovation Fertility's PGT-A Testing Is Greater Than 98% Accurate

224. The "informed consent" form provided to all consumers by Ovation Fertility misrepresents the accuracy of its PGT-A testing by stating:

> *The risk of misdiagnosis using current PGT-A technologies, while low (<2%), is still present.*

225. Further, reports provided to consumers titled the "Preimplantation Genetic Testing Report" misleadingly state that there is a diagnostic accuracy of 99% for PGT-A.[106]

ACCURACY:
Validation on positive controls demonstrated a diagnostic accuracy of 99% for PGT-A. Data above pertains to samples created using intracytoplasmic sperm injection (ICSI). In samples created with conventional insemination, diagnostic accuracy is reduced.

226. 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.[107]

227. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[108]

228. The testing run by Ovation clearly states that the test "was developed, and its performance characteristics determined by Ovation Genetics Clinical Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA)."

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[106] Ovation Genetics Preimplantation Genetic Testing Report, section titled "Accuracy".
[107] 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.
[108] 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.

2. Falsely Stating That PGT-A Testing Increases The Chance Of Pregnancy

229. On its website which is controlled by US Fertility, Ovation Fertility falsely marketed that PGT-A has been proven to improve the chance of pregnancy and a live birth.[109]

With PGT-A, only those embryos that are chromosomally normal, or euploid, are chosen for transfer, which has been proven to significantly improve the chances of pregnancy and a live birth. Transferring euploid embryos also reduces

230. The website also falsely stated that PGT-A improves pregnancy rates.[110]

may see referred to as preimplantation genetic screening (PGS) or preimplantation genetic diagnosis (PGD), has been proven to improve pregnancy rates and reduce the

chance of miscarriage, and it can also unlock the mystery of unexplained infertility, recurrent miscarriages and failed IVF cycles.

231. Ovation Fertility also misled consumers when it stated that a higher pregnancy rate of 62% versus 50% with traditional PGT-A.[111]

[109] https://www.ovationfertility.com/genetic-testing/pgt-a-testing/ (last visited May 31, 2023).
[110] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited February 2, 2024).
[111] https://www.ovationfertility.com/genetic-testing-options-for-patients/pgt-a-and-pgt-p/ (last visited March 31, 2023).

- Higher pregnancy rates: 62% vs. 50% with traditional NGS*

232. Ovation Fertility knows this statement is false and misleading to consumers as no valid scientific research based on validated studies has concluded this to be accurate.

233. In fact, research in 2016, just after Ovation Fertility announced its new venture to combine some of the nation's largest IVF laboratories into one entity, had already determined that PGT-A decreased live birth rates when compared to IVF without testing.[112]

234. Further, ASRM has repeatedly noted that pregnancy outcomes were similar between conventional IVF and PGT-A.[113]

3. Falsely Stating That PGT-A Testing Reduces The Risk Of Miscarriage

235. On its website, Ovation Fertility repeatedly made the false and misleading statement that PGT-A has been proven to reduce the chance of miscarriage.[114]

(PGS) or preimplantation genetic diagnosis (PGD), has been proven to improve pregnancy rates and reduce the

[112] 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.

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

[114] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited February 2, 2024).

chance of miscarriage, and it can also unlock the mystery of unexplained infertility, recurrent miscarriages and failed IVF cycles.

236. Specifically, Ovation Fertility marketed to consumers a reduced loss rate of only 8% with its PGT-A testing versus 23% with traditional PGT-A. [115]

- Reduced loss rate: 8% vs. 23% with traditional NGS*

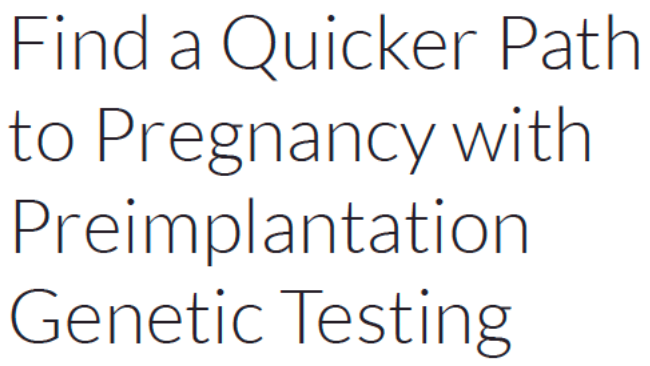
237. Defendants know these statements are false, deceptive, and misleading to consumers as there is no valid evidence to show that PGT-A decreases the chance of miscarriage.

