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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

M.M. and N.N.,

Plaintiffs,

v.

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

Defendants.

Case No.

**COMPLAINT FOR DAMAGES AND
DEMAND FOR JURY TRIAL**

COMPLAINT
CASE NO.

INTRODUCTION

1
2 1. Defendants CooperSurgical, Inc. (“CooperSurgical”) and The Cooper Companies, Inc.
3 (“Cooper Companies”) manufacture, market, and sell products to fertility clinics, including a culture
4 media product designed to support the growth and development of embryos created through in vitro
5 fertilization (“IVF”). The culture media is a nutrient-rich liquid that surrounds a fertilized egg during the
6 incubation period to help it develop into a viable embryo as part of the IVF process.

7 2. In December 2023, CooperSurgical recalled certain lots of its culture media products,
8 which had been sold to hundreds of fertility clinics across the United States, based on evidence that they
9 were defective and could actually harm and destroy embryos instead of helping them grow.

10 3. Plaintiffs M.M. and N.N. are a married couple that sought fertility treatment at a fertility
11 clinic in Florida, undergoing the invasive, expensive, and emotionally taxing process of IVF in the hopes
12 of having biological children.

13 4. Unfortunately, Plaintiffs’ fertility clinic used Defendants’ defective culture media
14 products. Using N.N.’s sperm, the clinic fertilized nine eggs purchased from a donor and placed them in
15 CooperSurgical’s culture media, on the expectation that it would help the fertilized eggs develop into
16 viable embryos.

17 5. Tragically, due to contact with Defendants’ products, the embryos were damaged and did
18 not result in successful transfer. Two embryos stopped growing before reaching day three. Five embryos
19 stopped growing before reaching day five. Plaintiffs attempted to transfer two embryos, but both failed as
20 a result of the contact with Defendants’ defective culture media.

21 6. Because of Defendants’ manufacturing, marketing, promoting, distributing, and/or selling
22 their defective culture media, Plaintiffs lost invaluable, irreplaceable property—embryos that could have
23 grown into their children—and were emotionally, physically, and psychologically damaged. Plaintiffs
24 bring this action to hold Defendants accountable for their conduct.

25 7. Plaintiffs seek damages, equitable relief, and other remedies from Defendants.
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JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a)(1) because Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds \$75,000.

9. This Court has personal jurisdiction over Defendants. They conduct substantial business in this District and intentionally availed themselves of the laws and markets of this District, and Cooper Companies resides in this district. A significant portion of the acts and omissions complained of occurred in the District.

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

INTRADISTRICT ASSIGNMENT

11. Assignment to the San Francisco or Oakland Division is proper under Local Rules 3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in Contra Costa County.

PARTIES

12. Plaintiff M.M. is a citizen and resident of Sarasota, Florida.

13. Plaintiff N.N. is a citizen and resident of Sarasota, Florida.

14. Given the sensitive nature of their claims, Plaintiffs are using randomized initials to protect their privacy. The Court approved this procedure, and Plaintiffs attach to this complaint a copy of the relevant Order, which shall constitute the plaintiff's and their counsel's agreement to comply with the requirements on the parties' stipulation agreeing to certain procedures regarding the use of pseudonyms.¹

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

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

¹ Exhibit A, Order Directing Clerk to Directly Assign and Relate Newly Filed Cases and to Allow Plaintiffs to Proceed Pseudonymously.

1 17. DOEs 1-10 are persons or entities of unknown places of residence or states of
2 incorporation that perpetrated the wrongdoing alleged herein. Plaintiffs will attempt to identify DOEs 1-
3 10 through discovery served on Defendants and third parties with whom Defendants interacted.

4 **FACTUAL ALLEGATIONS**

5 **A. In Vitro Fertilization Procedure**

6 18. IVF has become an established means of allowing individuals and couples the opportunity
7 to become pregnant using their biological material. IVF provides the flexibility to begin a family when it
8 makes sense for individuals and couples personally and professionally. IVF is also a way for those
9 suffering from infertility to start their families, using their own biological material.

10 19. An IVF cycle typically includes the following steps or procedures: (1) the patient takes
11 medications, including regular injections of hormones, to grow multiple eggs; (2) the clinic retrieves the
12 patient's eggs from the ovary or ovaries; (3) the eggs are inseminated with sperm; (4) the clinic cultures
13 any resulting fertilized eggs, fostering their development into embryos, including with the use of culture
14 media; (5) one or more embryo(s) are placed ("transferred") into the patient's uterus; and (6) the patient
15 takes additional hormones to support of the uterine lining to permit and sustain pregnancy.

16 20. In certain cases, additional procedures may be employed, including (1) intracytoplasmic
17 sperm injection ("ICSI") to increase the chance for fertilization; (2) assisted hatching of embryos to
18 potentially increase the chance of embryo attachment ("implantation"); and (3) cryopreservation
19 (freezing) of eggs or embryos.

