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SUPERIOR COURT FOR THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

A.B., an individual; and C.D., an individual

Plaintiffs,

v.

COOPERSURGICAL, INC.; THE COOPER COMPANIES, INC.; and DOES 1-50, inclusive,

Defendants.

Case No.

COMPLAINT

1. STRICT PRODUCTS LIABILITY—MANUFACTURING DEFECT
2. STRICT PRODUCTS LIABILITY—DESIGN DEFECT
3. STRICT PRODUCTS LIABILITY—FAILURE TO WARN
4. NEGLIGENCE/GROSS NEGLIGENCE
5. NEGLIGENT FAILURE TO RECALL
6. UNJUST ENRICHMENT

DEMAND FOR JURY TRIAL

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Plaintiffs A.B. and C.D. (collectively, "Plaintiffs") respectfully bring this Complaint against Defendants COOPERSURGICAL, INC. ("CooperSurgical") and THE COOPER COMPANIES, INC. ("The Cooper Companies"), and DOES 1-50 (hereinafter, collectively, "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. Defendants' defective product and negligent conduct destroyed Plaintiffs' precious and irreplaceable developing embryos.

2. Defendants manufactured, marketed, promoted, distributed, and/or sold media to be used for culturing and development of human embryos. Defendants marketed that their media provided "an optimized in vitro environment,"[1] which is necessary to ensure that fertilized human eggs can survive and develop into embryos viable for implantation.

3. Defendants further represented that they properly and adequately tested their embryo culture media before making the media available to the public, including clinics and/or healthcare practitioners who would use such embryo culture media for the storage of human embryos. They further claimed: "Our world class ISO 13485 and ISO 9001 certified manufacturing site consistently maintains the highest standards for product quality and reliability."[2]

4. Despite these representations, Defendants did not sufficiently test the embryo culture media that they manufactured, marketed, promoted, distributed, and/or sold. As a result, they sold defective lots of embryo culture media, which turned out to be toxic to human eggs, sperm, and embryos.

5. Defendants' manufacturing, marketing, promoting, distributing, and/or selling their toxic embryo culture media resulted in the death of Plaintiffs' developing embryos.

6. Only after Plaintiffs' embryos died due to contamination from Defendants' defective embryo culture media did Defendants recall multiple lots of their embryo culture media, including a lot that ruined Plaintiffs' embryos.

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[1] *Optimize Your Results*, COOPERSURGICAL, https://coopersurgicalfertility-jp.com/wp-content/uploads/Culture-Media-Brochure-V3-US_web.pdf, (last accessed Dec. 13, 2023).
[2] *Id.*

PARTIES

7. **Plaintiff A.B.** is a citizen of Los Angeles, California.

8. **Plaintiff C.D.** is a citizen of Los Angeles, California.

9. Given the sensitive nature of their claims, Plaintiffs are using pseudonymous initials in this litigation to protect their privacy. If the Court so requires, Plaintiffs will seek permission to proceed under these pseudonyms.

10. **Defendant The Cooper Companies** is a global medical device corporation boasting worldwide revenues of $3.6 billion. It is a Delaware corporation with its principal place of business in Alameda County, California. At all relevant times herein, Defendant The Cooper Companies was and is authorized to conduct business within the State of California, and distributed its products, including the above-referenced embryo culture media, within the State of California.

11. **Defendant CooperSurgical** is a wholly owned subsidiary of The Cooper Companies. CooperSurgical is a Delaware corporation, with its principal place of business in Trumbull, Connecticut. Defendant primarily manufactures medical devices for women's healthcare and fertility markets. At all relevant times herein, Defendant CooperSurgical was and is authorized to conduct business within the State of California, and distributed its products, including the above-referenced embryo culture media, within the State of California.

12. **Defendant DOES 1-50**: Plaintiffs are unaware of the true names or capacities, whether they are individuals or business entities, of Defendants DOES 1-50, and therefore sue them by such fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiffs will seek leave of this Court to insert the true names and capacities once they have been ascertained. Plaintiffs are informed and believe, and thereupon allege, that each of the fictitiously named Defendants is responsible for the conduct alleged in this Complaint and that, through their conduct, the fictitiously named Defendants actually and substantially caused Plaintiffs' injuries and damages.

13. Plaintiffs are informed and believes, and on that basis allege, that at all times material hereto: Defendants were, actually or ostensibly, the agents, representatives, and/or employees of each and every other Defendant; Defendants were acting within the course and scope of said alternative personality, capacity, identity, agency, representation, and/or employment; Defendants

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were the trustees, partners, servants, joint venturers, shareholders, co-conspirators, contractors, and/or employees of each and every other Defendant; the acts and omissions alleged herein, while committed individually, were made by Defendants through such capacity, and within the scope of their authority, and with the permission and consent of each and every other Defendant, as to make Defendants jointly and severally liable to Plaintiffs for the acts and omissions alleged herein.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the entire action by virtue of the fact that this is a civil action wherein the matter in controversy, exclusive of interest and costs, exceeds the jurisdictional minimum of the Court.