238. For example, researcher Santiago Munne 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.[116]

4. Falsely Stating That PGT-A Testing Reduces The Time To Pregnancy

239. Throughout its marketing, Ovation Fertility misled consumers by selling its PGT-A as providing a "Quicker Path to Pregnancy". [117]

[115] https://www.ovationfertility.com/genetic-testing-options-for-patients/pgt-a-and-pgt-p/ (last visited March 31, 2023).
[116] 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.
[117] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited March 31, 2023).



240. In fact, Ovation Fertility trademarked the term "A Quicker Path to Pregnancy" as part of its marketing, notwithstanding its misleading nature.[118]

241. Defendants know this is misleading and inaccurate as research has shown that utilizing PGT-A does not decrease time to pregnancy.[119]

5. Falsely Stating That PGT-A Testing Benefits All "Hopeful Parents" And Especially Those Of Advanced Maternal Age

242. Ovation Fertility stated on its website that PGT-A is for all individuals using IVF, especially those of advanced maternal age, which is a false, deceptive, and misleading statement,

[118] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited March 31, 2023).
[119] *See, e.g.*, Palmer, M., et al., Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy. Fertility and Sterility. Vol. 114, Issue 3. September 2020.

which also omits material information concerning the known scientific study results detailed above.[120]

PGT can be valuable for all hopeful parents using IVF to conceive and is especially useful and highly recommended for certain groups of patients, such as those with:

- Advanced maternal age (35 years or older)
- Previous IVF failure
- A previous child with a genetic condition
- A history of recurrent miscarriages
- Unexplained infertility
- Family history of genetic disease

243. These false, deceptive, and misleading claims above are contradicted by scientific evidence as well as the consensus statement of major reproductive health organizations such as ASRM. Researchers looking across age groups have found no benefit for PGT-A regardless of age on cumulative live-birth rate.[121]

244. In addition, research has concluded that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[122]

245. Furthermore, scientists have found that "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative birth rate per cycle start."[123]

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[120] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited March 31, 2023).
[121] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[122] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.
[123] 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.

246. Defendants' false, deceptive, and misleading statements promoting the use of its PGT-A for all is also in direct contradiction to the ASRM, which has concluded that PGT-A has showed no improvement in live birth rates.[124]

5. Falsely Stating That PGT-A Testing Increases The Chance Of A Healthy Baby And Leads To No More Mosaic Embryos

247. Defendants are aware that they are advertising PGT-A to vulnerable consumers pursuing IVF.

248. Ovation Fertility marketed its PGT-A testing as having a higher accuracy which means no more mosaic embryos. [125]

- No more mosaics: Higher accuracy enables actual euploid and aneuploid reporting; PGT-A+ provides origin of aneuploidy

249. This claim is false, deceptive, and misleading as research has proven that trophectoderm biopsy cannot predict the inner cell mass.[126]

250. Further, research has determined that PGT-A does not change the embryo.[127]

251. Therefore, it is impossible for PGT-A testing to result in no more mosaic embryos.

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

[125] https://www.ovationfertility.com/genetic-testing-options-for-patients/pgt-a-and-pgt-p/ (last visited March 31, 2023).

[126] 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).

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

252. Ovation Fertility also marketed its PGT-A as providing the best chance of creating a healthy pregnancy, which is also false, deceptive, and misleading:[128]

> fertility care providers, and represent the best available genetic tests to support selection of embryos with the best chance of creating a healthy pregnancy.

253. Research has shown that there is a threefold increase in live birth rates for those that did not have PGT-A testing performed and a reduction in live birth rates for the group where PGT-A was utilized.[129]

254. Thus, Defendants are misleading consumers by saying that PGT-A testing provides the best chance of a healthy pregnancy and leads to no more mosaic embryos.

6. Falsely Stating That PGT-A Testing Increases The Chance Of IVF Success

255. Ovation Fertility's website proclaimed that PGT-A increases the chance of IVF success.[130]

Who benefits from PGT-A?

PGT-A is becoming a standard part of every IVF cycle at many leading fertility practices and across the world. It is also recommended in certain cases to increase the chance of IVF success, or to help diagnose and overcome hidden causes of infertility in:

[128] www.ovationfertility.com/genetic-testing-options-for-patients/comprehensive-pgt/ (last visited March 7, 2024).
[129] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).
[130] https://www.ovationfertility.com/genetic-testing-options-for-patients/ (last visited March 31, 2023).

256. Defendants know this statement is misleading to consumers as there is no validated and scientifically supportable evidence to show that PGT-A improves the success of IVF, which has been further confirmed by major reproductive health organizations such as ASRM as detailed below and explicitly refuted by major insurance companies.