20 21. The success of IVF largely depends on growing multiple eggs at once and then retrieving
21 the eggs (egg retrieval process). To achieve this goal, patients undergo a strict regimen of injections with
22 hormones and other medicines. These injections can cause a plethora of known side effects, including but
23 not limited to bruising, redness, swelling, or discomfort at the injection site, bloating, weight gain, water
24 retention, bone loss, fatigue, headaches, muscle aches, abdominal pain, breast tenderness, vaginal yeast
25 infections, vaginal dryness, bone loss, hot flashes, mood swings, depression, nausea, vomiting, diarrhea,
26 clots in blood vessels and strokes. Women injected with these pharmaceuticals also run the risk of a
27 potentially fatal allergic reaction to the drugs. And up to 2% of women will develop Ovarian
28 Hyperstimulation Syndrome ("OHSS"), a life-threatening condition that can cause increased ovarian size,

1 nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, increased
2 concentration of red blood cells, kidney and liver problems, blood clots, kidney failure, and death.

3 22. IVF requires multiple doctor visits involving routine blood tests and invasive transvaginal
4 ultrasound examinations, which are often scheduled with very little advanced warning. IVF also places
5 restrictions on diet, work, and travel.

6 23. The egg retrieval process itself involves surgery conducted under anesthesia, where the
7 eggs are extracted with a large needle inserted through the vaginal wall. Risks of the egg retrieval
8 procedure include infection, bleeding, trauma to intra-abdominal organs, allergic reactions, low blood
9 pressure, nausea, vomiting, and in rare cases, death. After the retrieval procedure, a patient often
10 experiences residual pain for about a week and may need bedrest for several days.

11 24. Another potential risk is that the procedure will fail to obtain any eggs, or the eggs may be
12 abnormal or of poor quality and otherwise fail to produce a viable pregnancy.

13 25. Based on their age and medical status, women may undergo multiple rounds of retrievals
14 to obtain enough eggs or embryos to achieve their reproductive goals. This process can take months or
15 even years. On average, women and couples spend \$40,000-\$60,000 out of pocket for these services.

16 26. If and when viable eggs are retrieved, IVF and embryo culture occurs. Sperm and eggs are
17 placed together in specialized conditions (culture media, controlled temperature, humidity, and light) to
18 achieve fertilization. Sperm and eggs are submerged in culture media, which is a nutrient-rich liquid
19 designed to promote the growth and development of a fertilized egg into a viable embryo by replicating
20 the natural environment and fluids in a woman's reproductive system. When they develop successfully,
21 embryos grow and reach certain milestones for viability over the course of several days following
22 insemination.

23 27. After the egg retrieval process, IVF patients can either receive a fresh embryo transfer or a
24 frozen embryo transfer. A fresh transfer occurs after a few days of embryo development. Embryos are
25 selected for transfer and are placed in the uterine cavity with a tube. By contrast, a frozen transfer
26 involves cryogenically freezing the embryo, then after a period of time, unthawing the embryo and
27 placing it in the patient's uterus. Frozen transfers allow a patient to elect to genetically screen the embryos
28 to determine if any suffer from genetic abnormalities making them unsuitable for transfer. If multiple

1 viable embryos are created in an IVF cycle, patients can opt to do a fresh transfer of one or more embryos
2 and freeze others for later transfer attempts. Excess embryos of sufficient quality that are not transferred
3 can be frozen. So long as they are properly stored, frozen embryos can remain viable and be transferred
4 years after they are retrieved.

5 **B. The Loss of Eggs and Embryos Has Severe Consequences**

6 28. People who engage in fertility services make large monetary and emotional investments.
7 They endure painful and invasive procedures, financial stress, and the strain the process puts on their
8 mental health and relationships with others, all in the hopes that one day they will be able to have a child.

9 29. In addition to the physical burdens of IVF, the process is also emotionally grueling. The
10 success or failure of IVF, including egg retrieval and embryo storage, has substantial emotional and
11 psychological ramifications for those seeking to become parents.

12 30. For many, the IVF process represents their last hope for having children. Many women
13 experience and express strong feelings of anxiety, failure, hopelessness, and disappointment during this
14 process. The IVF process can affect a patient and her spouse or partner medically, financially, socially,
15 emotionally, and psychologically. Feelings of anxiety, depression, isolation, and helplessness are not
16 uncommon in patients undergoing IVF. Losing eggs and embryos provokes fear, devastation, and despair.
17 Many people experience grief and anguish when fertility treatment does not result in pregnancy or when
18 they lose fertility choices.

19 31. As discussed above, women take drug and hormone cocktails and injections over several
20 weeks to stabilize the uterine lining, stimulate ovaries into producing follicles, and stop these ovary
21 follicles from releasing eggs. A woman may be subjected to multiple injections each day, resulting in
22 bruising, swelling, and discomfort. The drug and hormone therapy may also trigger other side effects,
23 such as tiredness, nausea, headaches, and blood clots, as well as negative emotions. The process can limit
24 travel and other activities, entails numerous doctor visits, and often requires time off from work. The
25 retrieval procedure itself requires anesthesia, as well as insertion of a thick needle through the vaginal
26 wall to drain the ovary follicles of their fluid. After the procedure, a woman often experiences residual
27 pain for about a week and may need bed rest for several days. Some women suffer significant side effects,
28 such as ovarian hyperstimulation syndrome, requiring hospitalization.

