UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

CALLIE COOPER,	)	**Civil Action No.:** 1:18-cv-121
	)	
	)	
Plaintiff,	)	
	)	**JURY TRIAL DEMANDED**
v.	)	
	)	
	)	
DAVOL INC., and C.R. BARD,	)	
	)	
	)	
	)	
Defendants.	)	
	)	

ORIGINAL COMPLAINT

Plaintiff Callie Cooper, by and through her undersigned counsel, brings this Complaint for damages against Defendants Davol Inc., and C.R. Bard, and in support states the following:

1. This is an action brought on behalf of Plaintiff Callie Cooper, arising out of the failure of Defendants' hernia mesh product, Composix Kugel. As a result, Plaintiff has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

2. At all material times Plaintiff has been a citizen and resident of Missouri and the United States.

3. Davol, Inc. ("Davol") is incorporated in Delaware, with its principal place of business in Rhode Island. Davol is a medical device company involved in the research,

development, testing, manufacture, production, marketing, promotion and/or sale of medical devices. Such devices include hernia meshes composed of polypropylene, expanded polytetrafluroethylene (ePTFE), and a permanent polyethylene terephthalate (PET) ring.

4. C.R. Bard, Inc. ("Bard") is Davol's corporate parent/stockholder. Bard is incorporated and based in New Jersey. It is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices, and controls the largest share of the hernia mesh market. Bard participates in the manufacture and distribution of the Composix Kugel. It also manufactures and supplies Davol with material that forms part of the product.

5. At all material times Bard was responsible for Davol's actions, and exercised control over its functions, specific to the oversight and compliance with applicable safety standards relating to the Composix Kugel sold in the United States. In such capacity, Bard committed, or allowed to be committed, tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiff Callie Cooper to suffer injury and damages.

6. Defendants are individually and jointly and severally liable to Plaintiff Callie Cooper for damages she suffered, arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective Composix Kugel, effectuated directly and indirectly through their agents, servants, employees and/or owners, all acting within the course and scope of their agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all material times acting on behalf of Defendants and within the scope of their employment or agency.

VENUE AND JURISDICTION

8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiff Callie Cooper and Defendants. The amount in controversy exceeds $75,000.

9. This Court has personal jurisdiction over each Defendant pursuant to the Missouri Long-Arm Statute, RSMO § 506.500[?]. Defendants transact business within the State of Missouri, and contracted to sell and supply their Composix Kugel product in the State of Missouri. Defendants employ sales representatives in the State of Missouri to sell their products throughout the State, including the Composix Kugel implanted in Callie Cooper in Missouri. Defendants' tortious acts and omissions in the State of Missouri caused injury to Plaintiff.

10. Defendants have purposefully engaged in Missouri in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or other related entities, medical devices including the Composix Kugel, for which they derived significant and regular income. Defendants intended and reasonably expected that that their defective mesh products, including the Composix Kugel, would be sold and implanted in Missouri and could cause injury in Missouri.

11. Davol is registered to transact business in Missouri.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

FACTS COMMON TO ALL COUNTS

13. On or about September 18, 2012, Plaintiff Callie Cooper underwent repair of a umbilical hernia by Dr. Kean Griffith at Poplar Bluff Regional Medical Center in Poplar Bluff, Missouri. A Composix Kugel hernia patch 4.5" in diameter, Ref No. 0010204 Lot No. HUTJ1649 was implanted in Plaintiff during this repair.

14. Defendants manufactured, sold, and/or distributed the Composix Kugel to Plaintiff, through her physician, to be used for treatment of hernia repair.

15. On or about June 6, 2013, Plaintiff Callie Cooper underwent surgery by Dr. Darin M. Minkin to remove the failed Composix Kugel. Upon visualizing the Composix Kugel, Dr. Minkin noted "mesh has since retracted and is no longer covering hernia defect and has come up anteriorly towards the skin underneath the wound."

16. Plaintiff continues to experience complications related to the Composix Kugel. She will likely require additional surgeries to repair the damage from Defendants' product.

17. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of the Composix Kugel, including providing the warnings and instructions concerning their product.

18. Among the intended purposes for which Defendants designed, manufactured and sold the product was its use by surgeons for hernia repair surgeries. That was the purpose for which the Composix Kugel was implanted in Callie Cooper.