257. In fact, research in 2016 had already shown that PGT-A *decreased* live birth rates when compared to IVF without testing.[131]

7. Common Misrepresentations In Ovation Fertility's Uniform Patient Consent Form Reviewed By All Customers

258. Ovation Fertility provides a uniform Informed Consent Preimplantation Genetic Testing (PGT-A) for Aneuploidy Form ("Consent Form") that all customers are asked to sign prior to obtaining their PGT-A testing. The testing results that follow to the patient state that they are issued by Ovation Genetics.

259. The Consent Form states on the top of Page 1 that it is issued by Ovation Fertility.

260. The Consent Form states that "PGT-A can determine if an embryo has a chromosomal aneuploidy, so the chance of a miscarriage or conceiving a baby with a chromosomal aneuploidy is reduced with PGT-A."

261. The Consent Form also states that "The risk of misdiagnosis using current PGT-A technologies, while low (<2%), is still present. PGT-A testing is used to enhance pregnancy success."

[131] 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.

262. 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 uniformly rely – and do rely on – concerning their decision to purchase and utilize PGT-A.

263. These statements in the Consent Form mirror those that are discussed above and herein, and include, for example that (a) PGT-A testing is greater than 98% accurate, (b) PGT-A testing increases the chance of pregnancy, (c) PGT-A testing leads to a higher chance of a healthy pregnancy, and (d) PGT-A testing reduces the risk of miscarriage.

D. Additional Material Omissions

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

265. Further, Defendants omit to inform consumers that damage to embryos caused by biopsy may be the reason for unsuccessful IVF outcomes following PGT-A.[132]

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

267. Defendants have failed to inform consumers concerning the numerous scientific studies evidencing issues with PGT-A, as well as the opinions of major reproductive health organizations such as ASRM detailed above that conclude that PGT-A is unproven.

[132] 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).

268. Ovation Fertility informs consumers that a PGT-A biopsy is taken from the trophectoderm but does not inform consumers that science shows that the inner cell mass is more effective in self-correcting than the trophectoderm. Chromosomal abnormal embryos may self-correct downstream, which renders earlier biopsy results irrelevant, but Defendants omit this from consumers on Ovation Fertility's website and Consent Form, and otherwise.

269. The trophectoderm – from which the placenta develops – has been known to contain aneuploid cells even in chromosomally normal pregnancies, while the fetus, arising from the inner cell mass, remains chromosomally normal. Defendants omit this from consumers on Ovation's Fertility's website and Consent Form, and otherwise.

270. 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 as well on Ovation Fertility's website and Consent Form, and otherwise.

271. Further, with respect to self-correction that occurs in human embryos, Defendants fail to inform consumers on Ovation Fertility's website and Consent Form, and otherwise, that biopsy at the blastocyst stage may not accurately reflect the final chromosomal outcome of embryos.

272. Defendants also omits to inform consumers concerning the false positives and false negatives that occur with PGT-A, and the actual rates of false positives and false negatives shown through scientific study. Instead, it is represented that Ovation Fertility has a "state-of-the-art

genetics laboratory" and that it represents the "best available genetic tests to support selection of embryos with the best chance of creating a healthy pregnancy."[133]

273. Ovation Fertility further represents that it uses the "most advanced technology available" and "the most advanced PGT options available".[134]

274. In fact, Defendants promote PGT-A testing and their platform as "the most comprehensive preimplantation genetic testing available to aid in the selection of optimal-quality embryos to transfer as part of IVF".[135]

275. The scientific director of Ovation Fertility further misleadingly states that its testing would benefit patients by providing them with technology that had tremendous advantages over standard platforms.[136]

276. Scientific research has found concordance rates of reanalysis with original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results, and 42.6% for mosaic aneuploid results.[137]

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

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[133] www.ovationfertility.com/genetic-testing-options-for-patients/comprehensive-pgt/ (last visited March 7, 2024).
[134] http://www.ovationfertility.com/genetic-testing/ (last visited June 27, 2024).
[135] https://www.ovationfertility.com/pressreleases/ovation-fertility-licenses-genomic-predictions-lifeview-pgt-platform/ (last visited March 20, 2024).
[136] https://www.lifeview.com/20221020-Ovation_Fertility_Licenses.html (last visited March 20, 2024).
[137] Marin, D., et al., *Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance data.* Prenatal Diagnosis. Vol. 4, Issue 5. Pp. 545-553. April 2021.
[138] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocriniology (2016) 14:54.

278. Instead of informing consumers how errors with PGT-A testing can severely impact consumers, Ovation Fertility advises consumers against the transfer of embryos determined to be "abnormal."

