UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

J.G., individually and on behalf of all others similarly situated,

Plaintiff,

vs.

COOPERSURGICAL, INC.,

Defendant.

CASE NO.:

COMPLAINT (CLASS ACTION)

1. Strict Product Liability—Manufacturing Defect;
2. Strict Product Liability—Failure to Warn;
3. Negligence;
4. Negligent Failure to Recall;
5. Trespass to Chattels;
6. Unjust Enrichment.

(Jury Trial Demanded)

Plaintiff J.G. ("Plaintiff"), by and through her undersigned counsel, bring this Class Action Complaint on behalf of herself and a class of similarly situated individuals against CooperSurgical, Inc. ("Defendant" or "CooperSurgical"). Plaintiff bases her allegations upon her personal knowledge, information and belief, and the investigation of counsel, and allege as follows:

INTRODUCTION

1. Plaintiff brings this Class action against CooperSurgical, the manufacturer of various products used in fertility treatment and women's health. CooperSurgical manufactures a medium for culturing embryos, that is, a solution in which fertilized embryos (starting at just a single cell) develop sufficiently to be transferred to a patient's uterus to facilitate pregnancy.

2. The stage at which embryos are cultured is one of the final stages of an intensive, invasive, emotionally tolling, and expensive fertility treatment program, *in vitro* fertilization or "IVF". IVF is one of the most common fertility treatments for all types of infertility, and has been used to assist patients in obtaining a successful pregnancy for nearly fifty years.

3. IVF is, itself, an emotionally tolling and burdensome process. Patients are strictly monitored and placed on a highly regimented medication schedule, most of which require daily injections, frequent doctors' visits, and numerous ultrasounds, among other procedures. The effort culminates in two significant procedures—the "retrieval", where follicles that have matured in eggs are collected and removed from a patient's ovaries, and the "transfer", when a sufficiently developed embryo (or sometimes, embryos) are placed in the patient's uterus in hopes of facilitating a successful pregnancy and, ultimately, birth.

4. Between the two milestones of retrieval and transfer, fertility clinics perform techniques to fertilize the collected eggs and grow them to the blastocyte stage, where the embryo has sufficiently developed to attempt the transfer. This 5-6 day period occurs at the very end of

IVF, after patients expended time, effort, and significant expense. Patients have already learned the number of fertilized eggs, and for nearly a week, wait to hear if their embryos are ready for transfer.

5. The technique used to culture and grow embryos requires use of a medium, or solution, that provides the appropriate environment and nutrients for the embryos to grow and mature. CooperSurgical's medium, which it calls global Media ("Global Media") is one type of medium developed to culture embryos to the blastocyst stage and prepare them for transfer. It is used by clinics throughout the country as one of the primary "single step" media, which uses a single product as opposed to several products to culture the embryos.

6. Understandably, for patients, this stage is dramatic, tense, and stressful. With hope and pregnancy peeking around the corner, however, hundreds of fertility patients, including Plaintiff and the Class, learned that their embryos were irrevocably damaged and lost in the process.

7. On December 5, 2023, those patients learned why. CooperSurgical's Global Media had been shipped to fertility clinics throughout the United States with a serious and consequential defect. Rather than providing the nutrients and environment required for embryo growth, CooperSurgical's defective Global Media created an environment where embryos would, instead, be destroyed. It issued a notice and, subsequently, a recall of the defective Global Media.

8. However, for Plaintiff and the Class, those patients whose embryos had been cultured with the defective Global Media, the recall was too late. The Global Media had already finally ruined their embryos, thwarting the immense effort and expense of patients' IVF treatment and crushing patients' hopes for pregnancy and a child.

9. Understandably, the emotional toll of losing an embryo at the very last stage before transfer is significant, and such loss is associated with high rates of depression, anxiety, and other mental health issues. Moreover, patients must repeat the difficult, burdensome, and costly IVF treatment to pursue a pregnancy or abandon their hopes altogether. Even those who do repeat IVF face the chance that no eggs will be retrieved or fertilized.

10. CooperSurgical knew or should have known of the significant economic and emotional toll imposed on fertility patients through its manufacturing, selling, and shipping of defective Global Media to fertility clinics. Given that substantial and foreseeable risk, CooperSurgical had a duty to reasonably manufacture its Global Media and implement quality control measures to inspect, test, and ensure that its media met the required specifications.

11. CooperSurgical, however, breached that duty, failing to inspect the nearly 1,000 bottles of its defective Global Media that were manufactured and prepared for use on fertility patients' embryos. Indeed, CooperSurgical failed to identify the issue on its own at all, becoming aware that its Global Media was destroying embryos from its customers. By that point, irreparable damage was done to likely hundreds of embryos that were impaired, damaged, and lost.

12. Plaintiff brings claims on behalf of a Nationwide Class and a Connecticut Subclass of fertility patients whose embryos were impacted by the defective Global Media. Plaintiff and the Class seek to recover for the expense of IVF wasted when, at the very last stages, CooperSurgical's defective solution ruined the embryos that were developed, matured, and fertilized throughout the burdensome process. Plaintiff also seeks to recover for her lost and damaged embryos, which were irreparably harmed by the Global Media, ruining the opportunity to bring those embryos to life. Finally, Plaintiff seeks to recover for the significant and lasting emotional harm caused by the loss of one or more embryos. Plaintiff brings claims for Strict

Liability for a Manufacturing Defect, Strict Liability for Failure to Warn, Negligence, Negligent Failure to Recall, Trespass of Chattel, and Unjust Enrichment.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d). As required under CAFA, members of the proposed class are citizens of a State different from the Defendant, less than two thirds of the proposed class members reside within the same state as the Defendant, and the amount in controversy exceeds $5,000,000, excluding interest and costs, and the proposed class consists of more than 100 individuals.