19. Defendants represented to Plaintiff and her physician that the Composix Kugel was a safe and effective product for hernia repair.

FDA 510(k) CLEARANCE PROCESS

20. The "510(k) clearance process" of the U.S. Food & Drug Administration (FDA) refers to Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA). Under this process, medical device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976 (when the MDA was enacted).

21. No clinical testing or clinical study is required to gain FDA approval under this process. Instead, a given device was supposed to demonstrate substantial equivalence to a predicate medical device.

22. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

23. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices the FDA had approved for sale pre-1976 could be sold to patients in a matter of 90 days—without any clinical testing.

24. Therefore, clearance for sale under the 510(k) process does not equate to FDA approval of the cleared medical device.

25. At the request of the FDA in 2012, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, reaching the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

26. The NIH explained: "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to 1976 "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

27. Defendants cleared their Composix Kugel, and its related components, under the 510(k) Premarket Notification.

28. Immediately after the Composix Kugel was placed on the market, Defendants began receiving numerous notices of PET ring failures and other Composix Kugel defects. Defendants actively and intentionally concealed this notice of the defective and dangerous condition associated with the Composix Kugel from Plaintiff, her physicians, and the general public.

29. After the defective and dangerous Composix Kugel was already placed on the market, Defendants conducted physician screenings and reviews as early as 2002. An Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time. Whether intentionally or negligently, Defendants failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results. These complaints and concerns of the physician surveyors were actively concealed by Defendants from Plaintiff, her surgeons, and the public at large.

30. No later than September 2004, Defendants uncovered serious problems with the weld process involving the PET ring. Despite attempts to correct the problem at the manufacturing plant, Defendants found the corrective measures to be ineffective and the process still not in control. Defendants were aware these weld issues had existed from the time the Composix Kugel was originally placed on the market and all current lots suffered from this dangerous defect. This information was intentionally withheld from Plaintiff, her physicians, the

FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel using the PET ring.

31. In 2006, corporate executives informed the FDA that the spring and summer period of 2005 showed a marketed increase in the number of complaints with the Composix Kugel and the PET ring. Despite their knowledge of increasing complaints and complications, Defendants waited until August 30, 2005 to initiate a partial Composix Kugel distribution hold. Defendants actively and intentionally chose not to immediately inform Plaintiff, her physicians, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel using the PET ring. Defendants waited until December 2005 to notify the public of the potential severity of the complications which were resulting from the dangerous and defective Composix Kugel, and have since admitted that the product quality hold and release procedure was not applied on a timely basis.

32. An FDA Class I recall is issued for problems related to medical devices that are potentially life-threatening or could cause a serious risk to the health of the patients implanted with the devices.

33. On December 22, 2005, Defendants recalled many sizes of Composix Kugel under a Class I recall notice.

34. The Composix Kugel was recalled due to a faulty "memory recoil ring" (PET Ring) that can break under pressure. Incidents of ring migration, intestinal fistulae, bowel perforation and even death continue to be reported.

35. The FDA conducted the aforementioned EIR investigations in January and February of 2006. The results of these investigations determined, among other things, that Defendants:

- had excluded PET ring failure events which should have been included from their complication database, reports, and recall notices;
- misidentified numerous Composix Kugel complication events;
- failed to apply the product quality hold and release procedure on a timely basis;
- failed to properly follow the procedures for conducting design validation review;
- failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Composix Kugel complications;
- failed to provide full information which they knew regarding numerous Composix Kugel complaints;
- failed to actually perform strength testing on PET rings for all sizes of Composix Kugel before putting them into the stream of commerce;
- failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the PET ring failures and Composix Kugel complaints resulting in numerous inconsistencies and errors in the raw data and from the actual complaints and what was placed in the electronic databases.

36. Neither Plaintiff nor her physicians were aware of the defective and dangerous condition of the Composix Kugel or that this unreasonably defective condition was the cause of Plaintiff's injuries until after the product was removed.

37. Defendants failed to comply with the FDA application and reporting requirements.

38. Defendants were aware of the high degree of complications and failure rate associated with their Composix Kugel before it was recalled.

