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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

H.H. and I.I.,

Plaintiffs,

v.

THE COOPER COMPANIES, INC.; COOPERSURGICAL, INC.; and DOES 1-10, inclusive,

Defendants.

Case No. 4:24-cv-3568

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. Strict Products Liability—Manufacturing Defect;
2. Strict Products Liability—Design Defect—Consumer Expectations Test;
3. Strict Products Liability—Design Defect—Risk-Utility Test;
4. Strict Products Liability—Failure To Warn;
5. Negligence/Gross Negligence;
6. Negligent Failure to Recall;
7. Trespass to Chattels;
8. Unjust Enrichment

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Plaintiffs H.H. and I.I. (collectively, "Plaintiffs") respectfully bring this Complaint against Defendants COOPERSURGICAL, INC. ("CooperSurgical") and THE COOPER COMPANIES, INC. ("Cooper Companies"), and DOES 1-10 (hereinafter, collectively, "Defendants"), and allege as follows:

INTRODUCTION

1. After years of trying to conceive via in vitro fertilization ("IVF"), Plaintiffs H.H. and I.I. were devastated to learn that Defendants' defective product and negligent conduct destroyed, damaged, or rendered unusable their precious and irreplaceable embryos.

2. Plaintiffs have undergone multiple rounds of IVF since 2020. The most recent cycle was in late 2023.

3. On November 29, 2023, H.H. underwent an egg retrieval. Twelve eggs were retrieved, and nine were fertilized and placed in Defendants' embryo culture media to develop into embryos.

4. Plaintiffs transferred two embryos on January 23, 2024.

5. A week after the transfer, while Plaintiffs were waiting to learn whether it had been successful, Plaintiffs received an email from their clinic stating that Plaintiffs' embryos had been placed in CooperSurgical's faulty embryo culture media ("media"). The news created additional stress for Plaintiffs at a critical time, and the transfer was unsuccessful—H.H. did not become pregnant.

6. Defendants manufactured, marketed, promoted, distributed, and/or sold media that was intended to protect and nourish Plaintiffs' reproductive material and encourage development into healthy embryos.

7. On December 5, 2023, Defendants issued a recall[1] of three lots of media stating that it does the opposite of its intended use, creating a "risk to health" due to "impaired embryo development prior to the blastocyst stage."

[1] https://www.lieffcabraser.com/pdf/Cooper_Recall_Notice.pdf.

8. Defendants' manufacturing, marketing, promoting, distributing, and/or selling their defective media resulted in destruction of or damage to Plaintiffs' developing embryos and has caused panic, confusion, grief, distress, devastation, and irreparable damage to Plaintiffs.

9. Plaintiffs seek damages, equitable relief, and other remedies from Defendants as a result of their misconduct.

PARTIES

10. Plaintiff H.H. is an individual residing in Woburn, Massachusetts.

11. Plaintiff I.I. is an individual residing in Woburn, Massachusetts.

12. Defendant The Cooper Companies, Inc. is a Delaware corporation with its principal place of business in San Ramon, California, in Contra Costa County.

13. Cooper Companies is a publicly-traded global medical device corporation with worldwide revenues of $3.6 billion in 2023[2] and a market cap or net worth of $19.14 billion. Cooper Companies has nearly 15,000 employees located in 30 countries across Europe, Asia, Africa, and the Americas. Cooper Companies consists of two business units: 1) CooperVision, which manufactures contact lenses, and 2) CooperSurgical, which manufactures medical devices and fertility and genomic products for the women's health care market.

14. Defendant CooperSurgical, a wholly owned subsidiary of Cooper Companies, is a Delaware corporation with its principal place of business in Trumbull, Connecticut.[3]

15. CooperSurgical describes itself as the "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."[4] It has quickly acquired other IVF and reproductive health companies. In April 2018, CooperSurgical acquired the assets of The LifeGlobal Group and its affiliates, a leading global provider of IVF devices, for $125 million.[5] In January 2021 it acquired Embryo Options, a leader in cryo-storage software solutions for clinics and patients.[6] In

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[2] https://investor.coopercos.com/node/26401/pdf.
[3] https://fertility.coopersurgical.com/coopersurgical-to-acquire-generate-life-sciences/.
[4] https://www.coopersurgical.com/about-us.
[5] https://www.globenewswire.com/news-release/2018/04/03/1459615/0/en/The-Cooper-Companies-Acquires-The-LifeGlobal-Group-Expanding-Fertility-Solutions-Portfolio.html.
[6] https://fertility.coopersurgical.com/coopersurgical-acquires-embryo-options/.

November 2021, CooperSurgical acquired Generate Life Sciences, a privately held provider of donor egg and sperm for fertility treatments, fertility cryopreservation services and newborn stem cell storage (cord blood & tissue), for approximately $1.6 billion.[7] In November 2023, CooperSurgical acquired select Cook Medical assets focused primarily on the obstetrics, doppler monitoring, and gynecology surgery markets, for $300 million.[8]

16. On information and belief, CooperSurgical sold its recalled, defective culture media to more California-based fertility clinics than to clinics in any other State. A substantial number of California-based patients had their eggs and/or embryos exposed to the Recalled Media and destroyed as a result of that exposure.

17. A significant portion of the acts and omissions complained of occurred in California. Among those acts and omissions are the failures by CooperSurgical's leadership team to ensure the safe manufacture and design of the culture media, which occurred where CooperSurgical's leadership was located—in California. This is true both because CooperSurgical's CEO works out of California and because of the close involvement of Cooper Companies (located in San Ramon) in the operations of CooperSurgical. Other operational activity for CooperSurgical also occurs in California.