14. This Court has personal jurisdiction over Defendant. It conducts substantial business in this District and intentionally availed itself of the laws and markets of this District, and Defendant resides in this district. A significant portion of the acts and omissions complained of occurred in the District.

15. Venue is proper in this District under 28 U.S.C. § 1391 because Defendant resides in this District and a substantial part of the events or omissions giving rise to this action occurred in this District.

PARTIES

16. **Plaintiff** J.G. is a resident of Middlefield, Connecticut who obtained fertility treatment, including IVF treatment, from CNY Fertility—Albany. J.G's clinic confirmed it used the defective culturing medium during her IVF treatment to culture her fertilized embryos.

17. **Defendant** CooperSurgical, Inc. is a Delaware corporation with its principal place of business in Trumbull, Connecticut.

FACTUAL ALLEGATIONS

A. In-Vitro Fertilization: the "First Line" Infertility Treatment

18. Each year, hundreds of thousands of patients seek fertility treatment due to complications achieving or maintaining a pregnancy.

19. The National Institutes of Health estimates that 9% of men and 11% of women of reproductive age in the United States experience fertility problems.[1] Approximately 10% of couples are estimated to be unable to conceive naturally,[2] and that number increases with the age of the couples.[3] Some studies suggest that rate of infertility is increasing in the United States, including, in part, because couples now have children later.[4] The rate of infertility for women 30-39 is nearly double the rate of women under 30.[5]

20. With rising infertility and development of new technologies and methods to assist in achieving a pregnancy, the use of fertility treatments has grown.[6] Approximately four in ten adults have used fertility treatments or personally know someone who has, a rate that has grown substantially from just five years ago.[7] As of 2017, over 1 million babies were born in the United States through the use of IVF or other assisted reproductive technologies.[8]

21. Although fertility treatments vary depending on the cause of infertility, one of the most common methods of assisting a pregnancy is in-vitro fertilization or "IVF". IVF is

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[1] https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common
[2] *Id.*
[3] https://www.ccrmivf.com/blog/is-infertility-on-the-rise/
[4] *Id.*
[5] *Id.*
[6] https://www.pewresearch.org/short-reads/2023/09/14/a-growing-share-of-americans-say-theyve-had-fertility-treatments-or-know-someone-who-has/
[7] *Id.*
[8] https://www.pennmedicine.org/updates/blogs/fertility-blog/2018/march/ivf-by-the-numbers

considered the first line therapy for all causes of infertility[9] and is the leading treatment for several prevalent causes of infertility, including damaged fallopian tubes, unexplained fertility issues, and male-factor infertility.[10]

22. IVF is also used by couples seeking to prevent passing on dangerous or deadly genetic conditions. Upon achieving a successful IVF cycle, the blastocytes (or developed embryos) are genetically tested to identify any potentially fatal or debilitating traits. For instance, carriers of genetic conditions seek to avoid passing on fatal disease to their children, including Krabbe Leukodystrophy or Tay-Sachs disease (fatal conditions in newborns or toddlers) or Huntington's disease (fatal in adults in their 30s and 40s). Some couples also use IVF to prevent passing on genetic conditions that impose severe cognitive, behavioral, or physical disabilities.

23. IVF treatment involves intense and invasive monitoring and maintenance of a patient's ovulatory process to stimulate egg development and sophisticated laboratory techniques designed to fertilize the eggs and develop the embryos. All is done with the hope of obtaining embryos that develop sufficiently to the "blastocyte" stage, where they are ready to be transferred to the patient for a potential pregnancy.

24. In all, a single IVF cycle involves several steps: (1) patients take fertility drugs to stimulate ovaries to develop follicles which mature into eggs; (2) patients undergo a "retrieval" surgery, during which the eggs are obtained from the patient; (3) the eggs are then fertilized with sperm, creating embryos; (4) the embryos are cultured using media, with the goal of developing the egg over the course of five days; and (5) the cultured embryos, called blastocytes, are transferred to the patient's uterus in an attempt at pregnancy.

[9] *Id.*
[10] *Id.*

25. IVF requires enormous costs and effort by fertility patients, and often, little to none of the medical costs associated with IVF are covered by insurance. With medical and pharmaceutical costs, the average IVF cycle costs patients upwards of at least $25,000 for a single round of treatment. Many patients, however, also incur costs for additional treatments, including genetic testing of the embryos (because IVF is often used to eliminate or avoid passing on deadly or dangerous conditions) or other surgical procedures.

26. Moreover, IVF requires an intense and lengthy regimen of medications and doctor visits to ensure the follicles develop appropriately, to time the retrieval, and to facilitate fertilization and embryo growth. During a single IVF cycle, patients take medication daily, often including hormones administered through injections. The injections can cause a host of side significant effects, including, among other things, pain and discomfort. While follicles are developing, patients must undergo frequent medical testing and monitoring by their physicians and fertility care team, often requiring daily doctor visits and ultrasounds to monitor the progress of follicle development and to determine the appropriate time for retrieval.