39. Defendants were aware of the defect in manufacture and design prior to the recall of the Composix Kugel and prior to Callie Cooper's implantation surgery on September 18, 2012.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

40. Due to Defendants' acts of fraudulent concealment, they are estopped from relying on any statutes of limitations or repose. Such acts include Defendants' intentional concealment

from Callie Cooper and the general public that the Composix Kugel is defective, while continuing to market the product with the adverse effects described in this Complaint.

41. Given Defendants' affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known the Composix Kugel was defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

42. Plaintiff incorporates by reference the allegations in all prior paragraphs.

43. Defendants expected and intended their Composix Kugel to reach users such as Plaintiff in the condition in which the product was sold.

44. The implantation in Callie Cooper's body of the Composix Kugel was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

45. When the Composix Kugel was implanted in Plaintiff's body, the product was defectively manufactured.

46. Defendants' poor quality control and general non-compliance with industry standards resulted in the non-conformance of the Composix Kugel implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

47. Upon information and belief, Defendants utilized substandard, adulterated, and/or non-medical grade polypropylene and raw materials used to make the Composix Kugel product,

which deviated from their material and supply specifications. Non-medical grade polypropylene contains less anti-oxidants, resulting in early mesh degradation and failure.

48. As a direct and proximate result of Defendants' defective manufacture of the Composix Kugel, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

49. Plaintiff incorporates by reference the allegations in all prior paragraphs.

50. Defendants' Composix Kugel was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the product, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components, including: organ perforation; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

51. Defendants expected and intended the Composix Kugel to reach users such as Plaintiff in the condition in which the product was sold.

52. The implantation of the product in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold it.

53. The Composix Kugel implanted in Plaintiff failed to reasonably perform as intended. The product caused serious injury and had to be surgically removed via invasive surgery,

necessitating additional invasive surgery to repair the hernia that the product had initially been implanted to treat.

54. The Composix Kugel contains a defectively designed PET ring. The Composix Kugel is vulnerable to buckling, folding, and/or migrating due to weaknesses in the PET ring and the forces produced as the polypropylene and ePTFE of the Composix Kugel shrinks post implantation.

55. The risks of Defendants' Composix Kugel significantly outweigh any benefits that Defendants contend could be associated with the product. The PET ring—which is no longer utilized in any hernia mesh product sold in the United States—has a propensity to buckle or break, resulting in organ perforation and hernia recurrence.

56. The Composix Kugel is designed as a multi-layered patch, which increases the foreign body load and subsequent foreign body reaction, resulting in increased oxidation and subsequent mesh breakdown and failure.

57. The Composix Kugel is designed as a patch to be inserted through areas of the body with high levels of bacteria that can adhere to the mesh, resulting in infections, mesh breakdown, and further injuries.

58. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the Composix Kugel. Although ETO is an effective disinfectant, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores if ETO is used. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores.

59. The Composix Kugel, containing spores, will eventually cause an infection after implantation. The spores can remain dormant for extended periods of time, resulting in infections

months or years after the Composix Kugel was implanted. The following literature discusses the necessity of moisture during ETO sterilization:

A. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**

Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

60. The Composix Kugel is cytotoxic, immunogenic, and non-biocompatible, causing or contributing to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

61. When affixed to the body's tissue, the ePTFE layer of the Composix Kugel prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

62. The ePTFE layer provides an ideal bacteria breeding ground, in which bacteria cannot be eliminated by the body's immune response, thus allowing infection to proliferate.

63. The solid, flat, relatively smooth and continuous surface of Defendants' Composix Kugel inhibits the body's ability to clear toxins.

64. Defendants' Composix Kugel has a solid, flat, relatively smooth and continuous surface. Medical devices utilizing this design greatly increase the risk of tumor and cancer formation via the "Oppenheimer Effect":

A. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not at present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**

Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

B. In 1999, the World Health Organization's International Agency for Research on Cancer published *Surgical implants and Other Foreign Bodies*, which evaluated the carcinogenic risks of various surgical implants in humans. **Polymeric implants prepared as thin smooth films are possibly carcinogenic to humans.**

Surgical Implants and Other Foreign Bodies. IARC Monogr Eval Carcinog Risks Hum 74:1-409 (1999).