1 32. These invasive services are expensive. According to recent estimates, “a single IVF
2 cycle—defined as ovarian stimulation, egg retrieval and embryo transfer—can range from \$15,000 to
3 \$30,000, depending on the center and the patient’s individual medication needs.”² Clients typically pay
4 thousands of dollars for fertility drugs leading up to egg retrieval and may also spend hundreds of dollars
5 on acupuncture and other services recommended to them to improve outcomes. Depending on age and
6 health status, some women will undergo (and pay for) more than one IVF cycle, or if they freeze multiple
7 embryos, will pay thousands of dollars for each transfer attempted with an existing embryo.

8 33. Defendants are aware of the lengths to which people go to obtain eggs and create embryos,
9 how much they mean to patients, the patients’ emotional (and financial) investment in the survival of the
10 eggs and embryos, and the patients’ expectations that great care will be taken to preserve and protect the
11 eggs and embryos to avoid irreparable, devastating harm.

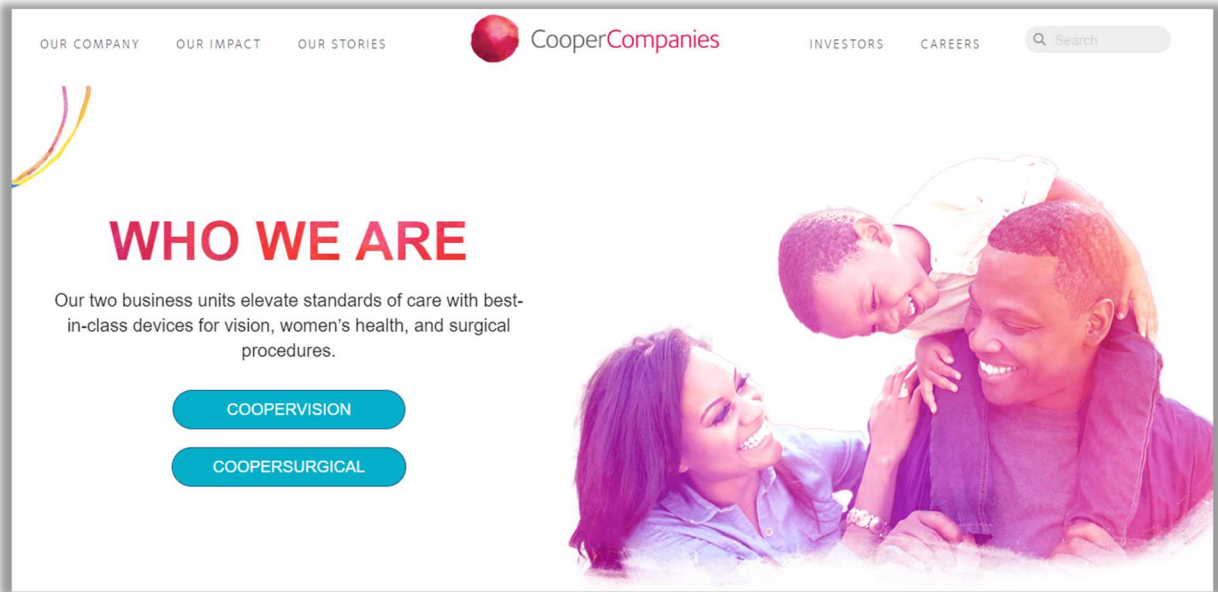
12 34. Eggs and embryos are precious. They offer the opportunity to fulfill one of the most
13 fundamental human urges: to become a parent and create one’s own family when the time is right. Eggs
14 and embryos are also irreplaceable. The most determinative factor in IVF success is the woman’s age at
15 the time her eggs were extracted. At some point, usually around her mid-40s, a woman can no longer
16 produce viable eggs. When preserved eggs or embryos are damaged or compromised, it may be
17 impossible for clients to build their family as they had planned.

18 **C. Defendants Manufacture and Sell Culture Media for Growing Embryos**

19 35. Cooper Companies consists of two business units: 1) CooperVision, which manufactures
20 contact lenses; and 2) CooperSurgical, which manufactures fertility products and medical devices for the
21 women’s healthcare market. Cooper Companies represents that “Our two business units,” CooperVision
22 and CooperSurgical, comprise “who we are,” as shown in the image from its website below.³

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28 ² <https://www.forbes.com/health/womens-health/how-much-does-ivf-cost/>.

³ <https://www.coopercos.com/our-company/>.



36. Operating through CooperSurgical, Defendant Cooper Companies is a prominent leader in the global IVF market.

37. The Cooper Companies has close involvement of in the operations of CooperSurgical. Cooper Companies employs and controls CooperSurgical’s top executive, President Holly Sheffield, whose employment agreement is exclusively with Cooper Companies. CooperSurgical’s four principals are all employed in California, and its mailing address is listed as the same California address as for The Cooper Companies: 6101 Bollinger Canyon Rd., Suite 500, San Ramon, California.