18. As stated in Cooper Companies' SEC filings, Cooper Companies employs and controls CooperSurgical's top executive, President Holly Sheffield.[9] Ms. Sheffield's employment agreement is exclusively with Cooper Companies.[10] Under that agreement, Ms. Sheffield "shall render exclusive, full-time services to [The Cooper Companies, Inc.] and its subsidiaries, and exercise such authority and perform such duties as assigned to [Ms. Sheffield] by [The Cooper Companies'] Chief Executive Officer (the 'CEO')."[11] Ms. Sheffield "shall perform services under this Agreement primarily at [The Cooper Companies'] office in Pleasanton, California[.]"[12]

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[7] https://fertility.coopersurgical.com/coopersurgical-to-acquire-generate-life-sciences/.

[8] https://investor.coopercos.com/news-releases/news-release-details/coopercompanies-expands-coopersurgicals-medical-device-portfolio.

[9] https://www.sec.gov/Archives/edgar/data/711404/000071140419000026/coo-ex104_2019x04x30x10q.htm

[10] *Id.*

[11] *Id.*

[12] *Id.*

Duties may be modified "at the sole discretion of the CEO" or Cooper Companies' Board of Directors.[13] Ms. Sheffield's employment agreement was recently incorporated by reference into Cooper Companies' FY23 Form 10-K.[14]

19. In its registration with the Connecticut Secretary of State, the mailing address for CooperSurgical is the same California address as for Cooper Companies: 6101 Bollinger Canyon Rd., Suite 500, San Ramon, California.[15] [16]

20. CooperSurgical's four principals are all employed in California. CooperSurgical filed a report with the Connecticut Secretary of State in 2024.[17] That report lists four principals, three of whom are employed in California with Cooper Companies: Cynthia Wallace, Secretary, San Ramon CA; Agostino Ricupati, Director, San Ramon CA; and Brian Andrews, Treasurer and Vice President, San Ramon CA.[18] The fourth, Holly Sheffield, lists the Trumbull, Connecticut business address of CooperSurgical but, as discussed, her employment agreement states that she works primarily in Pleasanton, California.[19]

21. In Cooper Companies' FY23 Form 10-K, Cooper Companies represents that it "operates through two business segments, CooperVision and CooperSurgical" and its "principal facilities" include 200,000 square feet in California, with operations including "Executive offices; . . . CooperSurgical research & development, distribution and administrative offices."[20]

22. CooperSurgical is registered with the California Secretary of State and is in good standing. CooperSurgical's most recent Statement of Information, lists San Ramon, CA as its

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[13] *Id.*

[14] https://investor.coopercos.com/node/26416/ixbrl-viewer

[15] https://service.ct.gov/business/s/onlinebusinesssearch?businessNameEn=CTFrDeWI2HxVjexDH%2BbhVBf%2BEJGZqve5IFVMLV0RaB4%3D

[16] https://bizfileonline.sos.ca.gov/api/report/GetImageByNum/136042025005125051214044203145015003171102170190

[17] https://service.ct.gov/business/s/onlinebusinesssearch?businessNameEn=CTFrDeWI2HxVjexDH%2BbhVBf%2BEJGZqve5IFVMLV0RaB4%3D

[18] *Id.*

[19] *Id.*

[20] https://investor.coopercos.com/node/26416/ixbrl-viewer

mailing address, lists two of three officers' addresses as San Ramon, CA, and lists a California Registered Agent for service of process.[21] CooperSurgical is in good standing with the California Franchise Tax Board and pays California state tax.[22]

23. Defendants have been working to secure a release of liability for *both* CooperSurgical and Cooper Companies from patients affected by the recalled, defective media. In a related action in this District, *F.G. et al v. CooperSurgical Inc. et al*, Case No. 4:24-cv-01261-JST (N.D. Cal.), CooperSurgical admitted that it is running a settlement program seeking "a full release of all claims relating to the recalled culture media."[23] Both Cooper Companies and CooperSurgical are named as released parties in the draft settlement agreement that they pressure affected patients to sign.[24] The draft release including Cooper Companies was created in January 2024.[25]

24. Doe(s) 1 through 10 are persons and/or entities, whose identities are currently unknown and who participated in the wrongs alleged herein. Plaintiffs are informed and believe, and based upon such information and belief, allege that each Doe Defendant is in some manner legally responsible for the faulty culture media that harmed Plaintiffs, including but not limited to being involved the manufacture, design, sale, distribution, and/or inspection of the defective culture media, or any other involvement in, or responsibility for, for the events and happenings herein referred to, and thereby caused injury and damages proximately and foreseeably to Plaintiffs as herein alleged.

25. Cooper Companies, CooperSurgical, and Does 1-10 will be referred to hereinafter collectively as "Defendants."

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[21] https://bizfileonline.sos.ca.gov/api/report/GetImageByNum/136042025005125051214044203145015003171102170190

[22] https://webapp.ftb.ca.gov/eletter/Home/Summary?entityID=3057113

[23] *Id*. Dkt. 30 at 3-4.

[24] *Walden v. CooperSurgical Inc. et al.*, Case No. 4:24-cv-00903-JD (N.D. Cal), Dkt. 39-7.

[25] *Id.*

JURISDICTION AND VENUE

26. Pursuant to 28 U.S.C. § 1332, this Court has jurisdiction over this action because this is a civil action between citizens of different states and the matter in controversy exceeds $75,000, exclusive of interest and costs.

27. This Court has personal jurisdiction over Defendants because Defendants are residents and/or do business in the State of California. Defendants have purposely availed themselves of the benefits, protections, and privileges of the laws of the State of California in conducting their business, and have purposely directed their activities in this State. Defendants market their products, including their Global Media, in the State of California. Cooper Companies' principal place of business is in San Ramon, California, and CooperSurgical holds offices in the State of California, including in the cities of Los Altos and Los Angeles.[26] Defendants have sufficient minimum contacts with this State to render the exercise of jurisdiction by this Court permissible.

28. Venue is proper in this Court because Defendant Cooper Companies' principal place of business is in Contra Costa County, which is within this District.

FACTUAL ALLEGATIONS

In Vitro Fertilization

29. IVF is an assisted reproductive technology ("ART") that requires surgically retrieving a woman's eggs and fertilizing them with sperm in a laboratory. The fertilized eggs, once developed into viable embryos, are then transferred into the woman's uterus.