15. This Court has personal jurisdiction over all Defendants. Each Defendant is, and at all relevant times herein was, a citizen of and/or authorized to conduct business in the State of California and/or conducted such business within the State of California, including the actions, dealings, and/or omissions that caused or contributed to the harm giving rise to this action.

16. Jurisdiction is proper pursuant to California Code of Civil Procedure section 410.10 because the actions and/or omissions of Defendants that give rise to this legal action occurred in Los Angeles County, California.

17. Venue is proper in this Court pursuant to California Code of Civil Procedure Section 395.5 because the incidents that give rise to this legal action occurred in Los Angeles County, California and because both Defendants transact business in Los Angeles County, California.

GENERAL FACTURAL ALLEGATIONS

General Background of Assisted Reproductive Technology

18. Many people struggling with infertility opt to work with clinics specializing in ART. In broad terms, ART describes fertility-related treatments in which human eggs, embryos, and/or sperm are manipulated to produce a pregnancy or preserve a client's ability to produce a pregnancy later in life. The most common type of ART is in vitro fertilization ("IVF").

19. During the IVF process, a fertility doctor surgically extracts eggs from a woman. Then, scientists called embryologists fertilize those eggs in a laboratory with sperm to create a viable embryo. The embryo can either be cryopreserved for later use or used right away by transplanting

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it into a woman's uterus to begin a pregnancy.

20. Unlike sperm collection, the process of extracting human eggs is lengthy, invasive, and physically-taxing. It typically involves a woman giving herself or receiving one to several injections of medication per day for weeks, frequent ultrasound monitoring and other tests to monitor egg development, and finally a surgery to collect the eggs. This is an expensive process that comes with many possible physical side effects, some of them serious and long-term.

21. Following the collection of the eggs, sperm is mixed with the eggs in a laboratory to create embryos.

22. Human eggs are a limited and precious resource. Every woman is born with a specific and limited number of eggs that does not increase but rather decreases over the course of her lifetime. In addition to the number decreasing, the egg quality also diminishes over time, with miscarriages and chromosomal abnormalities occurring more frequently for women who are older at the time of a natural conception and pregnancy. The most determinative factor in IVF success is the woman's age when her eggs were extracted. Specifically, eggs retrieved before a woman is thirty-five (35) years old are most likely to produce viable, healthy embryos.

23. Thus, one purpose of embryo preservation and storage is to allow couples to preserve reproductive material so that the embryos may be implanted at a later time and allow for flexibility in family planning.

The Importance of Embryo Culture Media in IVF

24. Embryo culture media plays a pivotal role in the IVF embryology laboratory, serving as the essential substance in which an egg is immersed, typically in a petri dish, when it is fertilized and during its initial development in the lab. Culture media is composed of a salt solution with the addition of other components, such as carbohydrates (pyruvate, lactate, and glucose) and amino acids.

25. After egg retrieval, the embryologist fertilizes the eggs with sperm, and then the fertilized eggs are given five to seven days in the culture media to develop to the blastocyst stage.

26. Embryologists closely monitor the cell development during this time period to determine if the embryos are developing as intended and in line with expected timelines. The count

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begins on "Day 0," or the day the eggs (or oocytes) were fertilized with sperm. On Day 1, the embryologists assess the eggs to see which have successfully fertilized and become embryos. Between Day 1 and Day 3, the embryos begin cell division in the "cleavage stage." By Day 4, the embryos typically enter the "morula stage," characterized by a compacted mass of cells. By Day 5, the embryo re-expands to the blastocyst stage, in which the embryo shows two distinct groups of cells: a distinct inner cell mass and an outer globe of cells. All embryo development is slightly different, and some embryos may develop later than others, but typically fertilized eggs that do not develop to blastocyst by the seventh day are not considered viable. The embryo culture media in a petri dish supports and protects the developing embryos in these critical early stages, just as a woman's body would do during natural conception.