38. Cooper Companies claims that “[w]e elevate standards of care with best-in-class devices for . . . women’s health, and fertility.”

39. CooperSurgical describes itself as “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.”⁴

40. Together, Defendants have positioned themselves as leaders in the reproductive health and infertility treatment fields.

41. Specifically describing its role in the fertility space, CooperSurgical’s website promises that “[w]hen you partner with us you become part of a truly global network of scientific leaders,

⁴ <https://www.coopersurgical.com/about-us>.

1 embryologists and clinical training experts, ready to support you with highly specialized solutions, both
2 for individual clinics and across large organizations. By providing you with optimal products, service and
3 training our aim is to offer you the best possible support to drive the efficiency of your clinic – and
4 achieve the best possible results.”⁵

5 42. CooperSurgical advertises its embryo culture media product, called Global Media, as a
6 “Single-step medium for uninterrupted embryo culture,” noting that it is “[d]esigned for D1-5 embryo
7 culture and transfer,” “[c]ontains energy substrates and essential amino acids to support embryo growth
8 and development,” and “[t]he performance of global has been demonstrated through 15 years of use and
9 500 independent publications using global medium.”⁶

10 43. Cooper Companies, through its management team, Board of Directors, and Executive
11 Committee, retains overall control of CooperSurgical’s budget, production goals, risk assessment, and
12 quality control.

13 44. Culture media for embryo development is designed to meet the nutritional needs of
14 developing embryos by providing necessary sources of energy, nutrients, and pH levels based on the
15 specific developmental stage of the embryo. Embryo culture media is typically comprised of multiple
16 ingredients including carbohydrates, amino acids, vitamins, magnesium, and growth factors. The nutrients
17 in the media are crucial to an embryo’s successful growth.

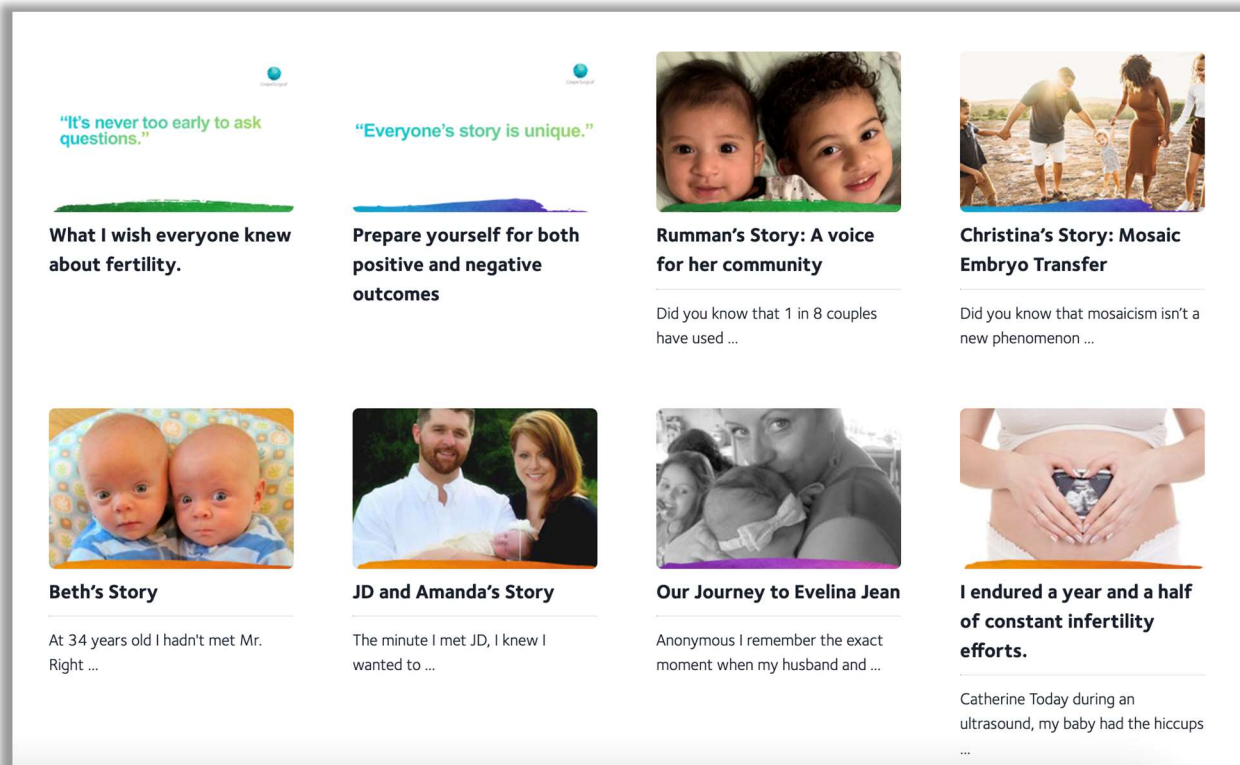
18 45. Magnesium is required for embryonic development and is a key element to repair
19 mutations during cell division. Insufficient magnesium levels in embryo culture media can cause embryo
20 growth to arrest and inhibit DNA repair.