30. To prepare for egg retrieval, women take drug and hormone therapies and endure injections over several weeks to stabilize the uterine lining, stimulate their ovaries into producing follicles, and stop the ovary follicles from releasing eggs. The injections can result in bruising, swelling, and discomfort. The drugs and hormones may also trigger other side effects, such as fatigue, nausea, headaches, allergic reactions and blood clots, as well as negative emotions. The process can limit travel, work, and other activities, entails numerous doctor visits, and often requires time off from work for both partners. After an ovulation trigger injection, women

[26] https://www.coopersurgical.com/contact-us.

proceed to the operating room for egg retrieval, where they are sedated or placed under general anesthesia, and undergo insertion of a needle through the vaginal wall and into each follicle in the ovary to drain the follicles of their fluid. The fluid in the follicle is then extracted into a test tube and studied under a microscope to look for eggs.

31. Residual pain from the egg retrieval procedure often lasts for about a week and bed rest may be required for several days. Some women suffer significant side effects such as ovarian hyperstimulation syndrome which causes the ovaries to painfully swell and can lead to hospitalization and even death.

Embryo Culture Media

32. The male partner typically produces a sperm sample on the same day as the egg retrieval. The eggs are then fertilized with the sperm and submerged in embryo culture media, usually in a petri dish, to develop into embryos.

33. When a fertilized egg divides, it becomes known as an embryo. Embryos are submerged, or "cultured," in the embryo culture media for approximately five to six days to develop to the blastocyst stage. Embryos of good quality are then transferred into the woman's uterus or frozen for future use.

34. Young, developing embryos are fragile and sensitive. The environment in which the embryo is developed is tightly controlled in an IVF laboratory setting. Even minor variations in an embryo's growing conditions can have devastating impacts on the embryo's development.

35. Embryo culture media is an essential part of the development of embryos through IVF. The culture media is developed to mimic the fluids in a woman's reproductive tract to closely approximate the natural environment and circumstances of a developing embryo. This provides the embryo the same advantages available to them in the female reproductive system.

36. Culture media for embryo development must meet the metabolic needs of preimplantation embryos by providing necessary sources of energy, nutrients, and PH levels based on the specific developmental stage of the embryo. The specific nutrients in the media are thus crucial to the embryo's successful growth.

37. Embryo culture media is a complex solution that is typically comprised of ingredients including carbohydrates, amino acids, vitamins, magnesium, and growth factors.

38. Magnesium is required for embryonic development, and is an essential component of embryo culture media.[27] Magnesium is one of the essential, crucial nutrients for embryonic and fetal growth and is a key element to repair mutations during cell division.[28] Deficient magnesium levels in embryo culture media can cause embryo growth to arrest and inhibit DNA repair.[29]

39. Embryologists closely monitor the embryos during each day of the embryo culture. After two days, the embryo is typically comprised of two to four cells. It is possible to transfer the embryo at this early stage if the embryos are developing poorly, or if few embryos are available. After three days, the embryo is typically comprised of six to eight cells. Typically, an embryo is cultured for at least five days, when the embryo has developed to a blastocyst comprised of greater than 64 cells. By this point, the blastocyst has two distinct cell types—surface cells, called the trophectoderm, that will later develop into the placenta, and an inner cell mass, which will become the fetus.

40. During this time, the embryo culture media is critical to an embryo's successful development. Culture media has been shown to not only impact an embryo's ability to develop into a healthy blastocyst, but also future fetal development and perinatal outcomes, including gestational age and birthweight.

The Unique and Precious Nature of Human Embryos

41. Defendants are aware of the lengths to which families go to extract eggs and create embryos, their emotional and financial investment in the survival of their embryos, and their expectations that their embryos will be handled with care to avoid irreparable, devastating harm.

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[27] Yuko Komiya et al., *Magnesium and Embryonic Development*, MAGENES RES. (2014) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4207262/; Liyou An et al., *Magnesium is a critical element for competent development of bovine embryos*, THERIOGENOLOGY (2019) doi.org/10.1016/j.theriogenology.2019.08.015.

[28] *Id.*

[29] *Id.*

42. Embryos are precious. They offer the opportunity to fulfill a fundamental human desire: to become a parent and start a family. Reproductive material has immense emotional and personal value. Families who do not use all of their embryos may donate them to a family member or another couple struggling with infertility, or toward beneficial research. Indeed, embryos may offer life-saving medical treatment options for anyone in the family down the road.

43. Embryos are also irreplaceable. Human eggs, also known as oocytes, are a limited resource. A woman has about one million eggs at birth and this supply diminishes at a rate of about 1,000 eggs per month. This decline is part of the natural aging process and is commonly referred to as a woman's biological clock. The loss of oocytes from the ovaries continues in the absence of menstrual cycles, and even when women are pregnant, nursing, or taking oral contraceptives. Egg quality diminishes with time, with miscarriages and chromosomal abnormalities occurring more frequently for older women. The most determinative factor in IVF success is the woman's age at the time her eggs were extracted. At some point, usually around her mid-40s, a woman can no longer produce viable eggs. If a couple is unable to use their preserved embryos it might be too late to go through another round of IVF, thereby making it impossible to get pregnant and start a family.

44. The success or failure of creating healthy embryos through IVF has substantial emotional ramifications for those seeking to become parents. Losing embryos provokes fear, devastation, and despair. Many experience grief and anguish when fertility treatment does not result in pregnancy or when their fertility choices diminish.

45. The loss or improper development of embryos naturally results in serious emotional harm to hopeful parents. Families undergoing IVF entrust their embryos to manufacturers such as Defendants. These hopeful parents invest the most precious parts of who they are, their reproductive material, which is their most valuable and irreplaceable property. Emotional distress stemming from embryo loss or damage is thus predictable.