27. Fertility patients may also experience Ovarian Hyperstimulation Syndrome, an extreme response to excess hormones often caused by the medications taken to trigger a retrieval. Ovarian Hyperstimulation syndrome can cause serious complications, including abdominal bloating and pain, blood clots, shortness of breath, rapid weight gain, and even death. Severe cases of Ovarian Hyperstimulation Syndrome require hospitalization, and the symptoms can last several weeks.

28. Even when retrieval and fertilization of the embryos is successful, patients must still wait for the embryos to develop. Over the course of five to seven days, embryos are cultured

in a media created specifically to promote the growth of the embryo into a blastocyte stage. That is, developing the fertilized embryo from a single cell into approximately one hundred cells.

29. Embryos that make it to the blastocyte stage are generally given grades based on the quality and size, so that the embryos most likely to result in a pregnancy may be transferred. When an embryo makes it to the blastocyte stage, it may be: (1) transferred immediately to the patient to attempt a pregnancy, known as a "fresh transfer"; (2) frozen and saved for use in a later attempt at a pregnancy, known as a "frozen transfer"; or (3) be biopsied for genetic testing of the embryo.

30. As such, patients may proceed through several cycles before experiencing a successful pregnancy or pursing an alternative path for building a family, including, for example, adoption or the use of a surrogate. Thus, while patients pay tens of thousands of dollars for a single cycle, patients in some cases incur hundreds' of thousand dollars in IVF treatment costs in hopes of achieving a pregnancy.

31. Consequently, IVF patients face a significant financial burden and emotional toll, due both to the IVF treatment and process itself and to the fertility complications or genetic risk factors that prompt IVF treatment.

B. CooperSurgical's Fertility and IVF-Related Products

32. CooperSurgical claims to be a "leading fertility and women's health company dedicated to putting time on the side of women, babies, and families at the healthcare moments that matter most in life." It offers a "range of innovative medical solutions" to "deliver rapid results, effective treatments, and more options at the right time, so that women, babies, and families experience more possibilities, faster than ever."

33. CooperSurgical represents that it has over 600 products related to women's health and fertility. Via those products, CooperSurgical brings in a significant profit. Indeed, it has experienced twelve consecutive quarters of "double-digit" growth in its fertility division, generating $1.2 billion in revenue last year.[11]

34. Among CooperSurgical's fertility-related products is Global Media, described as the "original single-step, protein-free medium for uninterrupted embryo culture".[12] The medium is "[d]esigned for D1-5 embryo culture and transfer" and "[c]ontains energy substrates and essential amino acids to support embryo growth and development[.]"[13]

35. Global Media is used at the tail end of IVF treatment. That is, CooperSurgical's Global Media is used after all the injections, oral and suppository medications, and doctor appointments led to the development of follicles, retrieval of embryos, and fertilization of the eggs. The last step before transfer—that attempt at a pregnancy—involves the culturing of the fertilized embryos using the Global Media with the hope of growing to the blastocyte stage where a transfer is possible.

36. The goal of Global Media, as with any medium used to culture embryos, is to improve the quality of the developing embryos and increase the chances to develop a viable embryo. The culture medium is designed to mimic the composition of the oviduct and uterine fluids to approximate the natural environment of the developing embryo. Consequently, it contains nutrients the embryos need to develop, including glucose and magnesium, and to maintain the appropriate acidity (measured in pH).

[11] https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/
[12] https://fertility.coopersurgical.com/art_media/global/
[13] *Id.*

37. Although other types of media exist, a "single step" medium, like Global Media, does not need to be changed between fertilization and the embryo transfer. According to one study, embryos can successfully develop in global one step media at least as successfully as in sequential media, where the media change as the embryos develop.[14] However, the authors implored that "it is essential that a high level of quality control exists in the laboratory", noting that "embryos cultured in-vitro [are] exposed to constant stress" and "[s]suboptimal culture conditions force the embryo to undergo adaptations, and thus lead to lower pregnancy and higher abortion rates." Other studies have noted "numerous studies" concluded that "the culture media employed during *in vitro* fertilization (IVF) cycles can influence implantation as well as pregnancy rates due to their effect on embryo quality."[15]

38. CooperSurgical is aware of the significance of high-quality media on embryo development and the risk that poor media have on the development of embryos and the success of a transfer. Indeed, CooperSurgical notes the "500 independent publications" evaluating its media across 15 years of use.[16] Its Instructions for Use, furthermore, explain that the medium is intended to provide conditions "optimal to support the growth and development of human embryos in vitro." It notes the host of nutrients required to help the embryo develop, including "glucose, lactate, pyruvate and all 20 amino acids" and provides strict instructions to ensure the product is effective.

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[14] Irmhild Gruber and Matthias Klein, *Embryo culture media for human IVF: which possibilities exist?*, J. Turkish German Gynecological Association 10 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3939101/.

[15] Mara Simopoulou, *et al*., *Considerations Regarding Embryo Culture Conditions: From Media to Epigenetics*, 32 In Vivo 451 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6000787/.

[16] https://fertility.coopersurgical.com/art_media/global/

C. CooperSurgical's Destructive Media and Recall

39. Although CooperSurgical understood the importance of its Global Media for the development of embryos and the need for high quality media for embryos to develop, CooperSurgical inexplicably failed to produce and distribute a product that met these standards.