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

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27 ⁵ <https://fertility.coopersurgical.com/about-us/>.

28 ⁶ <https://www.coopersurgical.com/product/global>; *see also*
https://fertility.coopersurgical.com/art_media/global/.

1 CooperSurgical’s website includes patient testimonials from families struggling with infertility, as shown
 2 in the screenshot from the website below, including articles titled “Christina’s Story: Mosaic Embryo
 3 Transfer,” “What I wish everyone knew about fertility,” and “I endured a year and a half of constant
 4 infertility efforts.”⁷



18 47. Defendants recognize that they engage in a peculiarly sensitive and emotional business by
 19 manufacturing and supplying IVF products used by families who face barriers to conceiving a healthy
 20 child.

21 48. CooperSurgical’s fertility division is highly profitable. Its CEO acknowledged that
 22 CooperSurgical experienced twelve consecutive quarters of “double-digit” growth in its fertility division,
 23 generating \$1.2 billion in revenue last year.⁸

27 ⁷ [https://www.coopersurgical.com/patients/patient-article-](https://www.coopersurgical.com/patients/patient-article-list?refinementList%5Blife_stage_name%5D%5B0%5D=I%20want%20kids)
 28 [list?refinementList%5Blife_stage_name%5D%5B0%5D=I%20want%20kids.](https://www.coopersurgical.com/patients/patient-article-list?refinementList%5Blife_stage_name%5D%5B0%5D=I%20want%20kids)

⁸ [https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/.](https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/)

1 **D. Recall of Defendants’ Embryo Culture Media**

2 49. In a letter dated December 5, 2023, CooperSurgical issued an Urgent Recall Notice for
3 certain lots of its Global Media culture product.⁹ Global Media Lots number 231020-018741, 231020-
4 018742, and 231020-018743 were recalled, with part numbers LGGG-100, LGGG-50, and LGGG-20.

5 50. The Recall Notice states “CooperSurgical has become aware of a sudden increase in
6 complaints regarding the aforementioned lots of this product,” acknowledged that the “risk to health is
7 impaired embryo development prior to the blastocyst stage,” and directed clinics who purchased the
8 product to quarantine and return it.¹⁰

9 51. According to regulatory authorities, CooperSurgical issued the recalls because the recalled
10 batches of the Global Media were deficient in magnesium.¹¹

11 52. Defendants knew or should have known that magnesium is a critical component and
12 essential element of embryo culture media, and that a lack of magnesium in the Global Media may result
13 in the destruction or arrested development of human embryos.

14 53. Defendants nevertheless failed to adequately monitor their manufacturing systems and
15 processes, and allowed for the production of embryo culture media without ensuring that sufficient
16 amounts of magnesium was included.

17 54. Defendants did not properly test or inspect the impacted lots of Global Media until after
18 receiving numerous complaints from fertility clinics that embryos cultured in Defendant’s Global Media
19 were dying at elevated rates.

20 55. The FDA posted a notice on its website regarding the recall in February 2024, estimating
21 that 994 bottles of culture media were affected, 481 of which were purchased by clinics across the United
22 States.¹²

23 _____
24 ⁹ Exhibit B, Cooper Surgical Recall Notice (December 5, 2023).

25 ¹⁰ *Id.*

26 ¹¹ <https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/>
27 (“Regulatory authorities have revealed that CooperSurgical issued recalls for several batches of its
28 I.V.F. product due to a crucial nutrient, Magnesium, being deficient”).

¹² <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205122> (noting distribution of
the recall product in the United States “Nationwide including in the states of AL, AZ, CA, CO, FL, GA,

1 56. A New York Times article on the recall reported that, according to Mitchel C. Schiewe, an
2 embryologist and a laboratory director at California Fertility Partners, “each bottle holds enough liquid
3 for multiple patients, though it’s unclear how many bottles were opened before the December recall. If
4 clinics used even half of the affected bottles, as many as 20,000 patients could have been affected.”¹³

5 **E. M.M. and N.N. were harmed by Defendants’ Defective Culture Media**

6 57. M.M. and N.N. are a married couple that sought help growing their family through IVF
7 treatment.

8 58. M.M. and N.N. engaged in IVF treatment at the CNY Fertility clinic in Sarasota, Florida.
9 They purchased from a donor ten eggs that were to be developed into viable embryos.

10 59. On or around November and December 2023, Plaintiffs’ fertility clinic fertilized nine of
11 the eggs with N.N.’s sperm and placed them in Defendants’ culture media.

12 60. All nine eggs were successfully fertilized, but due to the contact with Defendants’ culture
13 media, all the resulting embryos were damaged and destroyed. Two embryos stopped growing before
14 reaching day three. Five embryos stopped growing before reaching day five. Plaintiffs attempted to
15 transfer two embryos, but both failed as a result of the contact with Defendants’ defective culture media..