Defendants' Role in the IVF/ART Market

46. Defendants have positioned themselves as leaders in the reproductive health and infertility treatment fields.

47. Defendant CooperSurgical describes itself as "the global leader in IVF and reproductive genetics, providing innovative products and services for every step in the ART journey. Our company vision is a world with healthy women, babies and families."[30]

48. CooperSurgical boasts its ability to provide "unique solutions at every step of the ART cycle" and "industry-leading ART innovation."[31] CooperSurgical claims to offer "effective solutions that support clinical efficiency and engaged and supported patients. All to conceive, deliver, and protect healthy babies."[32]

49. Cooper Companies claims "We elevate standards of care with best-in-class devices for … women's health, and fertility."[33]

50. Cooper Companies owns a large stake in the women's health and fertility market, including through millions of dollars in assets it owns related to fertility products, including but not limited to the Bakri Postpartum Balloon, Cook's Cervical Ripening Balloon, and the Doppler Blood Flow Monitor portfolios.[34]

51. In April 2018, Cooper Companies acquired The LifeGlobal Group—"a leading global provider of in-vitro fertilization (IVF) devices." Cooper's president and CEO described this acquisition as "improving [Cooper Companies'] industry leading fertility business overall."[35]

52. In December 2021, Cooper Companies acquired Generate Life Sciences, "a leading provider of donor egg and sperm for fertility treatments, fertility cryopreservation services and newborn stem cell storage (cord blood & cord tissue)."[36]

53. Cooper Companies elected physician Maria Rivas to its board of directors in May 2021, in part based on her background in the field of fertility.[37]

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[30] https://fertility.coopersurgical.com/about-us/.
[31] https://fertility.coopersurgical.com/about-us/.
[32] https://www.coopersurgical.com/healthcare-providers/fertility-birth.
[33] https://www.coopercos.com/improving-lives/#elevating.
[34] https://investor.coopercos.com/news-releases/news-release-details/coopercompanies-expands-coopersurgicals-medical-device-portfolio.
[35] https://investor.coopercos.com/news-releases/news-release-details/cooper-companies-acquires-lifeglobal-group-expanding-fertility.
[36] https://investor.coopercos.com/news-releases/news-release-details/coopercompanies-completes-acquisition-generate-life-sciencesr.
[37] https://investor.coopercos.com/news-releases/news-release-details/coopercompanies-elects-

54. Cooper Companies' $875 million acquisition of Cook Medical's Reproductive Health business—"a manufacturer of minimally invasive medical devices focused on the fertility, obstetrics and gynecology markets"—in May 2022 demonstrates Cooper Companies' prominent role in the fertility industry. Cooper Companies' president and CEO commented on this acquisition by stating, "We're improving our international fertility footprint, especially within the Asia-Pacific region, and adding highly synergistic and respected labor and delivery devices to our ObGyn portfolio."[38]

55. CooperSurgical's mission states: "We are 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."[39]

56. CooperSurgical participates in symposiums and expos regarding IVF-related topics.[40] For example, CooperSurgical was a platinum-level sponsor for the American Society for Reproductive Medicines 2023 Scientific Congress & Expo.[41]

57. Operating through CooperSurgical, Defendant Cooper Companies is a prominent leader in the global infertility treatment market.

58. As a manufacturer and supplier of IVF products, the emotional concerns of Defendants' consumers, like Plaintiffs, are the essence of their work, as the very materials manufactured by Defendants play a critical role in the highly personal and emotionally-laden process of conceiving a child through IVF.

59. Defendants recognize the incredible value of the reproductive material that their products are designed to test and safeguard.

60. There are very few manufacturers of products for use in ART laboratories. Defendants operate in a very niche market. In this small and highly specialized space, Defendants are, upon information and belief, one of the largest manufacturers of ART products.

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maria-rivas-md-board-directors.

[38] https://investor.coopercos.com/news-releases/news-release-details/coopercompanies-acquire-cookr-medicals-reproductive-health.

[39] https://www.coopersurgical.com/about-us.

[40] https://fertility.coopersurgical.com/session/symposiums/.

[41] https://asrmcongress.org/.

Very few companies provide similar products, and these other companies are much smaller than Defendants.

61. Further, Defendants work very closely with IVF laboratories to provide IVF products to families, like Plaintiffs, who are desperately hoping to have a healthy baby.

62. Indeed, on its public website, CooperSurgical includes patient testimonials from families struggling with infertility.[42]

63. For example, one testimonial on CooperSurgical's website describes the experience of an embryologist facing infertility and undergoing IVF.[43] This testimonial recognizes the "incredible struggles that IVF patients go through," the "hysterics" that can arise from unexpected events in the IVF process, and the "devastation," "confusion," and "stress" that often arises during one's IVF journey.[44] The embryologist writes, "I look at every single embryo with awe about what it is capable of. I think about how my babies started from a little bundle of cells just like them. [. . .] I know how it feels to get that positive pregnancy test, to feel a baby grow inside me, the excitement of packing a hospital bag, setting up a nursery and bringing a baby home. I want this for every single person that I know is trying for a baby."[45]

64. CooperSurgical's website states, "At CooperSurgical, we understand the struggles that families facing infertility go through. Families #deservetoknow they are not alone, and that their family, friends, and CooperSurgical are here for them every step of the way."[46] This page of CooperSurgical's website provides greeting cards for families going through infertility to "help spread the message of support and empathy for families in need."[47] CooperSurgical writes,

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[42] https://www.coopersurgical.com/patients/patient-article-list?refinementList%5Blife_stage_name%5D%5B0%5D=I%20want%20kids&refinementList%5Bcondition_name%5D%5B0%5D=Infertility%20%26%20IVF&page=2.

[43] https://www.coopersurgical.com/patient-article/an-embryologists-journey-to-conceive-while-helping-others-on-the-same-path.

[44] *Id.*

[45] *Id.*

[46] https://www.coopersurgical.com/patient-article/our-greeting-card-initiative-is-here-to-send-a-message-about-infertility.

[47] *Id.*

"Thank you for your continued support as we work to create a more compassionate and understanding world for families facing infertility."[48]

65. Defendants recognize that they engage in a peculiarly sensitive and emotional business by manufacturing and supplying IVF products used by families, like Plaintiffs, who face barriers to conceiving a healthy child.