40. On December 5, 2023, CooperSurgical issued an Urgent Recall Notice for its Global Media culture product. In the notice, CooperSurgical states that it had "become aware of a sudden increase in complaints" regarding several lots of the Global Media and that "[p]erformance issues may lead to impaired embryo development prior to the blastocyte stage." CooperSurgical instructed its customers (the fertility clinics) to quarantine the affected product and respond to the recall notice to allow for its return.

41. According to regulatory authorities, CooperSurgical issued the recall due to inadequate amounts of magnesium that impaired growth of the embryos to the blastocyst stage. CooperSurgical knew or should have known that magnesium is a critical nutrient required in any culture medium used to develop embryos. It, furthermore, should have known that a lack of magnesium in the Global Media would destroy or irreparably impair the embryos.

42. CooperSurgical, however, failed to adequately monitor its manufacturing systems and processes and to implement quality control measures necessary to ensure that its Global Media was safe and effective for culturing embryos. Indeed, CooperSurgical failed to identify the magnesium deficiency in its product until long after it had been shipped to its clients and used on patients. CooperSurgical learned of the deficiency only after numerous patients suffered unexpectedly high rates of embryo loss, prompting the clinics to issue complaints and concerns to CooperSurgical directly.

43. CooperSurgical failed to properly test or inspect the impacted lots of Global Media. Consequently, approximately 994 bottles of culture medium were affected and 481 bottles of culture medium were purchased by clinics and used across the United States.

D. CooperSurgical's Media Substantially Harmed Fertility Patients

44. CooperSurgical knew or should have known that defective culture media would impose significant emotional pain and suffering on the IVF patients whose embryos used the solution and would furthermore undermine the thousands of dollars and substantial time and effort the fertility patients expended during their IVF cycles.

45. Infertile couples, even before attempting IVF, experience significant anxiety and emotional distress.[17] The IVF process itself also imposes substantial burdens on couples, including significant financial obligations, frequent invasive medical procedures, and substantial stress and anxiety associated with the outcomes of the IVF cycle.

46. At the point where CooperSurgical's Global Media was used, fertility patients had reached the very end of their IVF treatment, with the next stage a transfer and potential pregnancy. With the eggs retrieved and fertilized, patients whose embryos were impaired with CooperSurgical's defective solution were on the last step before being able to attempt a transfer. Consequently, CooperSurgical's defective solution ruined the significant expense, time, and effort the fertility patients to make it to that final step.

47. In addition to the lost value of their IVF treatment, patients also suffered emotional harm, distress, and trauma. The loss of an embryo at the end of IVF treatment eviscerates the hope and excitement of a long-awaited pregnancy. As one practitioner explains, "[l]osing a pregnancy

[17] https://www.cedars-sinai.org/blog/infertility-mental-health.html#:~:text=Studies%20have%20shown%20that%20infertile,feelings%20of%20grief%20and%20loss.

is losing a child" and the anxiety and depression from such a loss can last well over a year.[18] Furthermore, those "feelings can be especially intense if the pregnancy was long-awaited." [19]

48. Over 55% of women present with depression after spontaneous loss of a pregnancy, exacerbating the pain and suffering IVF patients likely experienced from their difficulties with infertility. For those who have experienced recurrent pregnancy loss, many experience severe depression and high levels of stress and their mental health is often negatively impacted even if they obtain a subsequent pregnancy.[20]

49. Ultimately, the loss of an embryo is the loss of a child. It is the loss of a potential pregnancy that, for IVF patients, has been elusive, turning a joyful opportunity into tragic loss. CooperSurgical's Global Media carelessly and tragically ruined the chance of pregnancy and eroded and undermined the pain, suffering, expense, and effort IVF patients incurred for that chance.

50. CooperSurgical understood the emotional trauma of failed pregnancies and infertility. In its blog, CooperSurgical wrote that "[f]ertility issues can affect your self-esteem, relationship, your emotional well-being and may even cause depression."[21] CooperSurgical noted that "[n]egative pregnancy tests, failed cycles" can lead to a host of harms and it listed several, including: (1) anxiety or feeling of anxiousness; (2) changes in appetite, weight, or sleep patterns; (3) difficulty concentrating; (4) difficulty maintaining social relationships; (5) frequently crying; (6) loss of appetite; (7) loss of interest in usual activities and relationships; (8) mood swings; (9)

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[18] https://online.nursing.georgetown.edu/blog/emotional-healing-after-miscarriage-guide-women-partners-family-friends/#:~:text=Depression%20and%20anxiety%20are%20common,the%20pregnancy%20was%20long%2Dawaited.

[19] *Id.*

[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9937061/

[21] https://www.coopersurgical.com/patient-article/can-infertility-support-groups-help-you/

persistent feelings of sadness or guilt; (10) preoccupations with infertility; (11) suicidal thoughts or thoughts of self-harm.[22]

51. CooperSurgical further noted that "[e]specially for women, not only do they have to deal with their grief and come to terms with the miscarriage, but they also have to manage the physical aspect of their loss."[23] CooperSurgical's defective solution, however, imposed the same harm, emotional loss, and grief on Plaintiff and the Class.

E. Cooper Surgical Imposed Significant Harm on Plaintiff

1. Plaintiff J.G.

52. Plaintiff J.G. and her husband obtained fertility treatment at CNY Fertility – Albany in New York. As part of that treatment, J.G. underwent IVF treatment. J.G. completed each stage of IVF treatment, proceeding through the costly, physically taxing, and emotionally burdensome process because it gave the opportunity to fulfill her hope of having a child.