65. The polypropylene mesh of the Composix Kugel was in itself dangerous and defective, particularly when used in the product in the manner intended by Defendants. The particular polypropylene material used in their product was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted adjacent to the bowel and other internal organs, as Defendants intended for the

Composix Kugel, it is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

66. The polypropylene portion of the Composix Kugel has a tendency to unravel, creating a sharp "fishing line" effect, which can slice through the patient's tissue.

67. These manufacturing and design defects associated with the Composix Kugel were directly and proximately related to the injuries Callie Cooper suffered.

68. Neither Plaintiff nor her implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of Composix Kugel. Moreover, neither Plaintiff nor her implanting physician was adequately warned or informed by Defendants of the risks associated with the product.

69. The appropriate treatment for complications associated with the Composix Kugel involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

70. Defendants' product was designed and intended for intraperitoneal implantation, which required it to be placed in contact with internal organs, thus unnecessarily increasing the risks of adhesion, erosion, fistula formation, and other injuries.

71. When the Composix Kugel was implanted in Callie Cooper, there were safer feasible alternative designs for hernia mesh products, including a flat, porous, non-coated, single-layer mesh placed away from the bowel, or a fully resorbable mesh.

72. The Composix Kugel product costs significantly more than competitive products due to its unique design incorporating polypropylene, ePTFE, and a PET ring, even though the design provided no benefit to consumers, and increased the risks to patients implanted with these devices.

73. The Composix Kugel implanted in Callie Cooper failed to reasonably perform as intended. The product therefore had to be surgically removed necessitating further invasive surgery to repair the very issue that the Composix Kugel was intended to repair. The product thus provided no benefit to Plaintiff.

74. As a direct and proximate result of the product's defective and unreasonably dangerous condition, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

75. Plaintiff incorporates by reference the allegations in all prior paragraphs.

76. When the Composix Kugel was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the product were inadequate and defective. As described above, there was an unreasonable risk the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

77. Defendants expected and intended the Composix Kugel to reach users such as Plaintiff in the condition in which the product was sold.

78. Callie Cooper and Plaintiff's physicians were unaware of the defects and dangers of Composix Kugel, and were unaware of the frequency, severity and duration of the risks associated with the product.

79. Defendants failed to warn of the propensity of the PET ring to break or buckle under the foreseeable stresses it would be subjected to within the abdomen.

80. No other company in the United States sold the dangerous and defective PET ring, which itself causes or increases the risks of numerous complications, including an increased risk of organ perforation, hernia recurrence, and chronic pain. Defendants provided no warning to

physicians about the risks or increased risks specifically associated with the unique design of the Composix Kugel.

81. Defendants failed to warn of the propensity of the Composix Kugel to contract and/or shrink once implanted.

82. Defendants failed to warn of the Composix Kugel's propensity to degrade, fragment, and disintegrate.

83. Defendants' failed to warn of the rate and manner of mesh erosion and/or extrusion.

84. Defendants' Instructions for Use provided with the Composix Kugel expressly understate and misstate the risks known to be associated specifically with the product, representing the associated complications such as inflammation merely as "possible complications." But the Composix Kugel will always incite severe inflammation once implanted. The inflammation caused by the Composix Kugel is chronic in nature and systemic, not acute localized inflammation.

85. Defendants' Instructions for Use for the product also failed to adequately warn Plaintiff's physician of numerous risks that Defendants knew or should have known were associated with the Composix Kugel, including the risks of immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, infections, bowel obstruction, or hernia incarceration or strangulation.

86. Defendants failed to warn that the ePTFE of the Composix Kugel provides the ideal breeding ground for bacteria, and prevents the body from properly clearly the infection.

87. Defendants failed to warn that ePTFE would degrade in the presence of an infection, creating an even more habitable structure for the infection to thrive.

88. Defendants failed to adequately warn Plaintiff or her physician about the necessity for invasive surgical intervention in the event of complications and failed to train the physician how to properly treat such complications when they occurred.

89. Defendants failed to adequately warn Plaintiff or her physician that the surgical removal of the Composix Kugel in the event of complications would leave the hernia unrepaired and much larger than the original; and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed product was intended to treat.