279. Specifically, Ovation Fertility's Consent Form states that embryos defined as "aneuploid" through PGT-A will not be transferred and that embryos reported as "abnormal" are not suitable for transfer. The Consent Form specifically states, "Embryos defined as aneuploid through PGT-A will not be selected for uterine transfer…"

E. Members of US Holdings, LLC, The Parent Of US Fertility, Have Also Utilized False and Misleading Statements To Increase Sales of PGT-A

280. In addition to the false and misleading marketing, advertising, and promotion of PGT-A by Defendants, members of US Fertility Holdings, LLC also utilize similar false, deceptive, and misleading statements to promote sales of PGT-A testing, while engaging in the critical material omissions set forth above.

281. For example, Fertility Centers of Illinois, PLLC, which is a member of US Fertility Holdings, LLC, misleadingly and falsely states on its website that PGT-A results in a significant increase in pregnancy rates and a decrease in miscarriage and that PGT-A has a high accuracy rate of 99%. The website includes that "All PGT-A testing also uses the most advanced technology available, known as Next-Generation Sequencing (NGS), which can detect chromosomal issues such as aneuploidies, mosaicism, and segmental alterations. NGS offers a high accuracy rate of 99%."[139]

282. Similarly, Reproductive Medicine Associates of New York, LLP, which is a member of US Fertility Holdings, LLC, misleadingly and falsely states on its website that PGT-A

[139] https://www.fcionline.com/treatments/genetic-testing/ (last visited October 14, 2024).

increases the chance of a healthy pregnancy, increases the likelihood of a successful transfer, and reduces the chance of pregnancy loss.[140]

283. Reproductive Science Center of SF Founder Holdings, Inc., which is a member of US Fertility Holdings, LLC, misleadingly and falsely states on its website that PGT-A testing results in fewer failed IVF cycles, lowers the risk of miscarriage, and greatly increases the chance of having a healthy child.[141]

284. SGF Holdings, LLC, which is a member of US Fertility Holdings, LLC, misleadingly and falsely states on its website that PGT-A testing determines which embryos have the correct number of chromosomes, increases the chance of implantation and live birth, and decreases the risk of miscarriage.

285. Members of US Fertility Holdings, LLC promote PGT-A testing by Ovation Fertility.

F. PGT-A Testing Has Enriched Defendants

286. The average cost of PGT-A is approximately $5,000 per IVF cycle and is an "add-on" expense to IVF not usually covered by insurance. For this reason, PGT-A is an extremely lucrative business for Defendants.

287. Invoices to patients are often issued by Ovation Genetics and sent by Ovation Fertility, which operate jointly together, and payment benefits and enriches all Defendants, which have operated together jointly as one combined platform controlled by US Fertility.

288. The Ovation Fertility Consent Form provides, in pertinent part: "The finance department at your IVF clinic will advise you of the fees for PGT-A. These fees are in addition to

[140] https://www.rmany.com/treatment-options/pgt-genetics (last visited October 14, 2024).
[141] https://rscbayarea.com/treatments/pgt.html (last visited October 14, 2024).

the cost of the IVF cycle. Although the risks associated with PGT-A are low, you are responsible for any additional medical costs incurred as a result of potential complications. Insurance coverage for PGT-A may not be available, and you are personally responsible for payment, including hospital, laboratory and physician fees."

289. Despite all the scientific literature concerning PGT-A set forth above, Ovation has marketed and advertised PGT-A to consumers as greater than 98% accurate, increasing the chance of pregnancy, decreasing the chance of miscarriage, leading to a higher chance of a healthy pregnancy, reducing the time to pregnancy, benefiting everyone, and reducing the number of mosaic embryos. Each of these claims are false and misleading, lack valid scientific support, and are made while Ovation at the same time omits and withholds critical material information that is necessary to make these statements not misleading.

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

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

291. Plaintiffs and Class members were injured at the time of sale and would not have purchased PGT-A from Ovation 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 affirmative misstatement and omission by Ovation separately and independently gives rise to each of the causes of action alleged below.

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

1. Rachel Klosowski and Adam Klosowski's Purchase of PGT-A Testing

293. Plaintiffs Rachel Klosowski and Adam Klosowski purchased PGT-A testing from Ovation in August 2023, September 2023, and October 2023 based upon the false, deceptive, and misleading statements described herein, including that PGT-A is greater than 98% accurate, increases the chance of pregnancy, decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, and reduces the time to pregnancy.

294. The Klosowskis' further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

295. The Klosowskis' relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $7,500 plus additional costs for PGT-A testing, which they would not have purchased absent the false and misleading misrepresentations and omissions.