53. During J.G.'s retrieval, her physicians collected four eggs, three of which were successfully fertilized, giving her three chances at a developed embryo to be used in a transfer for an attempted pregnancy.

54. Her fertility clinic used CooperSurgical's Global Media to culture embryos after retrieval. Unfortunately, the clinic received some of the defective batch of media and used that media to culture J.G.'s embryos. Consequently, all her embryos were lost.

55. Plaintiff, understandably, was devastated by the unexpected and complete loss of her embryos, which occurred in the very final stage before transfer. The loss of her embryos not only thwarted the time, effort, and expense of her IVF cycle, it imposed significant emotional harm

[22] *Id.*
[23] *Id.*

and distress due both to the shock and grief over the loss of her embryos and the fear, anxiety, and hopelessness caused from the possibility she may have lost her opportunity to have children.

56. Plaintiff seeks all damages, equitable relief, and remedies available under the law due to the loss of her embryos caused by CooperSurgical's defective Global Media.

CLASS ALLEGATIONS

57. Plaintiff brings this action on behalf of herself and all other similarly situated Class members pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seek certification of the following Nationwide Class:

> All individuals in the United States who had one or more embryos cultured using any of the lots of CooperSurgical's Global Media identified in the February 14, 2024 Class 2 Device Recall global Medium notice.

58. Excluded from the class is CooperSurgical and its subsidiaries and affiliates; all employees of CooperSurgical; all persons who make a timely election to be excluded from the class; government entities; and the judge to whom this case is assigned and his/her immediate family and court staff.

59. In the alternative, Plaintiff proposes the following Subclass:

> **Connecticut Subclass:** All residents of Connecticut who had one or more embryos cultured using any of the lots of CooperSurgical's Global Media identified in the February 14, 2024 Class 2 Device Recall global Medium notice.

60. Plaintiff reserves the right to, after conducting discovery, modify, expand or amend the above Class and Subclass definitions or to seek certification of a class or subclass defined differently than above before any court determines whether certification is appropriate.

61. **Numerosity**. Consistent with Rule 23(a)(1), the members of the Class are so numerous and geographically dispersed that joinder of all Class members is impracticable. Plaintiff believes that there are hundreds of members of the Nationwide Class and in the Subclass.

CooperSurgical's recall notice estimates nearly 1,000 affected bottles of the culture media, with nearly 500 purchased and used by clinics, indicating a significant number of patients impacted by the defective media. Additionally, Class members may be identified through objective means via fertility clinic records. Class members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. mail, electronic mail, internet postings, and/or published notice.

62. **Commonality and Predominance**. Consistent with Fed. R. Civ. P. 23(a)(2) and with 23(b)(3)'s commonality and predominance requirements, this action involves common questions of law and fact which predominate over any questions affecting individual Class members. These common questions include, without limitation:

a. Whether the recalled lots of CooperSurgical's Global Media contained a defect that impaired or destroyed embryos;

b. Whether defect in the recalled lots of CooperSurgical's Global Media resulted from a manufacturing defect;

c. Whether CooperSurgical is strictly liable for failing to timely recall the defective Global Media;

d. Whether CooperSurgical was negligent in failing to identify the defect in its Global Media;

e. Whether CooperSurgical was negligent in maintain adequate safety control and quality control measures in its manufacturing processes;

f. Whether the defect in its Global Media resulted from CooperSurgical's negligence;

g. Whether CooperSurgical owed a duty to Plaintiff and class members to ensure its Global Media was manufactured safely to ensure it would not harm embryos;

h. Whether CooperSurgical knew or should have known that its manufacturing process resulted in or could produce Global Media that was dangerous to embryos;

i. Whether CooperSurgical breached a duty to Plaintiff and the Class by distributing unsafe and dangerous Global Media;

j. Whether CooperSurgical trespassed the chattels of Plaintiff and class members by damaging their personal property—developing embryos—through exposure to Defendant's defective culture media;

k. Whether CooperSurgical was unjustly enriched through its conduct,

l. Whether Plaintiff and the Class suffered harm as a result of CooperSurgical's negligence, wrongful conduct, and other violations, and,

m. Whether Plaintiff and the Class are entitled to relief.

63. **Typicality**. Consistent with Fed. R. Civ. P. 23(a)(3), Plaintiff is a typical members of the Class. Plaintiff and the Class are each persons who obtained IVF treatment that resulted in fertilized eggs cultured using CooperSurgical's Global Media, which impaired, damaged, or destroyed the cultured embryos. Plaintiff's injuries are similar to other Class members and Plaintiff seeks relief consistent with the relief due to the Class.

64. **Adequacy**. Consistent with Fed. R. Civ. P. 23(a)(4), Plaintiff is an adequate representatives of the Class because Plaintiff is a member of the Class and is committed to pursuing this matter against CooperSurgical to obtain relief for themselves and for the Class. Plaintiff has no conflicts of interest with the Class. Plaintiff also has retained counsel competent and experienced in complex class action litigation of this type. Plaintiff intends to vigorously prosecute this case and will fairly and adequately protect the Class's interests.