16 61. The embryos that Plaintiffs lost are irreplaceable.

17 **AGENCY AND ALTER EGO ALLEGATIONS**

18 62. At all relevant times, each Defendant was a principal, agent, alter ego, joint venturer,
19 partner, or affiliate of each other, and in doing the acts alleged herein, was acting within the course and
20 scope of that principal, agent, alter ego, joint venture, partnership, or affiliate relationship. Each
21 Defendant had actual knowledge of the wrongful act of each other; ratified, approved, joined in,
22 acquiesced, or authorized the wrongful acts of each other; and retained the benefits of those wrongful
23 acts.

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28 IL, IN, IA, KS, KY, LA, MD, MA, MI, MO, NV, NJ, NM, NY, NC, OH, OK, OR, PA, RI, TN, TX,
UT, VT, VA, WA, WV”).

¹³ <https://www.nytimes.com/2024/02/15/health/cooper-surgical-ivf-embryos-lawsuits.html>.

1 **FIRST CAUSE OF ACTION**

2 **Strict Products Liability – Manufacturing Defect**

3 63. Plaintiffs incorporate the above and below allegations by reference.

4 64. Defendants are strictly liable to Plaintiffs for harm caused by manufacturing defects in
5 their culture media under California products liability law.

6 65. Defendants manufactured, tested, supplied, distributed, and/or sold the culture media used
7 on Plaintiffs' embryos.

8 66. Defendants' culture media contained at least one manufacturing defect when it left
9 Defendants' possession. The culture media was defective in that it differed from Defendants' intended
10 result, did not conform to Defendants' design or specifications, and/or differed from other typical units of
11 the same product. In particular, among other possible defects, the media lacked a sufficient level of
12 magnesium, such that it destroyed or hindered the development of human embryos.

13 67. Defendants' culture media was used as intended when it came into contact with Plaintiffs'
14 embryos.

15 68. The culture media's defect was a substantial factor in causing Plaintiffs' damages,
16 including economic loss, serious emotional distress, and other harm in an amount to be determined at
17 trial.

18 **SECOND CAUSE OF ACTION**

19 **Strict Products Liability – Design Defect**

20 69. Plaintiffs incorporate the above and below allegations by reference.

21 70. In addition, or as an alternative to the first cause of action, Defendants are strictly liable to
22 Plaintiffs for harm caused by design defects in the culture media under California products liability law.

23 71. Defendants manufactured, tested, supplied, distributed, and/or sold the culture media,
24 which was defectively designed under the consumer expectations test and/or the risk-benefit test.

25 **Consumer Expectations Test**

26 72. Defendants' culture media did not perform as safely as ordinary users of culture media
27 expect when used or misused in an intended or reasonably foreseeable way.

1 73. Defendants' culture media caused Plaintiffs' embryos to stop developing and prevented
2 them from reaching viability. Ordinary users do not expect culture media to prevent embryo development.

3 74. Defendants' culture media's failure to perform safely was a substantial factor in causing
4 Plaintiffs' damages, including economic loss, serious emotional distress, and other harm in an amount to
5 be determined at trial.

6 75. Defendants' culture media was used as intended when it came into contact with Plaintiffs'
7 embryos.

8 **Risk-Benefit Test**

9 76. Defendants' culture media's design was a substantial factor in causing Plaintiffs' damages,
10 including economic loss, serious emotional distress, and other harm in an amount to be determined at
11 trial.

12 77. In particular, the culture media, which should have promoted the development of human
13 embryos fertilized *in vitro* was defectively designed. Among other things, the culture formulation lacked
14 a sufficient level of magnesium, causing Plaintiffs' embryos to stop developing and preventing them from
15 reaching viability.

16 78. Any benefits to its design that Defendants may allege in answer to this complaint do not
17 outweigh the risks of the design, taking into account the gravity of the potential harm, the likelihood the
18 harm would occur, the feasibility of an alternative design, the cost of an alternative design, and any
19 disadvantage associated with an alternative design.

20 79. Defendants' culture media was used as intended when it came into contact with Plaintiffs'
21 embryos.

22 **THIRD CAUSE OF ACTION**

23 **Strict Products Liability – Failure to Warn**

24 80. Plaintiffs incorporate the above and below allegations by reference.

25 81. Defendants designed, manufactured, tested, supplied distributed, and/or sold the defective
26 culture media, including the culture media used on Plaintiffs' embryos.

27 82. Defendants' culture media had potential risks—including but not limited to defective
28 formulation due to a lack of magnesium—that were known or knowable in light of the scientific and

1 medical knowledge that was generally accepted in the scientific community at the time of the
2 manufacture, distribution, or sale of the culture media.

3 83. Defendants' culture media was defective and unreasonably dangerous when it left
4 Defendants' possession because it did not contain adequate warnings, including warnings concerning the
5 risk of defect that its formulation lacked sufficient magnesium and would stop embryos development.