27. The resulting embryos can then either be cryo-preserved or transferred to the uterus where a baby can form.

Defendants' Consolidation of the Fertility and Reproductive Health Device Markets

28. The Cooper Companies and CooperSurgical have worked quickly to solidify their primacy in the lucrative fields of reproductive and fertility healthcare, acquiring competitors to secure their place. In April 2018, CooperSurgical acquired LifeGlobal, a leading global provider of in vitro fertilization devices—including IVF media—for $125 million dollars. [3] In January 2021, it acquired Embryo Options, a company that provided streamlined case management and billing options for fertility clients. [4] The following month, it acquired AEGEA Medical, a California-based medical manufacturing company that creates devices used in reproductive medicine. [5] In March 2021, it acquired Safe Obstetric Systems, another company that manufactures reproductive medical

[3] *The Cooper Companies Acquires the LifeGlobal Group, Expanding Fertility Solutions Portfolio*, THE COOPER COMPANIES (April 18, 2023), https://www.coopersurgical.com/wp-content/uploads/The-Cooper-Companies-Acquires-The-LifeGlobal-Group-Expanding-Fertility-Solutions-Portfolio.pdf.

[4] Natalie Missakian, *Trumbull's CooperSurgical Acquires Illinois Firm*, HARTFORD BUSINESS (Jan. 6, 2021), https://www.hartfordbusiness.com/article/trumbulls-coopersurgical-acquires-illinois-firm.

[5] *CooperSurgical Buys US Firm AEGEA Medical*, NS MEDICAL DEVICES (Feb. 3, 2023), https://www.nsmedicaldevices.com/news/coopersurgical-aegea-medical/.

devices, for $52 million dollars. [6]

29. In November of the same year, CooperSurgical acquired Generate Life Sciences, a purveyor of donor sperm and eggs as well as other fertility services, for $1.6 billion. In February 2022, CooperSurgical acquired Cook Medical's reproductive health business for $875 million.[7] This company produces medical devices for fertility, obstetrics, gynecology, in vitro fertilization (IVF), and assisted reproductive technology (ART).[8]

30. Following this significant consolidation of the fertility medical device industry, fertility clinicians have reported a decline in Defendants' customer service and product quality.

Defendants' Embryo Culture Media

31. CooperSurgical and The Cooper Companies marketed and promoted their embryo culture media for use as the essential medium in which fertility clinics can fertilize eggs and create the embryos that would be the future children of fertility clients like A.B. and C.D.

32. Defendants further marketed and represented that their embryo culture media is subject to rigorous testing to ensure it is the highest quality embryo culture media available.

33. Specifically, CooperSurgical claims "[q]uality is our cornerstone," stating its "products undergo thorough quality testing before being released, to ensure consistent quality for your piece of mind."[9]

34. As Defendants knew or should have known, sterility and quality control are crucial to ensure that developing embryos in culture media are not harmed. Microbiological contamination may result in the demise of the patient's embryos and increases cost to both the patient and the clinics. Contamination can also cause DNA fragmentation, poor-quality embryos, early pregnancy

[6] Natalie Missakian, *CooperSurgical Buys UK Medical Device Maker for $52M*, HARTFORD BUSINESS (March 3, 2031), https://www.hartfordbusiness.com/article/coopersurgical-buys-uk-medical-device-maker-for-52m.

[7] *CooperCompanies to Acquire Cook Medical's Reproductive Health Business*, COOPERCOMPANIES (Feb. 7, 2023), https://investor.coopercos.com/news-releases/news-release-details/coopercompanies-acquire-cookr-medicals-reproductive-health.

[8] *CooperCompanies to Acquire Cook Medical's Reproductive Health Business*, MEDICAL DEVICE NETWORK (Feb. 8, 2022), https://www.medicaldevice-network.com/news/coopercompanies-cook-medicals-reproductive-health/?cf-view.

[9] *Quality and Certifications*, COOPERSURGICAL, https://www.coopersurgical.com/healthcare-providers/support-compliance/quality-certifications#qualityCerts (last accessed Dec. 13, 2023).

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loss, and/or preterm birth.[10]

35. Moreover, Defendants marketed that all their embryo culture media was properly tested, and thus that it could be relied upon and/or posed no harm in use with growing human embryos.

36. Defendants manufactured, marketed, distributed, and/or sold their embryo culture media while promoting that their embryo culture media was tested by superior methods, e.g., a Mouse Embryo Assay, to ensure that no embryotoxic exposure would occur.

37. However, Defendants knew or should have known that their embryo culture media was not properly and/or adequately tested and/or inspected for contamination, and thus posed a severe risk of destruction to growing human embryos.

Plaintiffs' Fertility Journey

38. Concerned about their advancing age, Plaintiffs turned to ART in an attempt to fulfill their dream of having children.

39. First, Plaintiff A.B. went through four unsuccessful IVF cycles, and experienced all the health strain and side effects attendant thereupon. When they failed to achieve usable embryos from these cycles, Plaintiffs had to come to the devastating conclusion that they would not be able to have children who were biologically related to Plaintiff A.B.