65. **Superiority**. Consistent with Fed. R. Civ. P 23(b)(3), class action litigation is superior to any other available means for the fair and efficient adjudication of this controversy. Individual litigation by each Class member would strain the court system because of the numerous members of the Class. Individual litigation creates the potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and the court system. By contrast, the

class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court. A class action would also permit customers to recover even if their damages are small as compared to the burden and expense of litigation, a quintessential purpose of the class action mechanism.

CLAIMS

COUNT I

Strict Product Liability—Manufacturing Defect

(on behalf of Plaintiff and the Class)

66. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

67. CooperSurgical is strictly liable to Plaintiff and the Class for harm caused by manufacturing defects in its culture media.

68. CooperSurgical is solely responsible for manufacturing, testing, supplying, distributing, and selling to fertility clinics the Global Media used for Plaintiff's and the Class's IVF treatment.

69. Specifically, CooperSurgical manufactures its Global Media and sells the media to IVF clinics for the express use of culturing embryos obtained via IVF.

70. The Global Media was defective and, thus, unable to fulfill its express purpose of adequately culturing embryos for use in pregnancy. Upon manufacturing by CooperSurgical, its Global Media contained at least one defect that differed from CooperSurgical's intended media, which failed to conform to CooperSurgical's designs, specifications, or other typical units of its media.

71. At the very least, the Global Media lacked sufficient amounts of magnesium, which were not present in the media according to CooperSurgical's specifications. Consequently, the

medium was unable to culture embryos—its express and sole purpose—and instead, impaired, destroyed, or damaged the embryos.

72. CooperSurgical's defective Global Media was used in an attempt to culture Plaintiff's and the Class's embryos. However, due to the manufacturing defect, Plaintiff and the Class lost their embryos or they were irreparably damaged.

73. Plaintiff and the Class suffered substantial harm as a result of the defect, including, among other things, financial and economic harm, loss property, lost opportunity of achieving a pregnancy, and serious and last emotional distress.

74. Plaintiff and the Class seek all remedies available for CooperSurgical's manufacturing defect.

COUNT II

Strict Product Liability—Failure to Warn

(on behalf of Plaintiff and the Class)

75. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

76. Plaintiff brings this strict liability claim against CooperSurgical for its failure to warn.

77. At all relevant times, CooperSurgical engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distribution, and promoting its Global Media for culturing embryos, which, due a defect, was unreasonably dangerous and impaired, damaged, and destroyed the embryos it was intended to culture.

78. Because CooperSurgical researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream

of commerce the Global Media, it had a duty to warn of the risks associated with the use of its Global Media, and to identify and disclose any defects that may cause harm.

79. At all times relevant, CooperSurgical had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure that the Global Media did not cause users and consumers to suffer from unreasonable and dangerous risks.

80. Additionally, CooperSurgical's Global Media had potential risks that CooperSurgical knew or should have known, including that inadequate or missing nutrients would inhibit or entirely prevent embryos from culturing, destroying them or irreparably damaging the embryos. Those risks were known or knowable due to the scientific and medical knowledge that was generally accepted in the scientific community at the time of the manufacture, distribution, or sale of the Global Media, including the hundreds of studies conducted on the Global Media that CooperSurgical acknowledged, reviewed, and noted on its website.

81. CooperSurgical's Global Media, however, was defective and unreasonably dangerous when it left CooperSurgical's possession because it did not contain adequate warnings, including warnings concerning the risk of defect that its formulation lacked sufficient magnesium and would stop embryos development.

82. The risks of a defect in its Global Media were well known to CooperSurgical, including the possibility that it would impair or destroy embryos. CooperSurgical knew and in fact intended that its Global Media would come into contact with embryos and designed the Global Media to provide the nutrients necessary for the embryos to develop further. However, the Global Media presented a substantial and foreseeable danger to embryos should it be misused or contain inadequate nutrients or other defects.

83. Ordinary patients would not have recognized the potential for risks and, in fact, often did not know the brand or type of any solution used to develop the embryos or any details about the method by which the media would facilitate growth or might cause harm. CooperSurgical, thus, had unique knowledge that patients did not, including the adequate quality control measures necessary to prevent or identify any defects in the Global Media.

84. CooperSurgical thus, had an obligation to warn patients but failed to adequately do so or to instruct patients of the potential risks of applying the culture media to embryos. A reasonable manufacturer, distributor, or seller under similar circumstances would have warned of the danger or instructed in the safe use of the culture media.

85. CooperSurgical had constructive notice or knowledge and knew, or in the exercise of reasonable care should have known, that the Global Media was dangerous, had risks, was defective in manufacture or design, including that it would destroy and prevent the development of embryos with which it would come into contact. CooperSurgical, however, failed to adequately warn or instruct of the potential risks of applying its defective culture media to human reproductive material.

86. CooperSurgical knew or should have known that failure to adequately warn about the risks of its Global Media would cause irreparable harm to those embryos that were treated with the Global Media.

87. CooperSurgical's defective medium was used in an attempt to culture Plaintiff's and the Class's embryos. However, due to the manufacturing defect, Plaintiff and the Class lost their embryos, or they were irreparably damaged.

88. Plaintiff and the Class suffered substantial harm as a result of the defect, including, among other things, financial and economic harm, lost property, lost opportunity of achieving a pregnancy, and serious and lasting emotional distress.