Defendants' Defective Embryo Culture Media

66. Defendants manufacture and market multiple lines of "cutting-edge ART culture media for IVF procedures."[49] These products are advertised as "[c]reating the optimal environment for human embryology procedures."[50]

67. Among Defendants' culture media is the CooperSurgical LifeGlobal global® Media (the "Global Media").

68. Defendants' Global Media is advertised by CooperSurgical as "the original single-step, protein-free medium for uninterrupted embryo culture."[51] The media "[c]ontains energy substrates and essential amino acids to support embryo growth and development."[52]

69. CooperSurgical advertises: "Our products undergo thorough quality testing before being released, to ensure consistent quality for your piece of mind. Our focus on quality at every level of our operations is audited and confirmed by our notified bodies, that delivers quality certificates."[53]

70. Specifically, Defendants advertise that the performance of the Global Media "has been demonstrated through 15 years of use and 500 independent publications using global medium."[54]

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[48] *Id.*
[49] https://fertility.coopersurgical.com/art-media-products/culture-media-for-ivf-procedures/.
[50] https://fertility.coopersurgical.com/culture-solutions/.
[51] https://fertility.coopersurgical.com/art_media/global/#toggle.
[52] *Id.*
[53] https://www.coopersurgical.com/healthcare-providers/support-compliance/quality-certifications.
[54] https://fertility.coopersurgical.com/art_media/global/#toggle.

71. Yet, on December 5, 2023, Defendants issued an Urgent Media Recall: Field Safety Notice[55] (the "Recall Notice") regarding certain lots of the Global Media (part numbers LGGG-100, LGGG-50, and LGGG-20; lot numbers 231020-018741, 231020-018742, and 231020-018743 (the "Recalled Lots")).

72. The Recall Notice states "CooperSurgical has become aware of a sudden increase in complaints regarding the aforementioned lots of this product" and identifies that "[t]he risk to health is impaired embryo development prior to the blastocyst stage."

73. Defendants did not immediately communicate the information contained in the Recall Notice to the public or the IVF community.

74. Defendants knew or should have known that embryo culture media is carefully formulated with specific necessary elements, and that a lack of such critical components, such as magnesium, in the Global Media may result in the destruction or arrested development of human embryos.

75. Despite this, on information and belief, Defendants failed to adequately monitor their manufacturing systems and processes, and allowed for the production of embryo culture media without ensuring that sufficient amounts of magnesium and/or other critical elements were included.

76. On information and belief, Defendants did not properly test or inspect the impacted lots of Global Media until after receiving numerous complaints from fertility clinics that embryos cultured in Defendant's Global Media were destroyed at elevated rates.

77. As a leading manufacturer and supplier of IVF products, including embryo culture media, Defendants knew that if the Global Media was contaminated or manufactured improperly, it could destroy human embryos upon contact, prevent the proper and healthy development of human embryos, have significant and adverse consequences for the survival outcome of embryos, and/or harm the children that result from those embryos. Accordingly, Defendants knew it was vitally important that their culture media was properly assembled, composed, tested and/or inspected prior to the distribution of such media.

[55] https://www.lieffcabraser.com/pdf/Cooper_Recall_Notice.pdf.

78. Despite this, Defendants failed to properly inspect, assemble, compose, and/or test its culture media, including the Recalled Lots of Global Media. Defendants knowingly put their culture media into the market when they knew or should have known that the Recalled Lots posed a substantial and unacceptable risk to human embryos, including Plaintiffs' embryos.

79. As described above, Defendants knew that people go to extraordinary lengths to obtain and use viable human embryos. Defendants knew that people place an extremely high value on their embryos, make substantial physical, emotional, and financial investments for their embryos, and expect that great care will be taken to preserve and protect the embryos in order to avoid irreparable harm to their embryos.

80. Defendants' conduct was despicable and was carried out by Defendants with a willful and conscious disregard of the rights and/or safety of others, including putting Defendants' profits over the safety of others, including Plaintiffs. 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.

81. On information and belief, Defendants previously have manufactured and sold numerous products used in ART, including other culture media, that were defective and sometimes recalled.[56]

Defendants' Devastating Destruction of or Damage to Plaintiffs' Embryos

82. Plaintiffs have limited options to have biological children. Plaintiffs were thrilled that IVF held the potential to do so.

83. Plaintiffs thus sought fertility treatments from CNY Fertility – Albany in Latham, New York.

[56] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=198891#:~:text=CooperSurgical%2C%20Inc.&text=It%20has%20come%20to%20CooperSurgical's,for%20embryo%20culture%20and%20development.&text=An%20URGENT%3A%20VOLUNTARY%20MEDIA%20RECALL,23%20was%20sent%20to%20customers;

84. After undergoing the physically and emotionally taxing process of preparing for, and undergoing, their seventh egg retrieval on or about November 29, 2023, Plaintiffs were thrilled to learn that twelve of H.H.'s eggs had been retrieved. Nine of those eggs were fertilized and placed in Defendants' Global Media. An embryo culture indicated that seven fertilized eggs were considered "good" quality, and two were considered "poor."

85. Plaintiffs transferred two embryos at CNY Fertility – Albany on January 23, 2024.

86. A week after the transfer, while Plaintiffs were waiting to learn whether it had been successful, Plaintiffs received an email from their clinic stating that Plaintiffs' embryos had been cultured in the recalled Global Media manufactured by Defendants.

87. The news created additional stress for Plaintiffs at a critical time, and the transfer was unsuccessful—H.H. did not become pregnant. Plaintiffs were devastated, and shocked to learn that Defendants' recalled Global Media had in fact destroyed, damaged, or rendered unusable their precious embryos.

88. Plaintiffs' embryos were profoundly important to them—their most sacred possessions. These embryos represented Plaintiffs' hopes and dreams to have a healthy biological child.