40. Nevertheless, they were determined to have children of their own. Plaintiff A.B. dreamed of carrying her own pregnancy to term and giving birth to Plaintiffs' children. Therefore, Plaintiffs decided to start the expensive and time-consuming process of finding an egg donor.

41. In mid-2023, Plaintiffs found their perfect donor—someone who not only shared physical characteristics with Plaintiff A.B., but who seemed to be a kindred spirit. The kinship that Plaintiff A.B. felt for this donor went a long way to easing Plaintiffs' reservations about using donor eggs. They connected with the then-twenty-two-year-old donor and ultimately were able to arrange for her to begin an egg retrieval cycle at Plaintiffs' fertility clinic.

[10] E. D. Borges, T. S. Berteli, T. F. Reis, A. S. Silva & A. A. Vireque, *Microbial Contamination in Assisted Reproductive Technology: Source, Prevalence, and Cost*, J ASSIST REPROD. GENET. (Dec. 10, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7000601/#CR60.

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The Retrieval

42. Plaintiffs' donor egg retrieval cycle was wildly successful, resulting in dozens of retrieved eggs. The clinic fertilized these eggs with Plaintiff C.D.'s sperm, resulting in thirty-four fertilized eggs on Day 1. This was an incredibly promising result, and Plaintiffs' fertility clinic led them to believe that they would be set for all their needs with this excellent number of fertilizations. Indeed, the clinic's embryologist later informed them that, statistically, these numbers should have resulted in twenty (20) blastocysts and, based on the donor's age at the time of egg retrieval, conservatively, at least eight of those would have been healthy viable embryos with a high percentage chance of achieving pregnancy.

43. Instead, on Day 5, the couple opened their embryology report to find that *none* of their embryos had developed to blastocyst stage.

44. Then, on Day 6, their doctor again called to say that still none had developed and that, statistically, this did not make sense given the donor's history, the history of Plaintiff C.D.'s sperm, and all other factors. Their doctor stated that something might have gone wrong in the lab, but that they could not find any evidence of malpractice in the lab's protocols. Ultimately, only one blastocyst developed, but after genetic testing was determined to be chromosomally abnormal.

45. Later, Plaintiffs spoke at length with the clinic's well-respected lab director. He told Plaintiff C.D. that their result was not normal and simply did not make sense. He warned that they might never know what happened.

The Investigation and Recall

46. The lab director decided to investigate. He began to reach out to embryologists at other labs, many of whom began to report similar instances of unexplained embryo death. The common thread between these cases: Defendants' embryo culture media.

47. The embryologists sent a formal letter to Defendants complaining that the media was causing unexplained loss of embryos. Only after this formal notification did Defendants issue a letter recalling their Embryo Culture Media Lots (the Recall Letter) in late 2023.

48. Following this belated recall, which was sent to fertility clinics but not to fertility clients, Plaintiffs learned from their fertility clinic that their developing embryos were killed due to

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contamination from Defendants' faulty and toxic embryo culture media. Those developing embryos were viable and should have successfully developed into more embryos than Plaintiffs could have hoped to have used. Instead, they were killed by Defendant's embryo culture media.

49. Shortly after CooperSurgical issued its Recall Letter, Plaintiffs were informed by their fertility clinic that the embryo culture media that killed their embryos was part of the Recalled Embryo Culture Media Lots.

50. Plaintiffs are devastated. They may no longer be able to have children with their chosen donor and Plaintiff C.D.'s genetic material as a result of Defendants' conduct.

CooperSurgical Knew or Should Have Known That the Recalled Embryo Embryo Culture Media Lots Posed an Unreasonable Risk to Developing Human Embryos

51. On information and belief, Defendants previously have manufactured and sold numerous products used in ART, including media used in the IVF process, that were defective and sometimes recalled.[11]

52. On information and belief, Defendants did not properly test the impacted lots of their Embryo Culture Media until after receiving formal complaints from numerous fertility clinicians—including those who worked on Plaintiffs' embryos—that developing embryos were dying due to their product.

53. As a manufacturer and distributor of numerous ART products, including embryo culture media, CooperSurgical knew that contaminated and/or toxic embryo culture media could kill developing human embryos. Accordingly, Defendants knew it was vitally important that their embryo culture media was properly tested and/or inspected prior to the distribution of such embryo culture media.

54. Despite this, Defendants failed to properly inspect and/or test their embryo culture media, including the recalled embryo culture media lots. Defendants knowingly put their embryo culture media into the market when they knew or should have known that the recalled embryo

[11] *See, e.g., Urgent: Media Field Safety Corrective Action - SAGE Vitrification Media Kit*, COOPERSURGICAL, (Feb. 27, 2023), available at: https://www.igj.nl/binaries/igj/documenten/waarschuwingen/2023/02/27/coopersurgical-tbd-sage-vitrification-media-kit/IT2075448+CooperSurgical+tbd+Sage+Vitrification+Media+Kit+_v2.pdf.

culture media lots posed a substantial and unacceptable risk to developing human embryos, including Plaintiffs' embryos.