89. Plaintiff and the Class seek all remedies available for CooperSurgical's manufacturing defect.

COUNT III

Negligence

(on behalf of Plaintiff and the Class)

90. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

91. At all relevant times, CooperSurgical was responsible for testing, developing, designing, manufacturing, marketing, selling, distribution, inspecting, and promoting its Global Media for culturing embryos, and as such, owed Plaintiff and the Class—those whose embryos would be cultured with the Global Media—a duty to exercise reasonable care.

92. CooperSurgical fully understood that its Global Media was effective when it contained appropriate and precise amounts of various nutrients and the appropriate pH. Consequently, CooperSurgical knew or should have known that failure to ensure the appropriate nutrients or pH would impede the ability of embryos to develop, and could damage or destroy them. CooperSurgical, therefore, knew or reasonably should have known that the Global Media needed to be designed, produced, manufactured, assembled, maintained, inspected, sold, and supplied properly, without defects and with due care, to be safely applied to any embryos.

93. As an entity that is active in fertility treatment products, CooperSurgical also understood the sensitive and emotional nature of the IVF treatment and the emotional burden infertility and IVF impose on patients. Cooper Surgical further knew that Plaintiff and the Class

were particularly susceptible to emotional distress and other emotional and mental harms due to the emotional distress of infertility and IVF treatment. Finally, CooperSurgical understood the financial and physical burden of IVF, and that inadequate media for culturing embryos would undermine the time, effort, and expense of patients' IVF treatment.

94. Given the risks of defective media for the embryos and fertility patients, CooperSurgical owed a duty to Plaintiff and the Class to manufacture, inspect, test, and implement adequate quality controls to ensure that its Global Media was safe and effective for development of human embryos and that the use of the Global Media would not damage, impair, or destroy those embryos.

95. Similarly, because CooperSurgical manufactures products used in fertility treatment and for the culturing of irreplaceable, and sensitive embryos, CooperSurgical assumed a duty to Plaintiff and the Class to ensure any culturing medium was safe.

96. Despite this, CooperSurgical negligently, recklessly, and carelessly failed to use reasonable care in the production, manufacturing, testing, inspecting, and implementing adequate quality control concerning its Global Media. As a result, its Global Media was not fit for use in culturing embryos but instead caused significant and irreparable damage to those embryos. Indeed, although CooperSurgical understands that precise amounts of specific nutrients must be administered to the embryo within the specified pH range, CooperSurgical's product, at the very least, lacked essential elements like magnesium necessary for embryo growth and development.

97. Furthermore, CooperSurgical failed to timely warn its customers of the dangers of its defective media, exacerbating the harm caused by the defect by allowing fertility clinics to continue using the Global Media even when CooperSurgical knew or should have known it would cause harm.

98. CooperSurgical's conduct is a significant departure from what a reasonable entity or person overseeing products used in the development of embryos would do given the high emotional and physical toll of infertility and IVF treatment.

99. As a direct and proximate result of CooperSurgical's negligence, including but not limited to its failure to reasonably produce, manufacture, inspect, test, and implement adequate quality control concerning its Global Media, Plaintiff and the Class were harmed. Specifically, due to the defective Global Media, Plaintiff and the Class suffered, among other things: (1) loss in the economic value of their IVF treatment, which was undermined by the damage to and destruction of the embryos obtained through IVF; (2) loss of the their embryos and the opportunity for a potential pregnancy; (3) emotional harm and distress from the loss of the embryos; and (4) incurred additional financial costs for further fertility or mental health treatment.

100. CooperSurgical's negligence substantially caused Plaintiff's and the Class's harms because the Global Media damaged and destroyed Plaintiff's and the Class's embryos and prevented those embryos from having the opportunity to develop to the blastocyte stage, where they could be transferred for an attempted pregnancy.

101. CooperSurgical acted willfully, wantonly, and with a conscious disregard for the safety of fertility patients, like Plaintiff and the Class, who CooperSurgical knew would submit their embryos for culturing using the Global Media. This is especially true because CooperSurgical knew of the substantial and harmful consequences of unsafe culturing media on the survival of the embryo and the emotional and financial health of the fertility patients.

102. CooperSurgical's defective medium was used in an attempt to culture Plaintiff's and the Class's embryos. Due to CooperSurgical's negligence, Plaintiff and the Class lost their embryos or they were irreparably damaged.

103. Plaintiff and the Class suffered substantial harm as a result of CooperSurgical's negligence, including, among other things, financial and economic harm, lost property, lost opportunity of achieving a pregnancy, and serious and lasting emotional distress.

104. Plaintiff and the Class seek all remedies available for CooperSurgical's negligence.

COUNT IV

Negligent Failure to Recall

(on behalf of Plaintiff and the Class)

105. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

106. CooperSurgical manufactured, tested, distributed, and sold defective bottles of its Global Media to fertility clinics throughout the United States. The defective Global Media was later used during Plaintiff's and the Class's IVF treatment to culture the retrieved and fertilized embryos.

107. CooperSurgical negligently recalled the defective Global Media by failing to timely implement the recall. CooperSurgical knew or reasonably should have known that its Global Media would damage or destroy embryos if the Global Media was not consistent with CooperSurgical's specifications and lacked adequate nutrients or an appropriate pH balance to facilitate embryo growth.

108. CooperSurgical, furthermore, should have known that use of defective Global Media would not only destroy embryonic cells, but would furthermore cause significant harm to fertility patients, both emotionally and financially, and render worthless patients' extensive and burdensome IVF treatments.