89. As a result of each Defendant's conduct, Plaintiffs have suffered foreseeable, serious, life-long harm, including the loss of their potential children.

90. As a result of each Defendant's conduct, Plaintiffs suffered emotional trauma, including shock, hopelessness, fear, devastation, anger, and grief over the loss of their embryos, the loss of their rights to control their fertility and fertility options, the loss of control over their reproductive futures, and the increased uncertainty and risk of future infertility.

91. Further, time is not on Plaintiffs' side, as they face increasingly daunting odds of achieving their family planning goals. H.H. is 45 and her egg quantity and quality will continue to decline as Plaintiffs attempt to preserve their dwindling fertility options.

92. Plaintiffs seek all damages, equitable relief, and remedies available under the law.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY—MANUFACTURING DEFECT

93. Plaintiffs incorporate the above and below allegations by reference.

94. Defendants manufactured, tested, supplied, distributed, and/or sold embryo culture media, including the defective Global Media used on Plaintiffs' embryos.

95. The Global Media contained a manufacturing defect when it left Defendants' possession. This defect included, but is not limited to, the Global Media containing difference(s) in its chemical structure or composition and/or toxicity, such as a lack of sufficient levels of magnesium and/or other critical elements, such that it destroyed or hindered the development of human embryos upon contact, in addition to the other serious risks discussed above.

96. Defendants 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, and was defective in manufacture, including because it could destroy and prevent the development of fragile human embryos.

97. The Global Media was used as intended when it came into contact with Plaintiffs' embryos.

98. As a result of Defendants' conduct, Plaintiffs were harmed as described herein.

99. A reasonable person in Plaintiffs' position would sustain emotional distress as a result of Defendants' manufacturing defect.

100. The defective nature of the Global Media was a substantial factor in causing Plaintiffs' harm.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY—DESIGN DEFECT—CONSUMER EXPECTATIONS TEST

101. Plaintiffs incorporate the above and below allegations by reference.

102. Defendants designed, manufactured, distributed, tested, supplied, and/or sold embryo culture media, including the defective Global Media used on Plaintiffs' embryos.

103. The Global Media was defective in design in that it did not perform as safely as an ordinary consumer would have expected it to perform when used in an intended or reasonably foreseeable way.

104. Defendants 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, and was defective in design, including because it could destroy and prevent the development of fragile human embryos.

105. As a result of Defendants' conduct, Plaintiffs were harmed as described herein, including by the destruction of their embryos.

106. A reasonable person in Plaintiffs' position would sustain emotional distress as a result of Defendants' conduct described herein.

107. The Global Media's failure to perform safely and effectively was a substantial factor in causing Plaintiffs' harm.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY—DESIGN DEFECT—RISK-UTILITY TEST

108. Plaintiffs incorporate the above and below allegations by reference.

109. Defendants designed, manufactured, distributed, tested, supplied, and/or sold embryo culture media, including the defective Global Media used on Plaintiffs' embryos.

110. The benefits of the Global Media's design are not outweighed by its risks, considering the gravity of the potential harm resulting from the use of the Global Media, the likelihood that the harm would occur, the feasibility of an alternative safer design at the time of manufacture, and the disadvantages of an alternative design.

111. Defendants 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, and was defective in design, including because it could destroy and prevent the development of human embryos upon contact.

112. As a result of Defendants' conduct, Plaintiffs were harmed as described herein, including by the destruction of their embryos.

113. A reasonable person in Plaintiffs' position would sustain severe emotional distress as a result of Defendants' conduct described herein.

114. Defendants' design of the Global Media was a substantial factor in causing Plaintiffs' harm.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY –FAILURE TO WARN

115. Plaintiffs incorporate the above and below allegations by reference.

116. Defendants designed, manufactured, tested, supplied, distributed, and/or sold the defective Global Media used on Plaintiffs' embryos.

117. The Global Media had potential risks—including but not limited to defective formulation due to, on information and belief, a lack of magnesium and/or other critical elements—that were known or knowable in light of 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.

118. The potential risks of destroying and preventing the development of human embryos upon contact presented a substantial danger when the Global Media was used or misused in an intended or reasonably foreseeable way. The ordinary consumer would not have recognized the potential for risks.

119. The Global Media was defective and unreasonably dangerous when it left Defendants' possession because it did not contain adequate warnings, including warnings concerning the risk of destroying and preventing the development of human embryos when used to culture human reproductive cells. Defendants failed to adequately warn or instruct of the potential risks of applying its defective Global Media to human reproductive material.

120. Defendants 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, and would destroy and prevent the development of human embryos upon contact.

121. Defendants knew or reasonably should have known that users may not have adequate quality control measures in place to detect the dangers of the Global Media before applying it to reproductive cells, and failed to adequately warn or instruct concerning the potential risks of applying the Global Media to reproductive cells when a reasonable manufacturer, distributor, or seller under similar circumstances would have warned of the danger or instructed in the safe use of the Global Media.

122. It was foreseeable to Defendants that the failure to adequately warn about the risks of the defective Global Media would cause irreparable harm, including the type of emotional distress suffered by Plaintiffs. A reasonable person in Plaintiffs' position would sustain severe emotional distress as a result of Defendants' failure to warn.

123. As a result of Defendants' failure to adequately warn, Plaintiffs were harmed as described herein. The lack of sufficient instructions and warnings was a substantial factor in causing Plaintiffs' harm.

FIFTH CAUSE OF ACTION

NEGLIGENCE/GROSS NEGLIGENCE

124. Plaintiffs incorporate the above and below allegations by reference.

125. Defendants and/or their predecessors-in-interest designed, produced, manufactured, assembled, sold, supplied and/or otherwise placed the defective Global Media into the stream of commerce, or maintained and inspected the Global Media, and owed a duty of care to those whose embryonic cells were tested upon using the Global Media, such as Plaintiffs, as a result. Defendants 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 safely test precious embryonic matter. Defendants knew or should have known that any changes in the Global Media could destroy or prevent the development of human embryonic cells when used for embryo culture. Defendants

and/or their predecessors-in-interest were negligent, reckless, and careless and failed to take the care and duty owed to Plaintiffs, thereby causing Plaintiffs to suffer harm.