55. As a manufacturer of numerous products for use in ART, Defendants knew that people go to extraordinary lengths to obtain and use viable human embryos. Defendants also knew that people place extreme value on their viable embryos, make substantial emotional and financial investments for their embryos, and that such people expect that great care will be taken to preserve and protect the embryos to avoid the irreparable harm of the death of their embryos.

56. Defendants' conduct was despicable and was carried out by Defendants with a willful and conscious disregard of the rights and/or safety of others. Defendants' conduct subjected Plaintiffs to cruel and unjust hardship in conscious disregard of Plaintiffs' rights. Moreover, as discussed herein, Defendants' conduct amounted to a deceit and/or concealment of material fact(s) known to Defendants with the intention on the part of Defendants to deprive individuals of property and/or legal rights and/or otherwise cause injury.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY—MANUFACTURING DEFECT

57. Plaintiffs re-allege and incorporate by reference herein each and every allegation contained in all other paragraphs in this Complaint as though fully set forth in this cause of action.

58. At all times relevant herein, Defendants manufactured, distributed, and/or sold embryo culture media to be used with developing human embryos, including the Recalled Embryo Culture Media Lots.

59. At the time the Recalled Embryo Culture Media Lots left Defendants' possession, the Recalled Embryo Culture Media Lots contained a manufacturing defect such that they differed from Defendants' intended result. This deviation included, but was not necessarily limited to, toxicity and/or contamination in the Recalled Embryo Culture Media Lots, such that the Recalled Embryo Culture Media Lots posed a fatal harm to developing human embryos upon their use for the culture and development of said embryos.

60. Embryo culture media from the Recalled Embryo Culture Media Lots was used (as intended), and it came into contact with Plaintiffs' developing embryos, which resulted in the tragic

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destruction of Plaintiffs' developing embryos.

61. The defect in the embryo culture media in the Recalled Embryo Culture Media Lots was a substantial factor in causing Plaintiffs' harm.

62. Defendants acted with a conscious disregard for the safety of consumers and/or users of its embryo culture media, including Plaintiffs, because, without limitation, Defendants were aware of the dangerous consequences of not properly or adequately testing their embryo culture media (including specifically the Recalled Embryo Culture Media Lots), they knew or should have known the embryo culture media (specifically, the Recalled Embryo Culture Media Lots) was not safe and posed a serious, toxic risk to irreplaceable developing human embryos, and failed to recall the Recalled Embryo Culture Media Lots before the embryo culture media was used to culture and develop Plaintiffs' embryos.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY—DESIGN DEFECT

63. Plaintiffs re-allege and incorporate by reference herein each and every allegation contained in all other paragraphs in this Complaint as though fully set forth in this cause of action.

64. Defendants designed, manufactured, distributed, and/or sold embryo culture media, including the Recalled Embryo Culture Media Lots, or caused such embryo culture media to be designed, manufactured, and/or sold.

65. The Recalled Embryo Culture Media Lots did not perform as safely or as effectively as an ordinary consumer would have expected it to perform when used or misused in a reasonably foreseeable manner.

66. Defendants had actual or constructive notice and knew, or in the exercise of reasonable care and diligence should have known, that the Recalled Embryo Culture Media Lots were defective in their design as discussed herein, including but not limited to their composite materials, resulting in the irreversible damage and destruction of Plaintiffs' developing embryos.

67. The benefits of the Recalled Embryo Culture Media Lots are not outweighed by their risks, particularly considering the potential harm resulting from their use on reproductive materials, including embryos; the likelihood of harm occurring; the feasibility of an alternative safer design at

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the time of manufacture; and the feasibility of more reliable testing methods and procedures.

68. Defendants had actual or constructive notice and knew, or in the exercise of reasonable care should have known, that the Recalled Embryo Culture Media Lots had significant risks, were defective in design, as discussed herein, and had an unreasonable increased risk of damage or destruction to stored reproductive materials, including embryos.

69. Plaintiffs were irreparably harmed because the Recalled Embryo Culture Media Lots were contaminated, toxic, and/or contained materials that were contaminated and toxic when used to culture or develop human embryos, such as those belonging to Plaintiffs.

70. As a direct and proximate result of the defective designs of the Recalled Embryo Culture Media Lots, Plaintiffs were harmed as described herein, including but not limited to the destruction of their embryos.

71. The failure of the Recalled Embryo Culture Media Lots to perform safely and effectively was a substantial factor in causing Plaintiffs' harm and damages.