6 84. The potential risks of destroying and preventing the development of human embryos upon
7 contact presented a substantial danger when Defendants' culture media was used or misused in an
8 intended or reasonably foreseeable way.

9 85. The ordinary consumer would not have recognized the potential for risks. Defendants
10 knew or reasonably should have known that users may not have adequate quality control measures in
11 place to detect the dangers of the culture media before applying it to reproductive cells, and failed to
12 adequately warn or instruct concerning the potential risks of applying the culture media to reproductive
13 cells when a reasonable manufacturer, distributor, or seller under similar circumstances would have
14 warned of the danger or instructed in the safe use of the culture media.

15 86. Defendants had constructive notice or knowledge and knew, or in the exercise of
16 reasonable care should have known, that the culture media was dangerous, had risks, was defective in
17 manufacture or design, including that it would destroy and prevent the development of human embryos
18 upon contact.

19 87. Defendants failed to adequately warn or instruct of the potential risks of applying its
20 defective culture media to human reproductive material.

21 88. It is not reasonable for Defendants to rely on Plaintiffs' medical providers to warn about
22 the risk of the product defect.

23 89. It was foreseeable to Defendants that failure to adequately warn about the risks of its
24 culture media would cause irreparable harm to those whose embryos were exposed to it during IVF,
25 including the types of emotional distress suffered by Plaintiffs.

26 90. As a result of Defendants' failures to adequately warn, Plaintiffs were harmed as described
27 herein. Defendants' failure to warn was a substantial factor in causing Plaintiffs' damages, including
28 economic loss, serious emotional distress, and other harm in an amount to be determined at trial.

1 91. Defendants' culture media was used as intended when it came into contact with Plaintiffs'
2 embryos.

3 **FOURTH CAUSE OF ACTION**

4 **Negligent Failure to Recall**

5 92. Plaintiffs incorporate the above and below allegations by reference.

6 93. Defendants designed, manufactured, tested, supplied distributed, and/or sold the defective
7 culture media, including the culture media used on Plaintiffs' embryos.

8 94. Defendants acted negligently by failing to recall their defective culture media products,
9 prior to their use in the IVF process for Plaintiffs' embryos.

10 95. Defendants knew or reasonably should have known that, when used as intended, the
11 culture media presented or was likely to present a danger to developing human embryos, including that it
12 would destroy and prevent the development of human embryos upon contact.

13 96. After Defendants sold the defective culture media to Plaintiffs' fertility clinic and before
14 the defective culture media was used on Plaintiffs' embryos, Defendants knew or reasonably should have
15 known that the culture media was insufficiently tested, monitored, and developed, and that it presented a
16 danger to developing human embryos, including that it would destroy and prevent the development of
17 human embryos upon contact. Nevertheless, at no point during this time period did Defendants recall,
18 repair, or warn of the danger posed by the defective culture media.

19 97. A reasonable manufacturer, distributor, or seller facing the same or similar circumstances
20 as Defendants would have recalled the defective culture media to ensure developing human embryos were
21 not endangered.

22 98. Defendants' failure to timely recall the defective culture media was a substantial factor in
23 causing harm to Plaintiffs. Had Defendants recalled the defective culture media before it was used on
24 Plaintiffs' embryos, Plaintiffs' fertility clinic would not have used it, and it would not have destroyed,
25 damaged, or prevented the development of Plaintiffs' embryos upon contact.

26 **FIFTH CAUSE OF ACTION**

27 **Negligence/Gross Negligence**

28 99. Plaintiffs incorporate the above and below allegations by reference.

1 100. Defendants owed Plaintiffs a duty to exercise the highest degree of care when they
2 designed, produced, manufactured, assembled, sold, supplied and/or otherwise placed the defective
3 culture media into the stream of commerce for use in the growth and development of human embryos.

4 101. Defendants knew or reasonably should have known that their culture media needed to be
5 designed, produced, manufactured, assembled, maintained, inspected, sold and supplied properly, without
6 defects and with due care, for safe use in the growth and development of human embryos. Defendants
7 were negligent, reckless, and careless and failed to take the care and duty owed to Plaintiffs, thereby
8 causing Plaintiffs to suffer harm.

9 102. Defendants breached this duty and were negligent in the design, manufacture, inspection,
10 and/or testing of their embryo culture media, and produced an unsafe, dangerous, and defective embryo
11 culture media that guaranteed the failure of embryotic viability during the IVF process.

12 103. Defendants could have reasonably foreseen that if Defendants' embryo culture media was
13 defective, consumers of the embryo culture media, like Plaintiffs, would have experienced economic
14 loss and serious emotional distress as a result of Defendants' breach of their duty of care.

15 104. As a direct and proximate result of Defendants' negligent acts and/or omissions, including
16 but not limited to, failing to properly or adequately test their embryo culture media, promoting and
17 marketing their embryo culture media as properly tested and safe for use on human embryos despite their
18 knowledge of its defective nature, defectively designing their embryo culture media, defectively
19 manufacturing their embryo culture media, and/or failing to adequately warn of the dangerous effects of
20 the culture media, Plaintiffs were harmed as described herein, including the destruction of their
21 developing embryos.