2. Michelle Schafer's Purchase of PGT-A Testing

296. Plaintiff Schafer purchased PGT-A testing from Ovation in February 2023 and June 2023 based upon Ovation's false, deceptive, and misleading statements detailed herein, including that PGT-A is greater than 98% accurate, increases the chance of pregnancy, decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, and reduces the time to pregnancy.

297. Plaintiff Schafer further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

298. Plaintiff Schafer relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $8,350 plus additional costs for PGT-A testing, which she would not have purchased absent the false and misleading misrepresentations and omissions.

3. Laura Mendoza's Purchase of PGT-A Testing

299. Plaintiff Mendoza purchased PGT-A testing from Ovation in November 2020 based upon Ovation's false, deceptive, and misleading statements detailed herein, including that PGT-A testing is greater than 98% accurate, increases the chance of pregnancy, decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, reduces the time to pregnancy, and leads to no more mosaics.

300. Plaintiff Mendoza further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

301. Plaintiff Mendoza relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $4,000 plus additional costs for PGT-A testing, which she would not have purchased absent the false and misleading misrepresentations and omissions.

4. Dori Shick's Purchase of PGT-A Testing

302. Plaintiff Shick purchased PGT-A testing from Ovation in May 2022 based upon Ovation's false, deceptive, and misleading statements detailed herein, including that PGT-A testing is greater than 98% accurate, increases the chance of pregnancy, decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, and reduces the time to pregnancy.

303. Plaintiff Shick further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

304. Plaintiff Shick relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $1,200 plus additional costs for PGT-A testing, which she would not have purchased absent the false and misleading misrepresentations and omissions.

5. Soupharack Vannasing's Purchase of PGT-A Testing

305. Plaintiff Vannasing purchased PGT-A testing from Ovation in November 2022 based upon Ovation's false, deceptive, and misleading statements detailed herein, including that

PGT-A testing is greater than 98% accurate, increases the chance of pregnancy, decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, and reduces the time to pregnancy.

306. Plaintiff Vannasing further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

307. Plaintiff Vannasing relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $2,080 plus additional costs for PGT-A testing which she would not have purchased absent the false and misleading misrepresentations and omissions.

6. Lauren Teverbaugh Purchase of PGT-A Testing

308. Plaintiff Teverbaugh purchased PGT-A testing from Ovation in June 2022, July 2022, April 2023, and September 2023 based upon Ovation's false, deceptive, and misleading statements detailed herein, including that PGT-A testing is greater than 98% accurate, increases the chance of pregnancy, decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, and reduces the time to pregnancy.

309. Plaintiff Teverbaugh further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

310. Plaintiff Teverbaugh relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $7,500 plus additional costs for PGT-A testing which she would not have purchased absent the false and misleading misrepresentations and omissions.

7. Janine Carlin and Jonathan Carlin's Purchase of PGT-A Testing

311. Plaintiffs Janine Carlin and Jonathan Carlin purchased PGT-A testing from Ovation in August 2023 based upon Ovation's false, deceptive, and misleading statements detailed herein, including that PGT-A testing is greater than 98% accurate, increases the chance of pregnancy,

decreases the chance of miscarriage, leads to a higher chance of a healthy pregnancy, and reduces the time to pregnancy.

312. Plaintiffs Carlin further purchased PGT-A testing based upon Ovation's omissions of material information as detailed above.

313. Plaintiffs Carlin relied upon Ovation's false and misleading misrepresentations and omissions and paid approximately $4,400 plus additional costs for PGT-A testing, which she would not have purchased absent the false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

314. 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").

315. In addition, the Klosowskis' bring this lawsuit on behalf of a class of all persons in the State of North Carolina who purchased PGT-A testing from Defendants (the "North Carolina Class").

316. In addition, Plaintiffs Schafer and Mendoza bring this lawsuit on behalf of a class of all persons in the State of California who purchased PGT-A testing from Defendants (the "California Class").

317. In addition, Plaintiffs Teverbaugh and the Carlins' bring this lawsuit on behalf of a class of all persons in the State of Louisiana who purchased PGT-A testing from Defendants (the "Louisiana Class").

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

319. In addition, Plaintiff Vannasing brings this lawsuit on behalf of a class of all persons in the State of Nevada who purchased PGT-A testing from Defendants (the "Nevada Class").

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

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

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

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

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

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

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

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

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

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

f. The date of Defendants' knowledge;

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

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

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

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

k. Whether Defendants were unjustly enriched as a result of their conduct.

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

325. **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.

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

327. **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.

328. 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.

329. **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

330. All Nationwide Class members have a nexus with Delaware, the state where Defendants are formed as limited liability companies, such that Delaware law should apply to all of them except for any state-specific claims identified below. In the alternative, if the Court finds that Delaware law does not apply to Class members residing outside of Delaware for any reason, then Class members residing outside of Delaware assert their claims under the laws of their respective states of residence.