72. Defendants acted with a conscious disregard for the safety of consumers and/or users of their embryo culture media, including Plaintiffs, because, without limitation, Defendants were aware of the dangerous consequences of not properly or adequately testing their embryo culture media (including specifically the Recalled Embryo Culture Media Lots), when it knew or should have known the embryo culture media (specifically, the Recalled Embryo Culture Media Lots) was not safe and posed a serious, toxic risk to irreplaceable human embryos, and failing to recall the Recalled Embryo Culture Media Lots before the embryo culture media came into contact with Plaintiffs' developing embryos.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY—FAILURE TO WARN

73. Plaintiffs re-allege and incorporate by reference herein each and every allegation contained in all other paragraphs in this Complaint as though fully set forth in this cause of action.

74. Defendants designed, manufactured, distributed, and/or sold embryo culture media to be used with human embryos, including the Recalled Embryo Culture Media Lots, and/or caused such embryo culture media to be designed, manufactured, distributed, and/or sold.

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75. The Recalled Embryo Culture Media Lots had risks, including but not limited to embryotoxicity, that were known and/or knowable in light of the generally accepted scientific knowledge at the time of manufacture, distribution and/or sale.

76. The risks of contaminated embryo culture media, including the Recalled Embryo Culture Media Lots, presented a substantial danger, including but not limited to embryotoxicity and destruction of viable embryos, when such embryo culture media was used as intended and/or in a reasonably foreseeable manner.

77. Despite their awareness that its embryo culture media, including the Recalled Embryo Culture Media Lots, was defective and contained an unacceptably increased danger to embryos, Defendants failed to warn consumers, including but not limited to Plaintiffs and Plaintiffs' fertility providers who purchased the embryo culture media, that the embryo culture media had not been properly and/or sufficiently tested, contained toxic raw materials, and/or had an increased risk of embryotoxicity.

78. Neither Plaintiffs nor their fertility providers knew or would have known or recognized the risks of the Recalled Embryo Culture Media Lots.

79. As a direct and proximate result of Defendants' failure to adequately warn of the dangerous and embryotoxic effects of the Recalled Embryo Culture Media Lots, Plaintiffs were harmed as described herein, including but not limited to the destruction of their embryos.

80. The lack of sufficient warnings was a substantial factor in causing Plaintiffs' harm and damages. Contaminated and harmful embryo culture media would not have been used with Plaintiffs' developing embryos if Defendants had provided sufficient warning in advance.

81. Defendants acted with a conscious disregard for the safety of consumers and/or users of their embryo culture media, including Plaintiffs, because, without limitation, Defendants were aware of the dangerous consequences of not properly or adequately testing their embryo culture media (including specifically the Recalled Embryo Culture Media Lots), when they knew or should have known the embryo culture media (specifically, the Recalled Embryo Culture Media Lots) was not safe and posed a serious, toxic risk to irreplaceable developing human embryos, and failing to recall the Recalled Embryo Culture Media Lots before the embryo culture media came into contact

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with Plaintiffs' embryos.

FOURTH CAUSE OF ACTION

NEGLIGENCE / GROSS NEGLIGENCE

82. Plaintiffs re-allege and incorporate by reference herein each and every allegation contained in all other paragraphs in this Complaint as though fully set forth in this cause of action.

83. Defendants designed, manufactured, distributed, and/or sold embryo culture media for use with human embryos, including the Recalled Embryo Culture Media Lots, or caused such embryo culture media to be designed, manufactured, and/or sold.

84. As manufacturers of embryo culture media for use with human embryos, Defendants owed a duty, including but not limited to Plaintiffs, to design, manufacture, inspect, and/or test their embryo culture media, including the Recalled Embryo Culture Media Lots, such that their embryo culture media was not toxic or hazardous when used with developing human embryos and/or did not contain toxic or contaminated materials.

85. Defendants owed Plaintiffs a duty to exercise the highest level of care in manufacturing, producing, inspecting, monitoring, and testing of their embryo culture media, including the Recalled Embryo Culture Media Lots, used for its intended purpose in IVF, ART, and/or embryology across the United States. Defendants owed Plaintiffs the highest degree of utmost care when maintaining, caring for, and otherwise protecting Plaintiffs' developing embryos.

86. Defendants owed a duty of care to Plaintiffs to act reasonably in the creation of embryo culture materials and to avoid destroying embryos or jeopardizing the viability of Plaintiffs' developing embryos, as a result of the special relationship between Plaintiffs and Defendants arising from the extremely sensitive services Defendants decided to perform: protect and preserve human embryos during the IVF process through the creation of embryo culture media.