22 105. These negligent acts and/or omissions were a substantial factor in causing Plaintiffs'
23 damages, including economic loss, serious emotional distress, and other harm in an amount to be
24 determined at trial.

25 106. Imposing a duty on Defendants to avoid causing emotional distress would promote the
26 policy of preventing future harm, insofar as they will be motivated to take steps to ensure that its embryo
27 culture media products are free from defects capable of destroying, damaging, or jeopardizing the
28 embryos they are designed to help develop. Imposing a duty on Defendants to avoid causing emotional

1 distress also furthers the community’s interest in ensuring that reliable fertility services are available to
2 those who wish to become parents.

3 107. The burden on Defendants from a duty to avoid causing emotional distress is fair and
4 appropriate, in light of the importance of the embryos they voluntarily agreed to protect, at considerable
5 cost to Plaintiffs.

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

9 109. Defendants acted willfully, wantonly, and with a conscious disregard for the safety of
10 consumers and/or users of their embryo culture media, including Plaintiffs, because Defendants were
11 aware of the dangerous consequences of not properly or adequately testing their embryo culture media,
12 they knew or should have known the embryo culture media lacked vital nutrients such that it posed a
13 severe risk to irreplaceable developing human embryos, and failed to recall the culture media before it
14 was used to culture and develop Plaintiffs’ embryos.

15 **SIXTH CAUSE OF ACTION**

16 **Trespass to Chattels**

17 110. Plaintiffs incorporate the above and below allegations by reference.

18 111. Plaintiffs owned or had the right to possess their reproductive material—their developing
19 embryos—that was destroyed by Defendants’ embryo culture media.

20 112. Defendants intentionally interfered with Plaintiffs’ possession of their developing embryos
21 by manufacturing a defective product that destroyed the material instead of safely culturing the fertilized
22 eggs to develop into healthy embryos, and by failing to recall or warn about the dangers of this product
23 before it was used on Plaintiffs’ reproductive material.

24 113. Plaintiffs did not consent to or authorize the use of a faulty and defective culture media on
25 their developing embryos.

26 114. Defendants caused physical damage to Plaintiffs’ personal property when the defective
27 culture media destroyed their developing embryos.

28

1 115. Defendants impaired the condition, quality, or value of Plaintiffs' personal property when
2 the defective culture media prevented the developing embryos from becoming viable.

3 116. Defendants' interference with Plaintiffs' reproductive material proximately caused harm
4 to Plaintiffs, as described herein, including by destroying their embryos.

5 117. As a foreseeable, direct and proximate result of the harm to Plaintiffs' reproductive
6 material caused by Defendants' trespass, Plaintiffs have suffered and continue to suffer injuries in an
7 amount to be determined at trial, including economic loss, serious emotional distress, and other harm in
8 an amount to be determined at trial. A reasonable person in Plaintiffs' position would sustain emotional
9 distress as a result of Defendants' conduct described herein.

10 **SEVENTH CAUSE OF ACTION**

11 **Unjust Enrichment**

12 118. Plaintiffs incorporate the above allegations by reference.

13 119. Plaintiffs conferred a tangible and material economic benefit on Defendants by purchasing
14 the defective culture media.

15 120. Defendants voluntarily and readily accepted and retained the benefits.

16 121. Plaintiffs would not have purchased the culture media had they known its defective nature.

17 122. This benefit was obtained unlawfully. Defendants marketed their embryo culture media as
18 being safe and effective for use on Plaintiffs' reproductive material. Defendants knew or should have
19 known that the payments rendered by Plaintiffs were given with the expectation that the embryo culture
20 media would have the qualities, characteristics, and suitability for use represented by Defendants.

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

24 124. It would be unjust and inequitable for Defendant to retain the benefit without paying the
25 value thereof.

26 125. Defendants have been unjustly enriched in retaining the benefits derived from the
27 purchase of defective culture media by Plaintiffs. Retention of the payments received under these
28 circumstances is unjust and inequitable because Defendants' representations and labeling of the recalled

1 embryo culture media lots was misleading to consumers, which caused injuries to Plaintiffs because they
2 would have not purchased the culture media had they known its true, defective nature.

3 126. Plaintiffs are entitled to restitution and to recover from Defendants all amounts wrongfully
4 and improperly retained in the amount necessary to Plaintiffs to the position they occupied prior to
5 purchasing and being harmed by the defective culture media.

6 **PRAYER FOR RELIEF**

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

- 9 a. an award of compensatory and/or restitutionary damages in an amount to be determined at
10 trial;
- 11 b. punitive and/or exemplary damages in such amounts as may be proven at trial;
- 12 c. prejudgment interest as permitted by law;
- 13 d. reasonable attorneys' fees and costs, as permitted for by law; and
- 14 e. such other and further relief as the Court deems equitable, just, or proper.

15 **DEMAND FOR JURY TRIAL**

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

17
18 Dated: September 6, 2024

Respectfully submitted,

19 /s/ Dena C. Sharp

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