90. Defendants represented to physicians, including Plaintiff's physician, that the ePTFE of the Composix Kugel would prevent or reduce adhesions; expressly intended for the Composix Kugel to be implanted in contact with the bowel and internal organs; and marketed and promoted the Composix Kugel for that purpose. Defendants failed to warn physicians that the Composix Kugel would potato chip as the ePTFE shrinks, which then exposes the polypropylene side of the Composix Kugel to the bowel and puts the patient at high risk for dense adhesions formation years after implantation.

91. With respect to the complications listed in the Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Composix Kugel were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

92. If Plaintiff and/or her physician had been properly warned of the defects and dangers of the Composix Kugel, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow it to be implanted, and Plaintiff's physician would not have implanted the product in Plaintiff.

93. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT IV: NEGLIGENCE

94. Plaintiff incorporates by reference the allegations in all prior paragraphs.

95. Although Defendants had a duty to use reasonable care in designing, testing, reporting, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Composix Kugel, they failed to do so.

96. Defendants knew, or in the exercise of reasonable care should have known, that their product was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom it was implanted. Defendants knew or should have known that Plaintiff and her physician were unaware of the dangers and defects inherent in the Composix Kugel.

97. Defendants knew or should have known that the Material Safety Data Sheet (MSDS) regarding the polypropylene used to manufacture their product prohibited permanently implanting polypropylene into the human body.

98. Defendants utilized non-medical grade polypropylene.

99. Defendants knew or should have known that polypropylene is not inert and will degrade, flake, chip, and disperse throughout the body once implanted.

100. Defendants knew or should have known that polypropylene induces a severe inflammatory response once implanted, and continues to induce a severe inflammatory response indefinitely or until removed.

101. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

102. Defendants knew or should have known that the Composix Kugel caused unreasonable harm and dangerous side effects that many users would be unable to remedy by any means. Nonetheless, Defendants continued to promote and market the Composix Kugel's use by consumers, including the Plaintiff.

103. It was foreseeable to Defendants that consumers, including Callie Cooper, would suffer injury as a result of Defendant's' failure to exercise ordinary care.

104. As a direct and proximate result of Defendants' negligence in designing, testing, reporting, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Composix Kugel, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF IMPLIED WARRANTY

105. Plaintiff incorporates by reference the allegations in all prior paragraphs.

106. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the Composix Kugel.

107. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and her implanting physician in fact used it; and Defendants impliedly warranted that the product and is component parts was of merchantable quality, safe and fit for such use, and adequately tested.

108. Defendants were aware that consumers, including Plaintiff and her physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Composix Kugel.

109. Defendants' Composix Kugel was expected to reach, and did in fact reach consumers, including Plaintiff and her physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

110. Defendants breached various implied warranties with respect to Composix Kugel, including the following:

A. Defendants represented to Plaintiff and her physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was save. But at the same time they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

B. Defendants represented to Plaintiff and her physician and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff and her physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time they fraudulently concealed information regarding the true efficacy of the Composix Kugel.

111. In reliance upon Defendants' implied warranties, Plaintiff, individually, and/or by and through his physician, used the Composix Kugel as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

112. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

113. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

114. Plaintiff incorporates by reference the allegations in all prior paragraphs.

115. Defendants negligently manufactured, designed, developed, tested, labeled, marketed and sold the Composix Kugel to Plaintiff.

116. On multiple occasions Defendants negligently concealed the harmful effects of the product from Plaintiff individually, and/or her physician. They continue to do so to this day.

117. On multiple occasions Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Composix Kugel to Plaintiff individually, and/or her physician. They continue to do so to this day.

118. Plaintiff was directly impacted by Defendants' negligence, in that she has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the product manufactured, sold and distributed by Defendants.

119. After Plaintiff sustained emotional distress, severe physical injuries, and economic loss, Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff and/or her physician.

120. Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff individually, and/or her physician, knowing that doing so would cause Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

121. As a proximate result of Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT VII: FRAUDULENT CONCEALMENT

122. Plaintiff incorporates by reference the allegations in all prior paragraphs.

123. At all material times it was known or knowable to Defendants that their product caused large numbers of complications. It also was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with the Composix Kugel. It was known or knowable to Defendants that the safety and efficacy of their product had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. And it was known or knowable to Defendants that the product was not safe and effective. Defendants continued nonetheless to represent that their product was safe and effective.

124. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their product, Defendants failed to disclose this information to Plaintiff, her physician, and/or public at large.

125. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and her physician the true facts concerning their product, *i.e.*, that the Composix Kugel was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and was likely to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Callie Cooper was implanted with Defendants' product.

126. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the product because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the Composix Kugel;

B. Defendants knowingly made false claims about the safety and quality of the product in documents and marketing materials; and

C. Defendants fraudulently and affirmatively concealed the defective nature of their product from Plaintiff.

127. The facts Defendants concealed and/or did not disclose to Plaintiff were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use Defendants' product.

128. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and her physician, with the intent to defraud them.

129. Defendants intentionally concealed or failed to disclose the true defective nature of the Composix Kugel, so that Plaintiff would request and purchase it, and healthcare providers would dispense, prescribe, and recommend it. And Plaintiff justifiably acted or relied upon the concealed or non-disclosed facts to her detriment.

130. At all material times, neither Plaintiff nor her physician was aware of the facts above. Had they been aware of those facts, they would not have acted as they did, *i.e.*, by reasonably relying upon Defendants' representations of safety and efficacy, and by utilizing Defendants' product. Defendants' failure to disclose this information was a substantial factor in the selection by Plaintiff's physician of Defendants' product. Defendants' failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

131. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

COUNT VIII: NEGLIGENT MISREPRESENTATION

132. Plaintiff incorporates by reference the allegations in all prior paragraphs.

133. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Composix Kugel had not been adequately tested and found to be a safe and effective treatment. Defendants breached that duty as their representations were false.

134. Defendants failed to exercise ordinary care in the representations concerning their product while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because they negligently misrepresented the Composix Kugel's high risk of unreasonable and dangerous adverse side effects.

135. Defendants also breached their duty in representing to Plaintiff, her physician, and the medical community that their product had no serious side effects different from older generations of similar products and/or procedures.

136. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew or had reason to know, that the Composix Kugel had been insufficiently tested, or had not been tested at all; and that it lacked adequate and accurate

warnings, and created a high risk, or a higher than acceptable reported and represented risk of adverse side effects. Those side effects include pain, graft rejection, graft migration, ring break, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

137. As a direct and proximate result of Defendants' conduct, Plaintiff Callie Cooper has been injured and sustained past and future severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

PUNITIVE DAMAGES

138. Plaintiff incorporates by reference the allegations in all prior paragraphs.

139. Defendants failed to adequately test and study the Composix Kugel to determine and ensure that the product was safe and effective prior to releasing it for sale for permanent human implantation. Further, Defendants continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe.

140. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Composix Kugel, they developed, designed and sold the Composix Kugel, and continue to do so, because the product has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective product, including the risk of failure and serious injury, such as suffered by Plaintiff.

141. At all material times, Defendants knew or should have known that the Composix Kugel was inherently more dangerous with respect to the following: the risk of ring break, organ perforation, foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries

and treatments to cure the conditions proximately related to the use of the product, as well as the other permanent and lasting severe personal injuries.

142. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Composix Kugel, which deprived Plaintiff and her implanting physician of vitally necessary information with which to make a fully informed decision about whether to use the product.

143. At all material times, Defendants also knew and recklessly and/or intentionally disregarded the fact that their product can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatments. However, Defendants recklessly failed to advise the medical community and the general public, including Plaintiffs, of that fact.

144. At all material times, Defendants intentionally misstated and misrepresented data; and they continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the Composix Kugel.

145. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Composix Kugel, with its increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of the complications and side effects.

146. At all material times, Defendants have concealed and/or failed to disclose to the public all of the serious risks and all of the potential complications associated with the product, so

as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

147. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff Callie Cooper demands judgment against Defendants individually and jointly and severally. Plaintiff also requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff Callie Cooper demands judgment against Defendants, individually and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiff; permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of Defendants' profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future costs of all proceedings;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: May 31, 2018

Respectfully submitted,

/s/ *Adam M. Evans*
Adam M. Evans (MO # 60895)
C. Brett Vaughn (MO # 66974)
HOLLIS LAW FIRM, P.A.
5100 W. 95th St.
Prairie Village, KS 66207
(913) 385-5400
(913) 385-5402 (fax)
adam@hollislawfirm.com
brett@hollislawfirm.com