126. As manufacturers of culture media for use with human embryos, Defendants owed a duty, including to Plaintiffs, to design, manufacture, inspect, and/or test their embryo culture media such that the media was properly formulated and contained the ingredients necessary for embryonic development, including but not limited to, on information and belief, sufficient levels of magnesium and/or other critical elements.

127. Specifically, and as described above, Defendants negligently designed, produced, manufactured, assembled, supplied, maintained, and/or tested and analyzed the Global Media by designing, producing, assembling, supplying, and/or failing to warn or correct through inspection, maintenance, monitoring, testing, and analysis the Global Media with multiple flaws in manufacture and/or design, including, but not limited to: an embryo culture media that, when applied to embryonic cells, would destroy or prevent the development of the cells.

128. The negligence and extreme carelessness of Defendants and/or their predecessors-in-interest includes, but is not limited to, the following:

a. Failure to use reasonable care in the design of the Global Media applied to Plaintiffs' fertilized eggs;

b. Failure to use reasonable care in the production of the Global Media applied to Plaintiffs' fertilized eggs;

c. Failure to use reasonable care in the manufacture of the Global Media applied to Plaintiffs' fertilized eggs;

d. Failure to use reasonable care in the assembly of the Global Media applied to Plaintiffs' fertilized eggs;

e. Failure to use reasonable care in supplying the Global Media applied to Plaintiffs' fertilized eggs;

f. Failure to reasonably and properly test and properly analyze the testing of the Global Media under reasonably foreseeable circumstances;

g. Failure to warn its customers about the dangers associated with use of the Global Media, in that the Global Media would destroy and prevent the development of human embryos upon contact;

h. Failure to utilize proper materials and components in the design of the Global Media to ensure it would not destroy and prevent the development of human embryos upon contact;

i. Failure to use due care under the circumstances;

j. Failure to take necessary steps to modify the Global Media;

k. Failure to promptly recall the Global Media;

l. Failure to properly design, manufacture, assemble, sell, distribute, supply, repair, and/or modify the Global Media; and

m. Failure to maintain safety systems and procedures to ensure that the Global Media would operate properly and safely culture human embryos.

129. Defendants' total lack of care is an extreme departure from what a reasonably careful entity would do in the same situation and constitutes negligence.

130. Plaintiffs were harmed by Defendants' negligence when their defective Global Media destroyed, damaged, or rendered unusable their embryos.

131. Defendants' carelessness and negligence directly and foreseeably damaged Plaintiffs. Defendants' negligent production of the defective Global Media foreseeably caused mental anguish and serious emotional distress, among other injuries, to Plaintiffs.

132. Defendants explicitly and intentionally are involved in the business of manufacturing products for the culture of human embryos in IVF laboratories, and know the sensitive and emotional nature of the IVF procedures for which their products are used. Defendants further knew that Plaintiffs would be particularly vulnerable to emotional distress and other harms, such as potentially being foreclosed from having an additional child, if their fertilized eggs failed due to Defendants' faulty product.

133. Given that Defendants manufacture products that are used for the culture and development of incredibly valuable, unique, personal, irreplaceable, and sensitive material—

human embryos—Defendants assumed a duty to Plaintiffs where emotional concerns are of the essence. The culture and development of embryonic cells is intertwined with Plaintiffs' most vital concerns, including comfort, happiness, and personal welfare. Manufacturing and supplying defective IVF products is likely to cause serious emotional distress to hopeful parents, like Plaintiffs, whose embryos were affected by the defective products. Thus, the negligence at issue here is of the type that would cause predictable emotional distress.

134. There was a close connection between Defendants' conduct and Plaintiffs' injuries. Plaintiffs experienced emotional distress and other harms because Defendants failed to act reasonably in all aspects of the creation of the defective Global Media.

135. Plaintiffs trusted that those responsible for designing, manufacturing, and selling the Global Media would use reasonable care to create a safe and working product for embryo culture. Defendants' carelessness with this precious task, and ultimately, with Plaintiffs' careful plans for parenthood, amounts to despicable conduct.

136. 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 the foreseeable loss of embryos during the IVF process.

137. Defendants acted willfully, wantonly, and with a conscious disregard for the safety of users of their embryo culture media, including Plaintiffs, because Defendants were aware of the dangerous consequences of not properly or adequately testing their embryo culture media (specifically the Recalled Lots of Global Media), Defendants knew or should have known the embryo culture media (specifically, the Recalled Lots of Global Media) lacked vital nutrients such that it posted a severe risk to irreplaceable developing human embryos, and Defendants failed to recall the Global Media before it was used to culture Plaintiffs' embryos.

138. Defendants' failure to use reasonable care in designing, manufacturing, and selling its Global Media was a substantial factor in causing Plaintiffs severe emotional distress. Defendants' misconduct has irreparably breached trust and caused uncertainty, anxiety, and fear among Plaintiffs and other affected families.

139. As a result of Defendants' negligence, Plaintiffs were harmed as described herein.

140. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

141. As a foreseeable, direct and proximate result of the harm to Plaintiffs' reproductive material caused by Defendants' negligence, Plaintiffs have suffered and continue to suffer injuries in an amount to be determined at trial, including severe emotional distress consisting of worry, shock, fright, horror, anguish, suffering, grief, and nervousness. A reasonable person in Plaintiffs' position would sustain emotional distress as a result of Defendants' conduct described herein.

SIXTH CAUSE OF ACTION

NEGLIGENT FAILURE TO RECALL

142. Plaintiffs incorporate the above and below allegations by reference.

143. Defendants acted negligently by failing to recall the Global Media prior to its use on Plaintiffs' reproductive material.

144. At all times relevant herein, Defendants designed, manufactured, produced, distributed, maintained, tested, supplied and/or sold the defective Global Media.