87. Defendants created this duty of care through their production of IVF embryo culture media, by marketing it as safe embryo culture media, and through Defendants' presence in the sensitive IVF and ART market and services that Defendants voluntarily undertook.

88. Imposing this duty on Defendants to avoid causing such emotional distress and financial harm is beneficial to public policy of preventing future harm in that Defendants will be

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motivated to ensure the safety of their IVF embryo culture media.

89. Defendants breached this duty and were negligent in the design, manufacture, inspection, and/or testing of their embryo culture media, including the Recalled Embryo Culture Media Lots, and thus produced an unsafe, dangerous, and defective embryo culture media that guaranteed the failure of embryotic viability during the IVF process. Specifically, Defendants breached this duty by failing to safely produce and further ensure the safety of their defective embryo culture media. Additionally, Defendants breached their duty by failing to timely recall the Recalled Embryo Culture Media Lots.

90. As a direct and proximate result of Defendants' negligent acts and/or omissions, including but not limited to, failing to properly or adequately test their embryo culture media (including the Recalled Embryo Culture Media Lots), promoting and marketing their embryo culture media as properly tested and safe for use on human embryos despite their knowledge of its contamination, defectively designing their embryo culture media, defectively manufacturing their embryo culture media, and/or failing to adequately warn of the dangerous and embryotoxic effects of the Recalled Embryo Culture Media Lots, Plaintiffs were harmed as described herein, including but not limited to the destruction of their developing embryos. Additionally, Defendants' breach caused damages in that Plaintiffs are now required to expend additional funds, time, and emotional happiness to go through the IVF process once again.

91. These negligent acts and/or omissions were a substantial factor in causing Plaintiffs' harm and damages.

92. Defendants could have reasonably foreseen that if Defendants' embryo culture media was defective, consumers of the embryo culture media, like Plaintiffs, would have experienced extreme emotional distress as a result of Defendants' breach of their duty of care.

93. It is also foreseeable to Defendants that Defendants' breach would cause such damages as discussed above given that an unsafe and defective embryo culture media would cause developing embryos to stall in development and lose viability. Defendants knew or should have known that embryo culture media is an extremely critical element in the viability of developing embryos.

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94. Defendants' acts and omissions constitute gross negligence because they are an extreme departure from what a reasonably careful person would do in the same situation to prevent foreseeable loss of embryos during the IVF process.

95. Defendants acted willfully, wantonly, and with a conscious disregard for the safety of consumers and/or users of their embryo culture media, including Plaintiffs, because, without limitation, Defendants were aware of the dangerous consequences of not properly or adequately testing their embryo culture media (including specifically the Recalled Embryo Culture Media Lots), they knew or should have known the embryo culture media (specifically, the Recalled Embryo Culture Media Lots) was not safe and posed a serious, toxic risk to irreplaceable developing human embryos, and failed to recall the Recalled Embryo Culture Media Lots before the embryo culture media came into contact with Plaintiffs' developing embryos. Defendants' actions and omissions had a probability of causing significant harm to Plaintiffs, and, in fact, did.

96. Defendants' failure to manufacture and ensure the safety of their embryo culture media (including the Recalled Embryo Culture Media Lots) to developing embryos has caused severe emotional distress and economic harm to Plaintiffs. As a result of Defendants' breach of duty, Plaintiffs have been forced to repeat the IVF process and suffer the loss of potential children.

97. Coping with this loss, as well as general infertility and IVF, is often extremely difficult and requires counselling.

98. As a result of this breach on part of Defendants, Plaintiffs suffered damages to be determined at trial, including their lost developing embryos, emotional distress, time, money, and other inconveniences suffered throughout the repetition of the IVF process. A reasonable person would struggle to cope with the losses suffered by Plaintiffs.

FIFTH CAUSE OF ACTION

NEGLIGENT FAILURE TO RECALL

99. Plaintiffs re-allege and incorporate by reference herein each and every allegation contained in all other paragraphs in this Complaint as though fully set forth in this cause of action.

100. At all times relevant herein, Defendants manufactured, distributed, and/or sold embryo culture media for use with human embryos, including the Recalled Embryo Culture Media

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Lots.

101. As manufacturers of embryo culture media for use with human embryos, Defendants owed a duty, including but not limited to Plaintiffs, to design, manufacture, inspect, and/or test their embryo culture media, including the Recalled Embryo Culture Media Lots, such that their embryo culture media was not toxic or hazardous when used to culture or develop developing human embryos and/or did not contain toxic or contaminated materials. Further, these Defendants had an ongoing duty following the manufacture, distribution, and/or sale of their embryo culture media, including the Recalled Embryo Culture Media Lots, to inform purchasers, consumers, and/or others who used their embryo culture media that the embryo culture media was toxic and/or hazardous and/or contained toxic or contaminated materials harmful to developing human embryos, and to immediately recall and/or remove such embryo culture media from the market to prevent harm.