COUNT I
Violation of North Carolina's Unfair Deceptive Trade Practices Act, N.C. Gen. Stat. Ann. § 75-1, *et seq*
(On behalf of Plaintiffs Klosowski and the North Carolina Class against Defendants)

331. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

332. Plaintiffs Klosowski bring this count individually and on behalf of the North Carolina Class.

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

334. The representations and omissions detailed herein 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 are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

338. 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 PGT-A testing but for Defendants' false promotion as detailed throughout this Complaint.

339. Consumers have thus paid unnecessarily for PGT-A and such injury is not outweighed by any countervailing benefits to consumers or competition.

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

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

342. Plaintiffs and the North Carolina Class are entitled to recover treble damages and other appropriate relief, as alleged below pursuant to N.C. Gen. Stat. Ann. §75-16.

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

343. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

344. 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."

345. 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.

346. 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 promoting PGT-A and/or by making misleading statements and omitting material information regarding the accuracy and reliability of PGT-A, and/or by making the additional false and misleading statements and omissions as alleged herein.

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

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

349. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiffs 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.

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

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

352. Plaintiffs and California Class members are reasonable consumers who, based on Defendants' conduct and/or misleading statements and omissions as alleged herein, did not expect that Ovation's PGT-A would not be consistent with those statements.

353. 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.

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

355. 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.

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

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

358. Plaintiffs 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 Defendant from continuing their unfair practices.

COUNT III
Violations of California Unfair Competition Law,
Cal. Bus. & Prof. Code §§ 17200, *et seq*. (Unlawful Prong)
(On behalf of Plaintiffs Schafer and Mendoza and the California Class against Defendants)

359. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

360. 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 violated the UCL.

361. Ovation, which is controlled by US Fertility as set forth herein, has committed "unlawful" acts and practices including breach of the implied warranty of merchantability, breach of the implied warranty of usability, California's Consumer Legal Remedies Act, fraud, and unjust enrichment.

362. More specifically, Ovation breached applicable warranties in connection with the marketing and sale of its PGT-A. Defendants marketed and promoted PGT-A testing, and Ovation sold it, to Plaintiffs and the California Class members, knowing that PGT-A testing was unproven, inaccurate, and unreliable.

363. Plaintiffs 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 Ovation had they known that it was unproven, inaccurate, and unreliable.

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

COUNT IV
Violations of California's Consumer Legal Remedies Act,
Cal. Civ. Code § 1750, *et seq*.
(On behalf of Plaintiffs Schafer and Mendoza and the California Class against Defendants)

365. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

366. Plaintiff Schafer and Plaintiff Mendoza are "consumers" as defined by Civil Code §§ 1761(d) and 1770 and have engaged in "transaction[s]" as defined by Civil Code §§ 1761(e) and 1770.

367. Defendants are a "person" as defined by Civil Code §§ 1761(c) and 1770 and has provided "services" as defined by Civil Code §§ 1761(b) and 1770.

368. 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.

369. Defendants' acts and practices violated the Consumers Legal Remedies Act because they failed to disclose information that was material to Plaintiffs 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.

370. Defendants had ample means and opportunities to alert Plaintiffs and California Class members that PGT-A was not supported by science as claimed by Ovation's advertising, marketing, and promotional materials. US Fertility, which has owned Ovation since acquiring it in 2023, helps to manage and provides various services to the IVF clinics that promote Ovation's PGT-A, and had the opportunity to disclose the facts about PGT-A to those clients' customers.

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

372. Defendants had a duty to accurately disclose the validity of PGT-A, the unsupported nature of the claims made by Ovation to consumers, and to accurately disclose the current state of science regarding PGT-A. Defendants had a duty to, through their advertising, marketing, and/or promotional activities with respect to PGT-A, not mislead consumers.

373. 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.

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

375. Plaintiffs 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.

376. Plaintiffs 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.

377. 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.

378. Pursuant to Civil Code § 1782(a), on July 9, 2024, Plaintiffs, individually and on behalf of the Class, sent a letter 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, Plaintiffs and the California Class Members seek money damages under CLRA.

COUNT V
Violations of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. § 51:1401, et seq.
(On behalf of Plaintiffs Teverbaugh and Carlin and the Louisiana Class against Defendants)

379. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

380. Plaintiffs Teverbaugh and Carlin bring this count individually and on behalf of the Louisiana Class.

381. Plaintiffs are "consumers" within the meaning of La. Rev. Stat. Ann.§ 51:1402.

382. Defendants are engaged in "trade" and "commerce" within the meaning of La. Rev. Stat. Ann.§ 51:1402 as they promote and/or sell Ovation and Ovation's PGT-A testing for sale to consumers within the State of Louisiana.