109. Consequently, CooperSurgical understood the need to immediately and effectively issue a recall of any defective Global Media to prevent its use in any treatment and to regularly

test and monitor the Global Media it manufactured to ensure it met any required specifications to be an effective solution for embryo growth.

110. Despite that, CooperSurgical continued to sell the defective Global Media, including to fertility clinics that treated Plaintiff and the Class, when it knew or should have known based on feedback from fertility medical providers that its Global Media contained a defect and after it had failed to adequately implement quality control measures necessary to ensure the Global Media satisfied the specifications and was adequately formulated to facilitate embryo growth.

111. A reasonable manufacturer, distributor, or seller facing the same or similar circumstances as CooperSurgical would have recalled the defective culture media to prevent harm to fertility patients or their embryos.

112. CooperSurgical's failure to timely recall the defective culture media caused harm to Plaintiff and Class members. Had CooperSurgical recalled the defective culture media before they were used on Plaintiff's and the Class's embryos, Plaintiff's and the Class's embryos would not have been damaged or destroyed by the media.

113. Because CooperSurgical failed to timely recall its Global Media, the media were used in an attempt to culture Plaintiff's and the Class's embryos. Due to a defect in the Global Media, Plaintiff and the Class lost their embryos or they were irreparably damaged.

114. Plaintiff and the Class suffered substantial harm as a result of CooperSurgical's negligent notice and recall of the defective Global Media, including, among other things, financial and economic harm, lost property, lost opportunity of achieving a pregnancy, and serious and lasting emotional distress.

115. Plaintiff and the Class seek all remedies available for CooperSurgical's negligent failure to recall its Global Media.

COUNT V

Trespass to Chattels

(on behalf of Plaintiff and the Class)

116. Plaintiff reallege the foregoing paragraphs as if fully set forth herein.

117. Plaintiff and the Class owned and had a right to possess their reproductive materials, including their developing embryos. CooperSurgical's Global Media damaged and destroyed Plaintiff's and the Class's embryos.

118. CooperSurgical intentionally interfered with Plaintiff's and the Class's possession of their embryos by manufacturing a defective product that destroyed the embryos instead of creating a safe environment for the embryos to grow and develop. CooperSurgical further interfered by failing to timely recall the defective solution or to warn about the dangers of the Global Media before its use to culture Plaintiff's and the Class's embryos.

119. Plaintiff and the Class did not consent to or authorize the use of faulty and defective culturing media on their developing embryos.

120. CooperSurgical's Global Media damaged Plaintiff's and the Class personal property when, due to a defect, the Global Media damaged, impaired, or destroyed the embryos, preventing their use in an attempted pregnancy.

121. CooperSurgical impaired the condition, quality, or value of Plaintiff's and the Class's personal property because the defective Global Media impaired the opportunity for the embryos to develop sufficiently for an attempted pregnancy.

122. CooperSurgical's interference with Plaintiff's and the Class's embryos caused them harm, including loss of their embryos, financial and economic harm, and serious and lasting

emotional harm. The harm Plaintiff and the Class suffered was a direct and foreseeable result of CooperSurgical's formulation of defective media for culturing embryos.

123. Plaintiff and the Class seek all remedies available for CooperSurgical's negligent failure to recall its Global Media.

COUNT VI

Unjust Enrichment

(on behalf of Plaintiff and the Class)

124. Plaintiff realleges the foregoing paragraphs as if fully set forth herein

125. Plaintiff and the Class conferred a tangible and material economic benefit on Defendant by paying fertility clinics that used, and paid CooperSurgical for, the Global Media. At least part of Plaintiffs and the Class's fertility treatment payments when to CooperSurgical, and CooperSurgical readily accepted those benefits.

126. Had Plaintiff and the Class known of CooperSurgical's defective Global Media or its inadequate measures for ensuring that the Global Media met required specifications and was formulated adequately—including, among other things, failing to adequately inspect, test, formulate, and implement quality controls—Plaintiff and the Class would not have paid for the use of the Global Media.

127. Any benefit CooperSurgical obtained from the sale and purchase of its defective Global Media was unfairly and wrongfully obtained. Although CooperSurgical represented that its Global Media would help promote the development of embryonic growth, it did the opposite, destroying, damaging, and impairing the viability of the embryos.

128. Further, CooperSurgical knew or should have known that the benefit it received from the sale and purchase of its Global Media was obtained under the expectation that the Global Media would have the ability to foster embryonic growth.

129. Permitting CooperSurgical to retain the benefit it received from the sale and purchase of its defective Global Media would be unjust and inequitable.

130. Plaintiff and the Class are entitled to restitution and to recover from CooperSurgical any amount unfairly and wrongfully obtained via the sale of its defective Global Media to Plaintiff and the Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, pray for the following relief:

a. An Order certifying the Classes as defined above, appointing Plaintiff as Class representatives, and appointing Plaintiff's counsel as Class counsel;

b. An award of all recoverable compensatory, statutory, and other damages sustained by Plaintiff and Class Members;

c. Equitable relief including disgorgement, unjust enrichment, and all other available relief under applicable law;

d. Reasonable attorneys' fees and expenses as permitted by applicable law;

e. Pre- and post-judgment interest as allowed by law; and,

f. Such further relief at law or in equity that this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,

Dated: February 4, 2025

/s/ D. Gregory Blankinship
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