145. Given the special relationship arising from the nature of the products Defendants market and sell, Defendants owed Plaintiffs a duty to exercise reasonable care with respect to the Global Media so as to avoid damaging Plaintiffs' reproductive material and jeopardizing their embryos' health and development. Embryo culture and development are intertwined with Plaintiffs' most vital concerns, including comfort, happiness, and personal welfare.

146. Defendants knew or reasonably should have known that, when used as intended, the defective Global Media was likely to present a danger to reproductive material. Defendants knew or reasonably should have known that the Global Media, when used on reproductive material, would destroy human cells and prevent their development. Moreover, Defendants knew or reasonably should have known that upon use of the defective Global Media, Plaintiffs' embryos would be destroyed, damaged, or rendered unusable.

147. When Defendants sold the Global Media for use on patients', including Plaintiffs', reproductive material, Defendant knew or reasonably should have known that the

Global Media was defective, including, but not limited to, by destroying, damaging, or rendering unusable the fertilized eggs.

148. Nevertheless, Defendants did not recall, repair, or warn of the danger posed by the defective Global Media prior to its use on Plaintiffs' developing embryo.

149. A reasonable designer, manufacturer, distributor, or seller facing the same or similar circumstances as Defendants in the exercise of reasonable care would have recalled the defective Global Media sooner to ensure the reproductive material was not endangered.

150. Plaintiffs experienced substantial harm due to Defendants' failure to timely recall the Global Media, including the loss of potential children.

151. Defendants' failure to timely recall the defective Global Media was a substantial factor in causing harm to Plaintiffs. Had Defendants recalled the Global Media before it was applied to Plaintiffs' fertilized eggs, the Global Media would not have been used on Plaintiffs' reproductive material and Plaintiffs' embryos would not have been destroyed, damaged, or rendered unusable.

152. Plaintiffs' harm occurred in the course of specified categories of activities, undertakings, or relationships in which negligent actions and negligent failures to act were especially likely to cause serious emotional harm: the culture of human embryos during the IVF process for families seeking to have children. It was reasonably foreseeable to Defendants that Plaintiffs would experience severe emotional distress as a result of any breach of their duty of reasonable care. A reasonable person in Plaintiffs' position would sustain severe emotional distress as a result of Defendants' conduct.

153. Recognizing that Defendants have a duty to avoid causing emotional distress and other harm will promote the policy of preventing future harm, by motivating Defendants to implement processes and systems reasonably likely to avoid harm to reproductive material moving forward. Such a duty also furthers the community's interest in ensuring that the safe culture of embryos is available to those who wish to become parents.

154. The burden on Defendants arising out of a duty to avoid causing emotional distress is fair and appropriate, in light of the importance of the reproductive material destroyed, damaged, or rendered unusable by the Global Media, at considerable cost to Plaintiffs.

SEVENTH CAUSE OF ACTION

TRESPASS TO CHATTELS

155. Plaintiffs incorporate the above and below allegations by reference.

156. Plaintiffs owned or had the right to possess their reproductive material—their fertilized eggs—that was destroyed, damaged, or rendered unusable by Defendants' Global Media.

157. Defendants intentionally interfered with Plaintiffs' possession of their fertilized eggs by manufacturing a defective product that destroyed, damaged, or rendered unusable the material instead of safely culturing the fertilized egg to develop into healthy embryos, and by failing to recall or warn about the dangers of this product before it was used on Plaintiffs' reproductive material.

158. Plaintiffs did not consent to or authorize the use of a faulty and defective culture media on their fertilized eggs.

159. Defendants caused physical damage to Plaintiffs' personal property when the Global Media destroyed, damaged, or rendered unusable their fertilized eggs.

160. Defendants impaired the condition, quality, or value of Plaintiffs' personal property when the Global Media prevented the fertilized eggs from developing into blastocysts.

161. Defendants' interference with Plaintiffs' reproductive material proximately caused harm to Plaintiffs, as described herein, including by destroying, damaging, or rendering unusable their embryos.

162. As a foreseeable, direct and proximate result of the harm to Plaintiffs' reproductive material caused by Defendants' trespass, Plaintiffs have suffered and continue to suffer injuries in an amount to be determined at trial, including severe emotional distress consisting of worry, shock, fright, horror, anguish, suffering, grief, and nervousness. A

reasonable person in Plaintiffs' position would sustain emotional distress as a result of Defendants' conduct described herein.

EIGHTH CAUSE OF ACTION

UNJUST ENRICHMENT

163. Plaintiffs incorporate the above and below allegations by reference.

164. Plaintiffs conferred a tangible and material economic benefit on Defendants by purchasing the defective Global Media.

165. Defendants voluntarily and readily accepted and retained the benefits.

166. Plaintiffs would not have purchased the Global Media had they known its defective nature.

167. This benefit was obtained unlawfully. Defendants marketed the Global Media as being safe and effective for use on Plaintiffs' reproductive material. Defendants knew or should have known that the payments rendered by Plaintiffs were given with the expectation that the Global Media would have the qualities, characteristics, and suitability for use represented by Defendants.

168. Defendants received benefits in the form of revenues from purchases of their Global Media to the detriment of Plaintiffs, who purchased defective embryo culture media that was not what Plaintiffs bargained for and was not safe and effective, as claimed by Defendants.

169. Thus, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

170. Defendants have been unjustly enriched in retaining the benefits derived from the purchase of Global Media by Plaintiffs. Retention of the payments received 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 Global Media had they known its true, defective nature.

171. Plaintiffs are entitled to restitution and to recover from Defendants all amounts wrongfully and improperly retained in the amount necessary to Plaintiffs to the position they occupied prior to purchasing and being harmed by the Global Media.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

1. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;
2. Compensation for past, present, and future economic and non-economic losses, in an amount to be determined at trial;
3. Punitive and/or exemplary damages in such amounts as may be proven at trial;
4. Attorneys' fees and costs;
5. Pre- and post- judgment interest; and
6. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

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

Dated: June 13, 2024

/s/ Sarah R. London

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