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

384. Defendants' acts and practices are unlawful in violation of 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).

385. Plaintiffs and Class Members suffered ascertainable loss of money because of the use or employment by Defendants of an unfair or deceptive method, act, or practice declared unlawful by La. Rev. Stat. Ann.§ 51:1405.

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

387. 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 PGT-A testing but for Defendants' false promotion as detailed throughout this Complaint.

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

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

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

391. Plaintiff and the Louisiana Class are entitled to recover damages and other appropriate relief, as alleged below pursuant to La. Rev. Stat. Ann.§ 51:1409.

COUNT VI
Violations of Texas Deceptive Trade Practices Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq*
(On behalf of Plaintiff Shick and the Texas Class against Defendants)

392. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

393. Plaintiff Shick brings this count individually and on behalf of the Texas Class.

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

395. Defendants are engaged in "trade" and "commerce" within the meaning of Tex. Bus. & Com. Code Ann. § 17.45 as they market, promote and sell PGT-A testing for sale to consumers within the State.

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

397. Defendants' conduct is substantially injurious to consumers. Such conduct has, and continues to cause, substantial economic damages to consumers because consumers would not have paid for PGT-A testing but for Defendants' false, misleading, and deceptive acts and practices as detailed throughout this Complaint.

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

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

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

401. Plaintiff provided notice to Defendants on July 9, 2024 of their claim under the Texas Deceptive Trade Practices Consumer Protection Act.

402. Plaintiff and the Texas Class are entitled to recover damages and other appropriate relief, as alleged below pursuant to Tex. Bus. & Com. Code Ann. §17.50.

COUNT VII
Violations of the Nevada Consumer Protection Act,
Nev. Rev. Stat. §§ 598.0903 and 41.600, *et seq*.
(On behalf of Plaintiff Vannasing and the Nevada Class against Defendants)

403. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

404. Plaintiff Vannasing brings this count individually and on behalf of the Nevada Class.

405. Plaintiff is a "consumer" within the meaning of Nev. Rev. Stat. § 598.0903.

406. Defendants engaged in deceptive trade practice by knowingly making false representations in the sale and advertising of goods. Nev. Rev. Stat. § 598.0915.

407. Defendants engaged in deceptive trade practice by making an assertion of scientific, clinical or quantifiable fact in an advertisement which would cause a reasonable person to believe that the assertion is true, unless, at the time the assertion is made, the person making it has possession of factually objective scientific, clinical or quantifiable evidence which substantiates the assertion. Nev. Rev. Stat. § 598.0925.

408. Defendants' acts and practices are deceptive trade practice under Nev. Rev. Stat. § 598.0923. 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).

409. Defendants engaged in consumer fraud. Nev. Rev. Stat. § 41.600.

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

411. 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 PGT-A testing but for Defendants' false promotion as detailed throughout this Complaint.

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

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

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

415. Plaintiff and the Nevada Class are entitled to recover damages and other appropriate relief, as alleged below pursuant to Nev. Rev. Stat. §41.600.

COUNT VIII
Breach of the Implied Warranty of Merchantability
(On behalf of Plaintiffs and the Class Against Defendants)

416. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

417. By operation of law, Ovation, as the provider and seller of PGT-A testing, for the entire relevant time period, and since March 2023 when it began to be controlled by US Fertility, impliedly warranted to Plaintiffs and the Class that PGT-A was of merchantable quality and fit for its ordinary and intended use.

418. 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*.

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

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

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

422. 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, some of which are members of US Fertility Holdings, LLC. The agreements between Defendants and Plaintiffs' and Class members' IVF clinics to use Ovation's PGT-A testing were designed and intended for the benefit of Plaintiffs and Class members to make decisions about their embryos and fertility treatment. Defendants understood that Plaintiffs and Class members would require that Ovation's PGT-A testing provide reliable and accurate information regarding their embryos and Defendants delivered Ovation's PGT-A tests to Plaintiffs and Class members understanding the need to meet these requirements.

423. 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 IX
Breach of the Implied Warranty of Usability
(On behalf of Plaintiffs and the Class Against Defendants)

424. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

425. By operation of law, Ovation, as the seller and provider of PGT-A testing for the entire relevant time period, and since March 2023 when it began to be controlled by US Fertility, warranted to Plaintiffs and the Class through their statements that PGT-A was usable for its ordinary and intended use.

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

427. 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*.