102. Defendants breached these duties and acted negligently by failing to recall their Recalled Embryo Culture Media Lots earlier, including before such embryo culture media came into contact with Plaintiffs' developing embryos.

103. For a significant period of time before they issued the recall of its Recalled Embryo Culture Media Lots, Defendants knew and/or should have known that, when used as intended, their Recalled Embryo Culture Media Lots were not properly or adequately tested for, among other things, toxicity, and posed an unreasonable increased risk of contamination to developing embryos.

104. Defendants knew, and/or reasonably should have known that the Recalled Embryo Culture Media Lots, posed a substantial risk of serious injury to the developing embryos with which the embryo culture media came into contact and/or was used to culture and develop human embryos.

105. Defendants knew and/or reasonably should have known that they had failed to properly or adequately test their Recalled Embryo Culture Media Lots before distributing and/or selling and/or causing such embryo culture media to enter the market.

106. A reasonable manufacturer, distributor, and/or seller in the same or similar circumstances would have recalled the embryo culture media and issued a notice to purchasers, consumers, and/or users—prior to the embryo culture media coming into contact with Plaintiffs' developing embryos—rather than continuing to allow the embryo culture media to be used, sold,

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distributed, and/or manufactured, thereby obfuscating the true risks of the embryo culture media to developing human embryos.

107. Despite the fact that they knew or should have known that the Recalled Embryo Culture Media Lots were defective, toxic, and posed an unacceptable risk of toxicity to developing embryos, Defendants failed to recall the embryo culture media.

108. Defendants acted with a conscious disregard for the safety of consumers and/or users of their embryo culture media, including Plaintiffs, because, without limitation, Defendants were aware of the dangerous consequences of not properly or adequately testing their embryo culture media (including specifically the Recalled Embryo Culture Media Lots), they knew or should have known the embryo culture media (specifically, the Recalled Embryo Culture Media Lots) was not safe and posed a serious, toxic risk to irreplaceable developing human embryos, and failed to recall the Recalled Embryo Culture Media Lots before the embryo culture media came into contact with Plaintiffs' developing embryos.

SIXTH CAUSE OF ACTION

UNJUST ENRICHMENT

109. Plaintiffs re-allege and incorporate by reference herein each and every allegation contained in all other paragraphs in this Complaint as though fully set forth in this cause of action.

110. Plaintiffs conferred benefits on Defendants in the form of monies paid to purchase Defendants' worthless and defective embryo culture media, i.e., the Recalled Embryo Culture Media Lots. These monies were not gifts or donations but were given in exchange for the Recalled Embryo Culture Media Lots.

111. Defendants voluntarily accepted and retained these monetary benefits mentioned above.

112. Because this benefit was obtained unlawfully, namely because of Defendants' marketing and sale of embryo culture media (including the Recalled Embryo Culture Media Lots) unfit for their intended use, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

113. Defendants received benefits in the form of revenues from purchases of their embryo

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culture media (including the Recalled Embryo Culture Media Lots) to the detriment of Plaintiffs, because Plaintiffs purchased mislabeled and defective embryo culture media (including the Recalled Embryo Culture Media Lots) that were not what Plaintiffs bargained for and were not safe and effective, as claimed by Defendants.

114. Defendants have been unjustly enriched in retaining the revenues derived from the purchases of the Recalled Embryo Culture Media Lots by Plaintiffs. Retention of those monies under these circumstances is unjust and inequitable because Defendants' representations and labeling of the Recalled Embryo Culture Media Lots was misleading to consumers, which caused injuries to Plaintiffs because they would have not purchased the Recalled Embryo Culture Media Lots had they known the true facts and nature of the Recalled Embryo Culture Media Lots.

115. Because Defendants' retention of the non-gratuitous benefits conferred on them by Plaintiffs is unjust and inequitable, Defendants must pay restitution to Plaintiffs for their unjust enrichment, as ordered by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

1) For past, present, and future non-economic damages in an amount to be determined at the time of trial;

2) For past, present, and future economic damages in an amount to be determined at the time of trial;

3) For compensatory, restitutionary, rescissory, general, consequential, punitive and/or exemplary damages, in an amount to be determined at trial;

4) For costs of suit herein;

5) For pre- and post-judgement interest as allowed by law;

6) For injunctive relief, in order to ensure that Plaintiffs' biological material does not come into contact with any more contaminated embryo culture media manufactured by Defendants; and

7) For such other and further relief as the Court may deem just and proper.

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DATED: December 14, 2023

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JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

DATED: December 14, 2023

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