428. Ovation, by its advertising, marketing, and sale of PGT-A to Plaintiffs and the Class, impliedly warranted that Ovation's product is usable.

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

430. Ovation 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.

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

432. 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, some of which are members of US Fertility Holdings, LLC. The agreements between Defendants and Plaintiffs' and Class members' IVF clinics to use Ovation's PGT-A 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 Ovation delivered their PGT-A tests to Plaintiffs and Class members understanding the need to meet these requirements.

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

434. 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 X
Fraud
(On behalf of Plaintiffs and Class Members against Defendants)

435. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

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

a. PGT-A testing benefits everyone pursuing IVF;

b. PGT-A testing is greater than 98% accurate;

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

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

e. PGT-A testing reduces the risk of miscarriage;

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

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

h. PGT-A testing leads to no more mosaic embryos.

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

438. Defendants knew or should have known that Ovation's misrepresentations and omissions were false and misleading and intended for consumers to rely on.

439. 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 alleged herein.

440. Defendants' false and deceptive statements and omissions induced Plaintiffs and Class members to purchase PGT-A from Ovation.

441. Defendants' advertising, marketing, and/or 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.

442. Absent Defendants' conduct, Plaintiffs and Class members would not have purchased PGT-A 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 that Ovation advertised.

443. 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 XI
Fraud by Concealment
(On behalf of Plaintiffs and Class Members against Defendants)

444. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

445. Defendants intentionally suppressed and concealed material facts about Ovation's 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 disclose these material facts to Plaintiffs and Class members.

446. 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.

447. 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 testing and incurred economic costs.

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

449. 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.

450. Defendants had a duty to disclose the truth about PGT-A because, through Defendants' advertising, marketing, website statements, Ovation's consent form, and/or promotional conduct aimed at 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.

451. 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.

452. Each Plaintiff and Class member was exposed to the representations and omissions described herein prior to and immediately after purchase. Each Plaintiff and Class member saw the same generalized representations as detailed herein, that were repeated by Ovation throughout their promotional materials. None of the informational sources that Plaintiffs and Class members

were provided, including advertisements, websites, Ovation's Consent Form, or other promotional activity by US Fertility, including in its role as a partner and manager of various IVF clinics, indicated the full truth about PGT-A testing as detailed herein.

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

454. 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.

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

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

457. 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 XII
Unjust Enrichment
(On behalf of Plaintiffs and Class Members against Defendants)

458. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

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

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

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

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

463. Ovation accepted monetary benefits from Plaintiffs and Class members at the detriment of Plaintiffs and Class members, which profits have flowed up to Defendant US Fertility.

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

465. 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 because of their wrongful conduct.

466. 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 Ovation.

Count XIII
Breach of Express Warranty
(On behalf of Plaintiffs and the Class Against Ovation)

467. Plaintiffs incorporate by reference all preceding allegations as if set forth fully here.

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

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

470. Through its marketing and advertising, including via its website, Consent Form, and as alleged herein, Ovation represented that its PGT-A is over 98% accurate and reliable, among other representations detailed here.

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

472. Ovation's PGT-A testing is therefore not what it was represented to be.

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

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

PRAYER FOR RELIEF

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

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

b. Award Plaintiffs and the Class members 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 provide notice of and disclose the true nature of PGT-A testing;

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

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

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

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

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

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

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

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

DEMAND FOR JURY TRIAL

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

Dated: October 31, 2024

Respectfully submitted,

/s/ Russell D. Paul
Russell D. Paul (Bar No. 4647)
BERGER MONTAGUE PC
800 N. West Street, Suite 200
Wilmington, DE 19801
Tel.: (302) 691-9545
Email: rpaul@bm.net

Shanon J. Carson (*pro hac vice forthcoming*)
Abigail Gertner (*pro hac vice forthcoming*)
BERGER MONTAGUE PC

1818 Market Street, Suite 3600
Philadelphia, PA 19103
Tel.: (215) 875-4656
Email: scarson@bm.net
Email: agertner@bm.net

Zoe Seaman-Grant (*pro hac vice forthcoming*)
BERGER MONTAGUE PC
1720 W Division
Chicago, IL 60622
Tel: 773-257-0255
Email: zseamangrant@bm.net

Allison S. Freeman (*pro hac vice forthcoming*)
Florida Bar No. 69539
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*)
MA BBO # 352361
JUSTICE LAW COLLABORATIVE LLC
210 Washington St.
No. Easton, MA 02356
Tel.: (508) 230-2700
Email: paula@justicelc.com

Attorneys for Plaintiffs

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: Class Action Suit Alleges PGT-A Testing from Ovation Fertility Is Misleadingly Advertised as Effective, Accurate